**ERIN CHELSEA CASSIDY, Esq.**
**K&L GATES LLP**
**ONE NEWARK CENTER 10TH FL**
**NEWARK, NJ, 07102-5285**
**973-848-4000**
**ERIN.CASSIDY@KLGATES.COM**
**KEN.DOELE@KLGATES.COM**
**Attorney Bar ID: 431832023**

SUPREME COURT OF NEW JERSEY

APP. DIV. # **A-001501-23**

SUPREME COURT # **090150**

Alison Beavan,
Plaintiff-Appellant,
v.
Allergan U.S.A., Inc.,
Defendant-Respondent,
and
Allergan Inc., f/k/a Inamed Corporation, Allergan PLC, and Abbvie Inc.,
Defendants.

NOTICE OF MOTION
MOTION FOR LEAVE TO APPEAR AMICUS CURIAE

**MOTION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE**

Attorney for CHAMBER OF COMMERCE
FOR UNITED STATES OF AMERICA

Dated: **07/28/2025**

**S/ ERIN CHELSEA CASSIDY**

David R. Fine (*Pro Hac Vice* Pending)
Varu Chilakamarri (*Pro Hac Vice* Pending)
Erin C. Cassidy (431832023)
**K&L GATES LLP**
One Newark Center, Tenth Floor
Newark, NJ 07102
Telephone: (973) 848-4000
*Attorneys for Proposed Amicus Curiae The Chamber of Commerce for the United States of America and The New Jersey Civil Justice Institute*

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| ALISON BEAVAN,<br><br>Plaintiff-Appellant,<br><br>v.<br><br>ALLERGAN U.S.A., INC.,<br><br>Defendant-Respondent,<br><br>And<br><br>ALLERGAN INC., f/k/a INAMED CORPORATION, ALLERGAN PLC, and ABBVIE INC.,<br><br>Defendants. | SUPREME COURT OF NEW JERSEY<br>DOCKET NO.: 090150<br><br>CIVIL ACTION<br><br>ON APPEAL FROM THE SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION<br>DOCKET NO.: A-1501-23<br><br>Sat Below:<br>Hon. Hany Mawla, P.J.A.D.<br>Hon. Robert M. Vinci, J.A.D.<br><br>**CERTIFICATION OF ERIN CHELSEA CASSIDY IN SUPPORT OF JOINT MOTION FOR LEAVE TO APPEAR AS *AMICI CURIAE***<br><br>I, **ERIN CHELSEA CASSIDY**, do hereby certify as follows:<br><br>1. I am an attorney-at-law of the State of New Jersey and an associate at K&L Gates LLP, attorneys for the Chamber of Commerce for the United States of America ("Chamber") and the New Jersey Civil Justice Institute |

("NJCJI") (collectively, "Proposed *Amici*").

2. I make this certification in support of the joint motion of Proposed *Amici* for leave to Appear as *Amici Curiae* and file a joint brief in the above-captioned matter. I have personal knowledge of the facts set forth herein.

3. The Chamber is the world's largest business federation. The Chamber represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. A significant number of the Chamber's members do business in New Jersey. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and state and federal courts.

4. To that end, the Chamber regularly files *amicus curiae* briefs that raise issues of concern to the nation's business community, including cases addressing expert testimony. The Chamber has participated as *amicus curiae* in other cases in New Jersey and around the United States addressing legal standards relevant to business and consumers. See, e.g., Robey v. SPARC Group LLC, 256 N.J. 541 (2024); Achey v. Cellco Partnership, 475 N.J. 446 (2023); Hrymoc v. Ethicon, Inc., 254 N.J. 446 (2023); see also In re Zantac (Ranitidine) Litig., No. 255, 2024, 2025 WL 1903760 (Del. July 10, 2025);

Drammeh v. Uber Techs., 105 F.4th 1138, 1139 (9th Cir. 2024); Helena Chem. Co. v. Cox, 664 S.W.3d 66 (Tex. 2023).

5. I respectfully submit that the participation of the Chamber will assist the Court in the resolution of the significant issues of public importance implicated by this appeal.

6. Moreover, the Chamber participated as an *amicus curiae* in this case before the Appellate Division and as a result, has an individual right to participate as *amicus curiae* before this Court.

7. The NJCJI is a bipartisan, statewide group comprised of small businesses, individuals, not-for-profit groups, and many of the State's largest business associations and professional organizations.

8. The NJCJI advocates for a civil justice system that treats all parties fairly, and it has a strong interest in the clear, predictable, and fair application of the law.

9. The NJCJI is concerned with the broader civil justice implications that cases such as this one may have on large and small businesses within the State. In that capacity, NJCJI monitors New Jersey legislation, offers comments on proposed amendments to New Jersey's Rules of Court, and participates as *amicus curiae* in matters of interest to its membership.

10. The NJCJI has appeared as *amicus curiae* before this Court in

important consumer and tort litigation. See, e.g., Padilla v. Young Il An, 257 N.J. 540 (2024); DeSimone v. Springpoint Senior Living, Inc., 256 N.J. 172 (2024); Dennehy v. East Windsor Regional Board of Education, 252 N.J. 201 (2022); Estate of Narleski v. Gomes, 244 N.J. 199 (2020); Spade v. Select Comfort Corp., 232 N.J. 504 (2018); In re Accutane Litig., 234 N.J. 340 (2018).

11. The special interest and the expertise of the NJCJI in this area of the law is substantial. I respectfully submit that the participation of the NJCJI will assist the Court in the resolution of the significant issues of public importance implicated by this appeal.

I certify that the foregoing statements are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: July 28, 2025

*/s/ Erin Chelsea Cassidy*

Erin Chelsea Cassidy
**K&L Gates LLP**
One Newark Center, 10th Fl.
Newark, NJ 07102
Phone: 1.973.848.4120
Erin.Cassidy@klgates.com
*Attorneys for Proposed Amicus Curiae The Chamber of Commerce for the United States of America and The New Jersey Civil Justice Institute*

**SUPREME COURT OF NEW JERSEY**
**DOCKET NO. 090150**

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| ALISON BEAVAN,<br><br>Plaintiff-Petitioner,<br>v.<br><br>ALLERGAN U.S.A., INC., AND ALLERGAN INC., F/K/A INAMED CORPORATION, ALLERGAN PLC, AND ABBVIE INC.,<br><br>Defendants-Respondents. | Civil Action<br><br>On Certification from the Superior Court, Appellate Division<br>Docket No. A-1501-23<br><br>Sat Below:<br>Hon. Hany A. Mawla, P.J.A.D.<br>Hon. Robert M. Vinci, J.A.D. |

# *AMICI CURIAE* BRIEF AND APPENDIX OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE NEW JERSEY CIVIL JUSTICE INSTITUTE IN SUPPORT OF DEFENDANTS RESPONDENTS


Varu Chilakamarri (*Pro Hac Vice Pending*)
K&L GATES LLP
1601 K Street NW
Washington, DC 20006
Telephone: (202) 778-9165
Facsimile: (202) 778-9100
varu.chilakamarri@klgates.com

*Counsel for* Amici Curiae *Chamber of Commerce of the United States and New Jersey Civil Justice Institute*

Erin C. Cassidy (431832023)
K&L GATES LLP
One Newark Center, Tenth Floor
Newark, NJ 07102
Telephone: (973) 848-4120
Facsimile: (973) 848-4001
erin.cassidy@klgates.com

David R. Fine (*Pro Hac Vice Pending*)
K&L GATES LLP
17 North Second Street, 18th Floor
Harrisburg, PA 17101
Telephone: (717) 231-5820
Facsimile: (717) 231-4501
david.fine@klgates.com

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The Chamber of Commerce of the United States of America (the "Chamber") and the New Jersey Civil Justice Institute ("NJCJI") file this *amici curiae* brief in support of Defendants-Respondents ("Allergan"). The trial court's admission of unreliable expert testimony raises significant questions about how rigorously courts exercise their gatekeeping role, particularly when assessing an expert's *application* of accepted methodologies to new fact patterns. By ceding these assessments to juries, trial courts disregard their essential gatekeeping function—posing serious risks to the business community and the consumers they serve.

## PRELIMINARY STATEMENT

Trial courts have a fundamental duty to ensure that the expert testimony presented to juries is reliable. This Court solidified that gatekeeping role in In re Accutane Litigation, 234 N.J. 340 (2018), and State v. Olenowski, 253 N.J. 133 (2023), making clear that reliability determinations should involve a rigorous review of an expert's methodology and reasoning.

But the admissibility standards remain inconsistently enforced in practice—especially when trial courts must evaluate whether an expert has reliably applied accepted methods to reach conclusions in any given case. Such challenges have led to further clarification at the federal level, including

amendments to Federal Rule of Evidence 702, that stress that experts must have "reliably applied" principles and methods to the facts of their case.

The trial court's admission of the expert testimony here provides a useful opportunity for the Court to reinforce the rigor of the gatekeeping role—specifically, by incorporating the 2023 federal amendment language into this Court's test for assessing reliability under New Jersey Rule of Evidence 702.

In this case, Plaintiff alleged that she received a defective Ozurdex injection manufactured by Allegan, which led to her blindness in one eye. Beavan v. Allergan, A-1501-23 (App. Div. Nov. 21, 2024) (slip op. at 6). Plaintiff received an injection from an Ozurdex lot that had been voluntarily recalled because 2.2% of the units could unintentionally produce a small silicone particulate. Id. at 4. Plaintiff's theory of liability was that a silicone particulate was discharged in her injection, causing her injury. Ibid. She offered expert testimony from Drs. Lalezary and Phillips supporting this theory. Ibid. Because there was no direct evidence of causation, her experts relied on a "differential diagnosis" methodology, which works by ruling in possible causes and then ruling out those that are shown not to have resulted in plaintiff's injury. Id. at 34. Allergan moved to exclude Plaintiff's expert testimony, arguing that the doctors failed to reliably apply the differential diagnosis methodology. The trial court denied Allergan's motion. Id. at 11.

Although the differential diagnosis methodology is, generally speaking, an established means of proving specific causation, the trial court did not rigorously review the experts' *specific application* of that methodology to Plaintiff's injury. Instead, the trial court wrongly treated that task as merely a question of weight for the jury. But to be admissible, expert testimony must be reliable both in method *and* application. On review, the experts' application proved unreliable, rendering their testimony inadmissible.

*First*, the experts did not reliably apply the methodology when they "ruled in" the silicone particulate as a potential cause of Plaintiff's injury. The experts had no basis—grounded in studies, tests, or peer-reviewed literature—for their general causation conclusion. They relied solely on the temporal association between Plaintiff's injury and her receiving an injection from a recalled lot. But temporal association at most can establish *correlation*, not causation, and thus cannot serve as a sufficient basis for a reliable opinion.

*Second*, the experts did not reliably apply the methodology when they "ruled out" various just-as-likely alternative causes. The experts again relied on temporality rather than using reliable scientific methods and procedures to justify independently eliminating each alternative.

This case therefore illustrates how an expert can invoke a generally reliable method (differential diagnosis) that theoretically may be applied

reliably in some circumstances, but engage in an unreliable application of that method to the specific facts and data at issue, ultimately resulting in an inadmissible opinion. The Appellate Division was right to reverse the trial court, and this Court should affirm. In doing so, it should clarify the contours of the trial court's rigorous gatekeeping role and incorporate the 2023 federal amendment language into its own reliable test.

## STATEMENT OF FACTS AND PROCEDURAL HISTORY

*Amici* refer to the facts and procedural history presented in Defendant's opposition to certification, *see* Db2-5.

## ARGUMENT

### I. New Jersey law requires trial courts to play a critical gatekeeping role by preventing unreliable expert testimony from reaching juries.

New Jersey Rules of Evidence 702 and 703 govern the admission of expert testimony, with Rule 702 providing the conditions under which experts may assist juries with technical knowledge, and Rule 703 requiring that such testimony be grounded in facts or data. Specifically, Rule 702 states that if "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue," then "a witness qualified as an expert by knowledge, skill, experience, training, or education may testify." N.J.R.E. 702. This Court has read Rule 702 to impose three prerequisites on expert testimony:

> (1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony.
>
> [Townsend v. Pierre, 221 N.J. 36, 53 (2015) (citations omitted).]

Central to this test has always been the trial court's duty to ensure that an expert's testimony is sufficiently reliable before it is presented to a jury.

### A. Trial courts must evaluate the soundness of an expert's reasoning and methodology when assessing admissibility.

In evaluating reliability, this Court was among the first to move away from a model of admitting expert testimony whenever it is generally accepted by others in the scientific community, and toward a model in which judges play a more rigorous gatekeeping role in independently assessing the soundness of an expert's reasoning and methodology. In re Accutane Litig., 234 N.J. at 347. Even before the U.S. Supreme Court moved in that direction in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), this Court shifted to this so-called methodology-based approach. That happened first in toxic tort matters, Rubanick v. Witco Chem. Corp., 125 N.J. 421, 447 (1991), and then more broadly for issues of medical causation, Kemp v. State of New Jersey, 174 N.J. 412, 430 (2002).

In Accutane, this Court reinforced the importance of the trial courts' role in examining the reliability of an expert's "reasoning and methodology":

> Properly exercised, the gatekeeping function prevents the jury's exposure to unsound science through the compelling voice of an expert. . . Difficult as it may be, the gatekeeping role must be rigorous. . . The court's function is to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs.
>
> [In re Accutane Litig., 234 N.J. at 390.]

Notably, the Court clarified that decisions about "what is reliable enough to be admitted" "are not credibility determinations that are the province of the jury, but rather legal determinations about the reliability of the expert's methodology." Id. at 389. The Court further announced that the federal Daubert factors should be incorporated into New Jersey trial courts' evidentiary assessments. Id. at 398-390.

Although Accutane was limited to civil cases and stopped short of declaring the State a "Daubert jurisdiction," see ibid., the Court has subsequently extended the methodology-based approach to criminal cases as well—increasing the importance of the trial courts' gatekeeper role. Olenowski, 253 N.J. at 154.

### B. Trial courts have unevenly regarded their gatekeeper role, with some relaxing their scrutiny of expert testimony.

Since Accutane, trial courts have begun addressing admissibility under a more complex lens, but some have struggled to engage with experts' reasoning and methodology, resulting in improper exposure of juries to unsound science. Indeed, the Appellate Division has repeatedly reminded trial courts of their rigorous gatekeeping roles—redirecting reliability assessments back to courts that had mislabeled them as credibility assessments for the jury.

For example, the Appellate Division reversed a significant jury verdict in Middlesex County, where plaintiffs had sued Johnson & Johnson over claims of asbestos-tainted talcum power. Barden v. Brenntag North America, Inc., No. A-0047-20, 2023 WL 6430088 (App. Div. Oct. 3, 2023). The trial court had improperly admitted expert testimony about whether substances in the product could cause cancer and the amount of plaintiffs' exposure to the product. Id. at *6-7. The Appellate Division found that the trial court erred by treating classic reliability questions—questions going to the soundness of the expert's methodology, reasoning, and the data relied on—as issues that could be vetted through cross-examination and left for the jury to resolve. Ibid. (reversing because "the court allowed the jury to hear unsound science labeled as expert and scientific when it allowed the jury to make credibility determinations, contrary to the explicit instructions in Accutane").

Similarly, in Fredella v. Twp. of Toms River, No. A-3196-21, 2024 WL 730342 (App. Div. Feb. 22, 2024), the trial court improperly admitted expert testimony on whether a victim of a car accident was under the influence. Id. at *7. Although the expert cited generally accepted principles, the trial court did not probe the expert's application of those principles to conclude that the plaintiff's earlier drug use adversely impacted his vision. Id. at *8 (explaining that although it was undisputed that heroin could cause plaintiff's contracted pupils, the expert made a logical leap in concluding that plaintiff's vision was impaired while driving). So too in Segar v. Consol. Rail Corp., No. A-1420-21, 2023 WL 6784978 (App. Div. Oct. 13, 2023), the trial court did not apply each Daubert factor when evaluating an expert's differential diagnosis opinion.

This trio of post-Accutane cases signal a need for this Court to reinforce the gatekeeper role of trial courts, including the requirement that trial courts thoroughly evaluate technical opinions to make threshold legal assessments of their reliability in both method and application.

### C. This Court should reinforce NJRE 702's requirement of a rigorous threshold assessment of an expert's reasoning and methodology.

#### 1. Unreliable expert evidence harms businesses and consumers.

Expert testimony plays a powerful role in influencing juries. "Jurors hold the testimony of expert witnesses in high regard when deliberating," and "studies have shown that expert testimony influences a juror's decision more

often than not." Miles J. Vigilante, Screening Expert Testimony After Kumho Tire Co. v. Carmichael, 8 J.L. & Pol'y 543 (2000). As one judge put it, "[n]o one seriously questions the proposition that so-called 'expert witnesses' can add an aura of authority to any asserted opinion." Hon. Charles R. Richey, Proposals to Eliminate the Prejudicial Effect of the Use of the Word "Expert" Under the Federal Rules Evidence, 154 F.R.D. 537, 545 (1994). This is particularly true in products liability cases, where plaintiffs' causation theories often require understanding complex medical issues, and expert evidence can make or break a case. See Rubanick, 125 N.J. at 433.

But the admission of unsound scientific opinions can significantly harm businesses and consumers. The *amici* here include both national and New Jersey industry organizations. The business community they represent is greatly impacted by incorrect admissibility decisions, as the resulting verdicts expose manufacturers and distributors to unjust liability and can be detrimental to the State's economy and to consumers in several ways.

First, exposing juries to unsound science can drive baseless and excessive verdicts. See Barden, 2023 WL 6430088, at *1 (reversing over $223 million dollar verdict because of admission of unreliable expert testimony). Indeed, the mere threat of such verdicts can pressure businesses into unjust

settlements, divert resources from innovation and consumer benefit, and distort judicial administration from fact-finding to fear-driven compromise.

Second, relaxed admission standards for expert testimony can also incentivize plaintiffs to forum shop to bring claims in states where the trial courts' gatekeeper role is inconsistently applied or underdeveloped. Victor E. Schwartz & Cary Silverman, The Draining of *Daubert* and the Recidivism of Junk Science in Federal and State Courts, 35 Hofstra L. Rev. 217, 273 (2006) ("In order to prevent forum shopping and encourage consistency and predictability, both federal and state court judges should carefully adhere to the 'gatekeeping' function outlined in Daubert."). Forum shopping concerns are particularly salient in the tort context, because litigation relating to the same product often proceeds in numerous jurisdictions. The fact that several claims are proceeding past summary judgment in one forum can have significant effects on the commencement and settlement of claims across the country, and when one jurisdiction is perceived as having more "flexible" standards for admitting expert testimony, more suits are likely to be brought there. See Malerie Ma Roddy, Consumer Protection: Forum Shopping in Talc Cases, Nat'l L. Rev. Prod. Liab. & Mass Torts Blog (Dec. 7, 2016).[1]

[1] Available at https://tinyurl.com/yr79fhf3.

Finally, liability premised on unsound science carries real-world consequences for business and consumers, including beneficial products being pulled from the market and companies shutting down. See, e.g., U.S. Chamber Inst. for Legal Reform, Fact or Fiction: Ensuring the Integrity of Expert Testimony at 5 (Feb. 2021) (describing effects of improper adverse products liability verdicts on pharmaceutical availability).[2] Even the most conscientious and careful businesses will have no choice but to increase the price of their products to make up for the expense of unpredictable and expensive liability. These are not merely hypothetical risks. For example, Bendectin, the only FDA-approved medication blunting symptoms of morning sickness, was driven from the market by courts admitting dubious "expert" testimony that went against overwhelming scientific consensus. See Schwartz, 35 Hofstra L. Rev. at 224–25. Unless courts remain vigilant against unsound opinions offered under an expert's imprimatur, consumers will inevitably have to pay more for a broad range of goods and services or forgo them entirely.

[2] Available at https://tinyurl.com/4sza59zk.

### 2. This Court should adopt the federal rule amendment language reinforcing that reliability assessments extend to an expert's specific application of even generally reliable methods.

This case presents a unique opportunity to illustrate the importance of making rigorous reliability assessments as a threshold admissibility matter, rather than—as was done below—treating potential deficiencies in an expert's application of methods as merely issues of credibility and weight. See Pa80 (denying motion to exclude and concluding that "the failure to cite scientific data, analysis, literature, or studies outside of the case materials . . . goes to the weight of the experts' testimony, not its admissibility").[3]

Indeed, the failure of many federal courts to fulfill their gatekeeping role drove the recent amendments to the Federal Rules of Evidence. In 2023, Federal Rule of Evidence 702 was amended so that the wording of the fourth factor of the test[4] underscores that the "expert's opinion reflects a reliable

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[3] "Pa" refers to the appendix to Plaintiff's Petition for Certification. "Da" refers to Defendant's appendix in support of appeal filed with the Appellate Division.

[4] The prior version of the Federal Rule read:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify . . . 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

application of" principles and methods "to the facts of the case." Fed. R. Evid. 702(d). That amendment was intended "to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology," and that jurors may "lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support." Fed. R. Evid. 702, Advisory Committee's Note to 2023 Amendment; see also U.S. Chamber Inst. for Legal Reform, Comments to the Advisory Committee on Evidence Rules and its Rule 702 Subcommittee, at 6-7 (Nov. 9, 2020).[5] While the federal amendment was not a substantive change, see Advisory Committee Note, it serves as a structural reminder that the courts' gatekeeping role requires not simply considering whether an expert cites a reliable methodology, but whether the expert's *specific application* of that reliable methodology to the facts of the case is itself reliable.

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> (d) the expert has reliably applied the principles and methods to the facts of the case.
>
> [Fed. R. Evid. 702 (Nov. 2023).]

As revised, subsection (d) now states: "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case."

[5] Available at https://tinyurl.com/y39xs8me.

The Delaware Supreme Court recently took a similar step, emphasizing that it was equally critical for Delaware trial courts to determine whether experts "reliably applied" appropriate methodologies rather than labeling "them as questions for the jury." In re Zantac Litig., No. 255, 2024, 2025 WL 1903760, at *1, 13 (Del. July 10, 2025) (noting that although Delaware Rule had not been amended, it tracks federal analogue in substance, and that federal amendment was "not substantive" and simply "clarified" existing standard).

By similarly adopting the 2023 federal amendment language and reinforcing the need for careful review of experts' application of even generally reliable scientific methodologies, this Court would provide necessary clarity and greater uniformity to this area of the law. It would also help prevent the New Jersey courts from becoming a forum-shopping magnet jurisdiction for weak claims relying on dubious application of science.

## II. The trial court's methodological flaws highlight the need for clarity.

### A. Trial courts must review how experts apply scientific theories of causation when assessing the reliability of expert testimony.

In a products-liability action, a plaintiff must prove both general and specific causation. In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig., 509 F. Supp. 3d 116, 157 (D.N.J. 2020). As noted, "differential diagnosis" is a technique of establishing the cause of a plaintiff's medical problem by first "ruling in" all causes plausibly supported by reliable

science (*i.e.*, general causation), and then "ruling out" those causes that did not specifically produce the plaintiff's condition. Creanga v. Jardal, 185 N.J. 345, 356 (2005); see also Faigman, David L. (2022), Evidence: A Brief Guide to Differential Etiology, The Judges' Book: Vol. 6, Article 9.[6] "In attacking the differential diagnosis performed by the plaintiff's expert, the defendant may point to a plausible cause of the plaintiff's illness other than the defendant's actions. It then becomes necessary for the plaintiff's expert to offer a good explanation as to why his or her conclusion remains reliable." Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 808 (3d Cir. 1997).

Because a differential diagnosis involves a two-step process, assessing an expert's application of a differential diagnosis will necessarily require evaluating the expert's methodology and reasoning at both steps. Creanga, 185 N.J. at 359. Simply "uttering the phrase 'differential diagnosis,' does not make an expert's opinion admissible." Id. at 358. Thus, even though "the method of differential diagnosis is clearly a reliable methodology in general, that does not answer the question of admissibility." Poust v. Huntleigh Healthcare, 998 F. Supp. 478, 496 (D. N.J. 1998). Instead, the trial court must "delve into the particular witness's method of performing a differential diagnosis to determine if his or her ultimate conclusions are reliable." Ibid.

[6]Available at https://tinyurl.com/mr2u3y3e.

On the first step of a differential diagnosis, the "expert must determine that the proffered cause of the plaintiff's injury is in fact capable of causing that kind of injury." See Faigman, at 57. "General causation is the gravamen of scientific research." Ibid.

On the second step of a differential diagnosis, the "court is justified in excluding evidence if an expert utterly fails to offer an explanation for why the proffered alternative cause was ruled out." Creanga, 185 N.J. at 358 (citation modified). In "rejecting the alternative hypotheses, the expert must use 'scientific methods and procedures' and justify an elimination on more than 'subjective beliefs or unsupported speculation.'" Ibid. (citation omitted).

### B. The trial court failed to assess whether the experts reliably applied the differential diagnosis approach.

The Appellate Division correctly concluded that Drs. Lalezary and Phillips' causation testimony should have been excluded as unreliable. Their testimony was unreliable because their application of a differential diagnosis rested on baseless speculation as to both general and specific causation.

#### 1. Plaintiffs' experts did not reliably apply a differential diagnosis when "ruling in" the silicone particulate.

Experts "must be able to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the

methodology are scientifically reliable." In re Accutane Litig., 234 N.J. at 382. Neither Dr. Lalezary nor Dr. Phillips did this for general causation.

When pressed, neither could provide an affirmative basis—grounded in scientific data, analysis, or peer-reviewed literature—for concluding that a silicone particulate could cause this injury. See Da62; Pa 174-175; Pa94-95. Put differently, neither expert reliably applied the first step of the differential diagnosis by "ruling in" the silicone particulate in the first instance.

Nevertheless, the trial court found their conclusions reliable, based on the timing of Plaintiff's injury in relation to her receiving an injection from a recalled lot. Pa126. But the trial court did not look behind the experts' statements, to see whether they provided a sound basis for concluding that either of these factors—temporal association and a voluntary recall—establishes causation. Critically, neither factor does.

*First*, a temporal association at most establishes correlation not causation. Courts, including New Jersey's federal court, have routinely explained that "reliance on a temporal relationship in the absence of scientific studies, authoritative research or peer review is insufficient to constitute a reliable opinion." Moody v. Gen. Mills, Inc., No. 04-1942, 2006 WL 6872309, at *1 (D.N.J. Feb. 9, 2006) (collecting cases); see In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1232 (D. Colo. 1998) ("[T]emporal relationship by itself,

provides no evidence of causation"); Schmaltz v. Norfolk & W. Ry. Co., 878 F. Supp. 1119, 1122 (N.D. Ill. 1995) ("It is well settled that a causation opinion based solely on a temporal relationship is not derived from the scientific method"); Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1319 (9th Cir. 1995) (on remand from Supreme Court, finding inadmissible testimony of expert who primarily relied on "timing" of drug ingestion to opine that it caused birth defect); see also Myrlak v. Port Authority, 157 N.J. 84, 98 (1999) ("The mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect.").[7]

Here, the experts clearly relied on the temporal association between the Ozurdex injection and the injury as the basis for their opinions that: (1) a silicone particulate was generated by Plaintiff's product (*i.e.*, the defect); (2) that it entered her eye; and (3) that a silicone particulate could cause the type of injuries that she later suffered. See Da186 (Dr. Lalezary testifying in deposition that "it's more likely that she had some kind of defective device implanted," because she did not have problems from prior injections, so it "would be more than coincidental"); Da82-83 (Dr. Phillips testifying in

[7] While this and other courts have suggested that a temporal association may in some circumstances play a role in analyzing *specific* causation, those circumstances are limited to where general causation is otherwise established and there is likewise an otherwise reliable basis for finding specific causation. See Creanga, 185 N.J. at 359; In re Breast Implant Litig., 11 F. Supp. 2d at 1232.

deposition that silicone particulate could have caused the injury because "it's the only thing that was different" this time). These explanations were based on correlation inferred from temporal proximity, not studies, tests, or literature.

*Second*, while the experts cited the voluntary recall as a basis for concluding that the Ozurdex injection had a defect that caused the injury, they failed to provide any non-conclusory reason why this recall (or any data underlying it) would support "ruling in" the silicone particulate. See Da186 (Lalezary Dep); Da73-74 (Phillips Dep).

To the extent that a voluntary recall can be relied on by an expert, it is only worth what the expert can reasonably glean from it. See generally Manieri v. Volkswagenwerk A.G., 151 N.J. Super. 422, 433 (App. Div. 1977) (explaining that "recall letter by itself does not make a prima facie case or shift the burden of proof. It does not prove that the defect existed at the time of the accident. This must be proved independently"); Barry v. Manglass, 389 N.Y.S. 2d 870, 877 (1976) (holding that recalled letters were admissible where defect referred to in recall was established by independent expert testimony to be cause of accident). But here, the experts did nothing more than point to the fact of the recall. That approach cannot pass muster under Rule 702. Indeed, "there may be myriad reasons, including an abundance of caution or the avoidance of lawsuits, why a manufacturer may warn of a possible

phenomenon without being convinced that it is a genuine risk." In re Mirena IUD Prods. Liab. Litig., 202 F. Supp. 3d 304, 323 (S.D.N.Y. 2016), aff'd, 713 F. App'x 11 (2d Cir. 2017). Moreover, there are important public policy reasons to discourage elevating recall documents to the status of evidentiary admissions, because that would leave "jurors to speculate" and "chill free and frank discussion by manufacturers of drugs or devices." Ibid.

**2. Plaintiffs' experts did not reliably apply a differential diagnosis when "ruling out" alternative causes.**

Because a differential diagnosis involves a two-step process and Plaintiffs' experts did not reliably apply the first step, the Appellate Division's conclusion can be affirmed on that basis alone. But the trial court's reliability assessment was similarly flawed at the second step.

Plaintiff's experts acknowledged that there were several potential alternative causes for her injury, including: (1) numerous eye surgeries and procedures; (2) the Ozurdex injection, which itself (as non-defective) carries a risk for retinal detachment; and (3) a Retisert silicone insert that she also had, "which was ten times larger" than the alleged silicone particulate and which "dislocated contemporaneously with her injury." Beavan, slip op. at 35.

The only reason the experts gave for "ruling out" these potential causes was that Plaintiff had been exposed to them before and had not suffered this injury. See, e.g., Da187 (Lalezary Dep.). Here again, the experts relied on

temporal association, which is not a sound method. And even if inference from temporal proximity could be a viable method for establishing causation, the trial court did not engage the experts' reasoning to determine whether that method was reasonably applied here.

Notably, although the Plaintiff had been exposed to other potential causes without injury, the experts failed to explain why that fact alone justified ruling out those alternative causes—especially when those alternative causes pose *new risk* with each new exposure. For example, Dr. Lalezary agreed that each time Plaintiff received an Ozurdex injection, it constituted an "independent risk factor" for developing retinal detachment. Da175.

But Rule 702 requires the trial court to assess whether the expert offers a reasonable explanation for ruling out plausible alternative causes, based on scientific methods and procedures, not unsupported speculation. Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584, 609 (D.N.J. 2002); see also Creanga, 185 N.J. at 358. The trial court failed in this obligation.

**3. The Appellate Division correctly reversed the trial court.**

By not scrutinizing the experts' application of the differential diagnosis to the Plaintiff's circumstances, the trial court would have permitted the jury to find liability under a boundless theory of causation—one that is essentially based on nothing more than temporal association. That would be a remarkable

proposition. If a plaintiff can establish a circumstantial-evidence claim for manufacturing defects without independently establishing that the defect could cause the type of injury suffered and without reliably excluding reasonable alternative causes, this State will surely see more product liability lawsuits. Indeed, whenever a plaintiff suffers any injury following use of a recalled product—regardless of the nature of the recall—a plaintiff would have a basis for bringing in expert testimony to "rule in" the product as a potential cause of injury. Such a rule-in-by-recall approach would easily extend to manufacturers across industries, significantly altering the manner that drug, cosmetic, and various other companies would account for legal risk and market participation.

Rule 702 serves to insulate the judicial process from such rampant misapplication of scientific principles. But as the errors below illustrate, courts and parties would benefit from this Court reinforcing that rigorous gatekeeping function by incorporating the language of the 2023 federal rule amendments into this Court's own reliability test—emphasizing that Rule 702's command applies equally to an expert's method and his or her application of that method to the specific facts of any given case.

## CONCLUSION

For the foregoing reasons, this Court should affirm.

Respectfully submitted,

By: *s/ Erin Chelsea Cassidy*

Erin C. Cassidy (431832023)
K&L GATES LLP
One Newark Center, Tenth Floor
Newark, NJ 07102
Telephone: (973) 848-4120
Facsimile: (973) 848-4001
erin.cassidy@klgates.com

David R. Fine (*Pro Hac Vice Pending*)
K&L GATES LLP
17 North Second Street, 18th Floor
Harrisburg, PA 17101
Telephone: (717) 231-5820
Facsimile: (717) 231-4501
david.fine@klgates.com

Varu Chilakamarri
(*Pro Hac Vice Pending*)
K&L GATES LLP
1601 K Street NW
Washington, DC 20006
Telephone: (202) 778-9165
Facsimile: (202) 778-9100
varu.chilakamarri@klgates.com

*Counsel for* Amici Curiae *Chamber of Commerce of the United States and New Jersey Civil Justice Institute*

**TABLE OF *AMICI CURIAE* APPENDIX ("ACA")**

2023 WL 6430088
Only the Westlaw citation is currently available.

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey, Appellate Division.

Roslyn BARDEN, individually and as Executrix and Executrix Ad Prosequendum of the Estate of Douglas Barden, Estate of Douglas Barden, Darlene Pastore Etheridge, individually and as Executrix and Executrix Ad Prosequendum of the Estate of David Charles Etheridge, Estate of David Charles Etheridge, D'Angela M. McNeill-George, and Elizabeth Ronning, individually and as Executrix and Executrix Ad Prosequendum of the Estate of William Ronning, and the Estate of William Ronning,
Plaintiffs-Respondents,
v.
BRENNTAG NORTH AMERICA, INC., individually and as Successor-in-Interest to Mineral Pigment Solutions, Inc., as Successor-in-Interest to Whittaker Clark & Daniels, Inc., Brenntag Specialties, Inc., f/k/a/ Mineral Pigment Solutions, Inc., as Successor-in-Interest to Whittaker, Clark & Daniels, Inc., Cyprus Amax Minerals Company, individually and as Successor-in-Interest to American Talc Company, Metropolitan Talc Company, Inc., Charles Mathieu, Inc., Resource Processors, Inc., Sierra Talc Company, United Talc Company, Imerys Talc America, Inc., f/k/a Luzenac America, Inc., individually and as Successor-in-Interest to Windsor Minerals, Inc., American Talc Company, Metropolitan Talc Company, Inc., Charles Mathieu, Inc., Resource Processors, Inc., Imerys U.S.A., Inc., Imerys Talc Vermont, Inc., Whittaker Clark & Daniels, Inc., individually and as Successor-in-Interest to American Talc Company, Metropolitan Talc Company, Inc., Charles Mathieu, Inc., and Resource Processors, Inc., Union Carbide Corporation, Defendants,
and
Johnson & Johnson, Johnson & Johnson Consumer, Inc., f/k/a Johnson & Johnson Consumer Companies, Inc.,
Defendants-Appellants.

DOCKET NOS. A-0047-20, A-0048-20, A-0049-20, A-0050-20
|
Argued September 27, 2023
|
Decided October 3, 2023

On appeal from the Superior Court of New Jersey, Law Division, Middlesex County, Docket Nos. L-1809-17, L-0932-17, L-7049-16, and L-6040-17.

**Attorneys and Law Firms**

Peter G. Verniero argued the cause for appellants (McCarter & English, LLP, and

  

Sills Cummis & Gross, PC, attorneys; Peter G. Verniero, John C. Garde, and Michael S. Carucci, on the briefs).

Denyse Clancy (Kazan, McClain, Satterley & Greenwood) of the California bar, admitted pro hac vice, argued the cause for respondents (Szaferman, Lakind, Blumstein & Blader, PC, and Cohen, Placitella & Roth, PC, Denyse Clancy, and Chris J. Panatier (Simon Greenstone Panatier, PC) of the Texas, California, and Pennsylvania bars, admitted pro hac vice, attorneys; Moshe Maimon, Denyse Clancy, Christopher Placitella, Chris J. Panatier, and Robert E. Lytle, on the brief).

Before Judges Haas, Gooden Brown and Puglisi.

**Opinion**

PER CURIAM

***1** In these consolidated appeals, Johnson & Johnson (J&J) and Johnson & Johnson Consumer, Inc. (J&JCI) (collectively defendants) appeal from judgments dated July 24, 2020, which awarded plaintiffs[1] compensatory damages totaling $37,300,000 and punitive damages totaling $186,500,000. For the reasons that follow, we reverse and remand the matter to the trial court for a new trial.

I.

We begin by briefly summarizing the procedural history most pertinent to the issues raised on appeal.

Plaintiffs filed complaints alleging that defendants were involved in mining and processing asbestos-containing products, including Johnson's Baby Powder (JBP) and Shower to Shower (STS), which were sold and caused them to develop mesothelioma following their long-term use of these products.[2] On February 1, 2019, the trial court issued a sua sponte order consolidating the four cases for trial.

By the time of trial, the only remaining claims against defendants were under the New Jersey Products Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, premised upon a failure to warn and design defect theories. In addition, McNeill-George presented a claim for defective manufacturing. Beginning on June 29, 2019, and lasting for approximately thirty-three non-consecutive days, the trial court conducted the liability and compensatory damages phase of the jury trial.[3]

On July 11, 2019, the trial court granted plaintiffs' motion in limine to preclude comments by defense counsel aimed at prejudicing the jury against plaintiffs' counsel. During the course of the trial, the court reiterated the terms of this order to defense counsel.

On July 15, 2019, the trial court denied defendants' motion in limine to exclude expert opinion from James Webber, Ph.D., and also denied defendants' request for an N.J.R.E. 104 hearing. Ten days later, the court denied defendants' motion in limine to exclude expert testimony from Jacqueline

  

M. Moline, M.D. The court also denied defendants' request for an N.J.R.E. 104 hearing.

On August 5, 2019, the trial court denied defendants' motion to exclude expert testimony from William E. Longo, Ph.D. and their request for a N.J.R.E. 104 hearing. On that same date, the court denied defendants' motions to strike Webber's and Moline's expert opinions. The court later denied defendants' motion to strike Longo's expert opinion.

In response to remarks defense counsel made during closing arguments, the trial court struck defense counsel's entire summation for violating its prior rulings concerning the conduct of the attorneys. The court denied defendants' motion for a mistrial.

***2** On September 11, 2019, the jury returned verdicts in favor of plaintiffs and awarded them compensatory damages in varying amounts.[4] The trial court then excused the jury, having determined that the punitive damages phase of the trial would proceed before a new jury panel.[5] On February 9, 2020, the jury rendered verdicts awarding punitive damages to plaintiffs. The court denied defendants' motion for a new punitive damages trial. Later, the court reduced the amount of the punitive damages awards. These appeals followed.

On appeal, defendants allege that the trial court erred during the evidentiary trial when it: allowed plaintiffs' experts to testify that non-asbestiform versions of the six asbestiform minerals, called "cleavage fragments," could cause mesothelioma; sua sponte consolidated the trials of the four groups of plaintiffs; struck defendants' entire closing argument; and made cumulative errors as to the admission of evidence that enticed the jury to accept plaintiffs' allegations that defendants' products contained asbestos and caused plaintiffs' mesothelioma. As to the punitive damages phase of the proceedings, defendants contend that the court erred when it: empaneled a new jury to decide punitive damages; denied defendants' motion for a new punitive damages trial; and failed to conduct an appropriate post-trial review of the punitive damages awards.

## II.

Defendants' primary argument is that the trial court erred by admitting expert testimony from Webber, Moline, and Longo. Specifically, defendants allege that the court abused its discretion when it denied their motions seeking N.J.R.E. 104 hearings because the testimony of Webber, Moline, and Longo was unreliable, not supported by generally accepted methodologies, and unsupported by the facts in the record. Additionally, defendants contend that the court failed to make sufficient findings under In re Accutane Litigation, 234 N.J. 340, 388 (2018), to justify its decision to admit the experts' opinions. Defendants rely on our decision in Lanzo v. Cyprus Amax Minerals Co., 467 N.J. Super. 476, 504-18 (App. Div. 2021) to further support these arguments.

Having considered defendants' contentions

on this point in light of the record and the applicable law, we agree that the trial court misapplied the well-established judicial gatekeeping procedures required by our courts and that the error was not harmless in regard to the testimony of Webber, Moline, and Longo. Therefore, we reverse and remand for a new trial.

A. STANDARD OF REVIEW AND THE TRIAL COURT'S GATEKEEPER ROLE IN THE ADMISSION OF EXPERT TESTIMONY

A reviewing court will apply an abuse of discretion standard of review when "assessing whether a trial court has properly admitted or excluded expert scientific testimony in a civil case." Accutane, 234 N.J. at 348, 392. On appeal, the trial court's ruling should be reversed only if it was "so wide off the mark that a manifest denial of justice resulted." Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999). Notably, harmless error should be disregarded and, instead, only errors "clearly capable of producing an unjust result" will cause the reversal of a jury verdict. Velazquez v. City of Camden, 447 N.J. Super. 224, 232 (App. Div. 2016) (quoting R. 2:10-2). A trial court's failure to perform its gatekeeping function by allowing experts to testify concerning untested opinions is error clearly capable of producing an unjust result. Lanzo, 467 N.J. Super. at 517-18.

***3** Expert testimony is governed by N.J.R.E. 702, which states that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise." There are three prerequisites to determine whether expert testimony is admissible, namely:

> (1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony.
>
> [Accutane, 234 N.J. at 348 (quoting State v. Kelly, 97 N.J. 178, 223 (1984)) (Handler, J., concurring in part and dissenting in part).]

Importantly, the Accutane Court touched on an important distinction when a court is charged with determining whether to admit expert testimony: a trial court is tasked with making legal determinations about the reliability of an expert's methodology, which is not to be confused with a credibility determination in the province of the jury. Id. at 388. As a result, the Accutane Court "clarif[ied] and reinforce[d] the proper role for the trial court as the gatekeeper of expert witness testimony." Id. at 389. It instructed the trial courts "to assess both the methodology used by the expert to arrive at an opinion and the underlying data used in the formation of the opinion." Id. at 396-97. This "rigorous" role is critical because the court's gatekeeping function prevents the jury from exposure to unsound

science that is labeled expert or scientific. Id. at 390.

When engaging in this analysis, the court must determine whether comparable experts accept the soundness of the presented methodology and evaluate the reasonableness of relying on the type of data and information underlying the expert's opinion. Id. at 390, 396-97. To aid in the evaluation of an expert's methodology, the Accutane Court encouraged trial courts to incorporate the Daubert[6] factors, which are both helpful and non-exhaustive. Id. at 398.

In general, several of the pertinent Daubert factors include:

> 1) Whether the scientific theory can be, or at any time has been, tested;
>
> 2) Whether the scientific theory has been subjected to peer review and publication, noting that publication is one form of peer review but is not a "sine qua non";
>
> 3) Whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the technique's operation; and
>
> 4) Whether there does exist a general acceptance in the scientific community about the scientific theory.
>
> [Ibid.]

Thus, under the standard set forth in Accutane, the party seeking to admit the testimony must show that the expert "applies his or her scientifically recognized methodology in a way that others in the field practice the methodology." Id. at 399-400. Notably, an expert should not selectively choose from the scientific landscape. Id. at 400.

The Court has also provided guidance for evaluating expert testimony in Rubanick v. Witco Chemical Corp., 125 N.J. 421, 449 (1991), when it held that "a scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." It emphasized that "[t]he critical determination is whether comparable experts accept the soundness of the methodology, including the reasonableness of relying on this type of underlying data and information." Id. at 451.

***4** Overall, the proposed expert's testimony should be excluded when it does not satisfy our Court's standards for a sound methodology and the reasonable reliance on the type of data and information used by other experts in the field. Accutane, 234 N.J. at 400. When an expert's opinion lacks the requisite foundation, it is an inadmissible net opinion or a bare opinion that has no support in factual evidence or similar data. Pomerantz Paper Corp. v. New Cmty. Corp., 207 N.J. 344, 372 (2011).

B. DEFENDANTS' CHALLENGE TO WEBBER'S TESTIMONY

Defendants claim that Webber provided unreliable opinions that non-asbestiform

cleavage fragments cause cancer. Specifically, defendants contend that the court erred when it allowed Webber to testify that asbestos can include non-asbestiform minerals and all fibers and, also, that non-asbestiform cleavage fragments can cause cancer. Defendants allege that the court should have held an N.J.R.E. 104 hearing, Webber's opinions were unreliable, and his statements on these topics were unreliable net opinions unsupported by data or a sound methodology.

**i. Webber's testimony at trial**

After hearing oral argument on defendants' motion to exclude Webber's testimony and request for an N.J.R.E. 104 hearing, the court denied defendants' motion without analysis and stated that defendants' concerns could be addressed during cross-examination. During oral argument, plaintiffs' counsel noted that Webber had testified before the same court in other matters and that Webber's testimony would be "exactly" what he had done in Lanzo in terms of giving an opinion as to whether there is asbestos in JBP.

At trial, Webber testified that the geological definition of "asbestos" is a particle that contains long thin fibers that are flexible and have high tensile strength. However, Webber stated that a fiber that lacks high tensile strength and good flexibility can still be asbestos, be dangerous, and cause mesothelioma, but it would not be as commercially useful. For example, he claimed that "tremolite fibers" are asbestos.

Webber further explained that the definition of "regulated asbestos" is long, thin, individual fibers with an aspect ratio of 3:1 or greater and with substantially parallel sides. Fibers that meet the definition of regulated asbestos have been related to asbestos disease. Later in his testimony, Webber stated that "non-talc needles," elongated particles with parallel sides, are considered fibers by the regulated asbestos definition.

When asked about cleavage fragments, Webber testified that they could form by breaking an amphibole rock. Occasionally, an amphibole rock could break into elongated particles that could meet the definition of a fiber if the particles have an aspect ratio of greater than 3:1 and parallel sides. Webber explained that these particles would be counted as asbestos fibers because there would be no way to differentiate whether the particle came from a crushed amphibole rock or a fiber of asbestos.

Webber explained that he was aware of arguments about the hazardousness, toxicity, or dangerousness of the cleavage fragment fibers. He stated that a cleavage fragment lacks the properties associated with a geologist's definition of asbestiform. Also, a cleavage fragment would not meet the definition of asbestos or be hazardous in instances where a cleavage fragment formed a chunk and lacked the problematic aspect ratio. However, when a cleavage fragment forms a fiber, it would be considered hazardous from an environmental health perspective because it has an aspect ratio of greater than 3:1 and essentially parallel

  

sides. Moreover, although most cleavage fragments would not be small enough to reach the alveoli part of the lungs, Webber stated that a cleavage fragment that was a fiber could reach the alveoli and be hazardous.

***5** To reach his conclusions, Webber generally relied upon "Surface Charge Measurements of Amphibole Cleavage Fragments and Fibers" published by the Bureau of Mines in 1980 (the Surface Charge Article). Webber did not discuss the details of the publication, the parameters of the study, or any of the scientific analysis. Without specifying, Webber stated that there is "some evidence" in the literature that the surface charge of a particle is a bio-activator that can cause the mesothelium or alveoli to react and lead to cancer. Webber cited only to the abstract of the publication to support his conclusion that the surface charge of asbestos fibers was the same as those of elongated cleavage fragments with the same aspect ratio.

Next, Webber generally cited to a United States Geological Survey entitled "Mineralogy and Morphology of Amphiboles Observed in Soils and Rocks in El Dorado Hills, California" dated 2006 (the 2006 Geological Survey). A small portion of the discussion section of the survey was read to the jury, and this passage stated that the definition of asbestos can vary based on the source of the particles and the purpose of the particles in an industry. Without discussing the details of the publication or any studies contained therein, Webber concluded that when a person is trying to define asbestos in environmental terms, an analyst must look at the aspects of fibers that are pertinent to human health.

Next, over defendants' objections, Webber relied upon a United States Environmental Protection Agency (EPA) Region 9 report dated April 20, 2006, entitled "Response to the November 2005 National Stone, Sand, & Gravel Association Report Prepared by the R.J. Lee Group, Inc. 'Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project' " (the 2006 EPA Region 9 Response) when forming his conclusions that the EPA made no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape. To support this conclusion, Webber merely read the same sentence from the publication to the jury and stated that he agreed with it. Further, to validate his notion that cleavage fragments could impact human health, Webber selected a few other sentences from the report that stated the cleavage fragment hypothesis needed to be studied further before experts could conclude that such particles are benign.

Again over defendants' objections, Webber next relied upon a 2009 article by Gregory Meeker from the United States Geological Survey (the Meeker article) as the basis for his conclusion that using the term "asbestiform" to differentiate a hazardous from a non-hazardous substance has no foundational basis in medical sciences. During cross-examination, Webber admitted that: he did not perform any exposure analysis or research to see if there were any trace amounts of asbestos in JBP; there was no scientific study published in peer review literature that concludes that JBP or STS increases a person's risk of mesothelioma;

and there have never been any published papers or studies that have concluded that cleavage fragments have the same health effects as asbestos or increase a person's risk for mesothelioma.

In addition, Webber admitted that: the Occupational Safety and Health Administration (OSHA) concluded that there was not enough substantial evidence to conclude that non-asbestiform versions of tremolite, anthophyllite, and actinolite present the same health effects as asbestos; and OSHA concluded that cleavage fragments do not have similar health effects as asbestos. Finally, when confronted with his prior publication from 2004 where he stated that not all particles with 3:1 aspect ratios are asbestos fibers, Webber explained that his prior statement was not "well-advised."

**ii. The Lanzo court's analysis of Webber's prior testimony**

***6** In Lanzo, we agreed with J&JCI and Imerys Talc America, Inc., the defendants in that case, that the trial court erred by abusing its discretion, and that the error was not harmless, when it allowed the jury to hear Webber's opinion that non-asbestiform minerals that are similar in size to asbestiform minerals can cause mesothelioma. Lanzo, 467 N.J. Super. at 503. During that trial, the court did not hold an N.J.R.E. 104 hearing to perform the analysis required by Accutane, failed to assess Webber's methodology, and did not consider Webber's underlying data. Id. at 507.

In front of the Lanzo jury, Webber stated that cleavage fragments had the same potential to cause disease as asbestos fibers with similar aerodynamic dimensions and, also, that he was not aware of any studies showing that non-asbestiform cleavage fragments can cause mesothelioma. Id. at 508-09. Further, Webber failed to cite to any authority for his claims that cleavage fragments present the same risk as asbestos fibers because of their identical chemical composition and bio-durability. Ibid.

We further took issue with the sources that Webber relied upon. Id. at 509. First, we held that a study by the pathologist Victor Roggli was insufficient to support the conclusion that non-asbestiform tremolite causes mesothelioma because the study did not distinguish between asbestiform and non-asbestiform fibers. Ibid. Second, we found that Webber's decision to cite a single quote from a paper entitled "Differentiating Non-Asbestiform Amphibole and Amphibole Asbestos by Size Characteristics" published in the December 2008 Journal of Occupational and Environmental Hygiene co-authored by Dr. Martin Harper and the National Institute of Occupational Safety and Health (NIOSH) was insufficient to explain the scientific basis for Webber's opinion that non-asbestiform amphibole particles could meet the definition for a fiber. Ibid. Moreover, a later NIOSH publication clarified that the inclusion of non-asbestiform minerals in the definition of airborne asbestos fibers was based on inconclusive evidence. Id. at 509-10.

Third, we ruled that Webber's reliance on the 2009 Meeker article was flawed. Id. at 510. In particular, the 2009 Meeker article's claim that using the term asbestiform to differentiate between hazardous and non-hazardous substances had no basis in the medical science. Ibid. Meeker failed to report a scientific study and the article was not peer reviewed. Ibid. Finally, we held that Webber's reliance on the 2006 EPA Region 9 Response was problematic because the publication claimed that the EPA made no distinction between fibers and cleavage fragments of the same chemical composition, size, and shape. Ibid. Notably, the EPA publication did not cite to any studies and Webber failed to discuss any details in his testimony. Ibid.

As to Webber's testimony specifically, we explained that his opinion that non-asbestiform cleavage fragments could cause mesothelioma was untested and he failed to show that his theory was generally accepted in the scientific community. Id. at 511. Further, we ruled that the trial court erred because it failed to establish that Webber's methodology involved data and information of the type reasonably relied upon by experts in the field, failed to assess Webber's methodology, and failed to consider the underlying data that Webber used to form his opinion. Ibid.

**iii. In the present case, the trial court erred by admitting Webber's expert testimony and the admission of this testimony was not harmless error**

***7** Here, as in Lanzo, the trial court failed to perform its gatekeeping role in assessing the underlying reasonableness of Webber's methodology and underlying data in forming his opinion. When citing to a limited number of publications, Webber failed to identify the data he used to form his opinion and did not discuss how the authorities he relied upon provided comparable data from other experts in the same field. Rather he only generally stated, without explanation or discussion, that the sources he relied upon were similarly relied upon by other unspecified experts.

Tellingly, when discussing the Surface Charge article, Webber did not discuss the details of the study or the parameters under which surface charges were evaluated. Webber only briefly referenced one sentence from the abstract to support his conclusion that cleavage fragments could cause cancer. Similarly, when discussing the 2006 Geological Survey, Webber extrapolated his idea that when studying asbestos in the environment, an analyst should look at the effects of asbestos on human health. There was no support in Webber's testimony that the 2006 Geological Survey made this connection or explained how he reached his conclusion.

Significantly, two of Webber's sources in the present case were explicitly criticized in Lanzo: the 2009 Meeker article; and the 2006 EPA Region 9 Response. In Lanzo, we stated that the 2009 Meeker article did not report the results of a scientific study, was not peer reviewed, made controversial claims, and did not support the proposition that non-asbestiform minerals can cause cancer. Id. at 510-11. Further, we explained

that the 2006 EPA Region 9 Response provided no details of any studies, made no distinctions between asbestiform fibers and cleavage fragments; and did not state that exposure to cleavage fragments caused mesothelioma. Ibid. Webber's testimony as to these two sources is similarly faulty in the present case.

As to the trial court's gatekeeping function, it failed to hold an N.J.R.E. 104 hearing and made no legal determinations of reliability about Webber's methodology. Rather, the court allowed the jury to hear unsound science labeled as expert and scientific when it allowed the jury to make credibility determinations, contrary to the explicit instructions in Accutane.

Further, an application of the Daubert factors does not support the admission of Webber's testimony as his theories were untested, not subject to peer-review, and not generally accepted in the scientific community. Importantly, Webber did not explain the standards he applied to reach his conclusions and instead set forth bare conclusion in the form of an unsupported opinion. For the court's part, it did not assess Webber's methodology or underlying data used to form his opinion. Therefore, the court mistakenly exercised its discretion when it admitted Webber's testimony.

The trial court's error in admitting the testimony was harmful error because it was "so wide off the mark that a manifest denial of justice resulted." Green, 160 N.J. at 492. Webber theorized that cleavage fragments could cause mesothelioma without support and the testimony bolstered plaintiffs' claims that their illnesses were linked to particles that could have been present in talcum powder. Although Webber did not opine that cleavage fragments were in JBP or STS, he linked the existence of cleavage fragments to mesothelioma.

Moreover, the jury heard testimony from Longo, another of plaintiffs' experts, that the tool he used to identify fibers[7] could not distinguish between whether a fiber was asbestiform or non-asbestiform. As a result, the implication is that all fibers could cause mesothelioma if either asbestiform fiber particles or fiber-shaped non-asbestiform cleavage fragments can cause cancer. Thus, the jury heard unsupported theories that cleavage fragments could cause cancer and we are satisfied this error was "clearly capable of producing an unjust result." Velazquez, 447 N.J. Super. at 232. As a result, the jury verdict must be overturned and a new trial held.

## C. DEFENDANTS' CHALLENGE TO MOLINE'S TESTIMONY

***8** Defendants also allege that the trial court should have precluded or stricken Moline's expert testimony. Specifically, defendants contend that the court erred when it allowed Moline to testify that non-asbestiform cleavage fragments and asbestiform fibers have the same health effects and, also, that defendants' products caused plaintiffs' mesothelioma.

**i. Moline's testimony at trial**

After hearing oral argument, the trial court denied defendants' motion seeking an N.J.R.E. 104 hearing and to exclude Moline's testimony regarding cleavage fragments. It held that Moline's testimony was not cumulative and confined her testimony to the parameters of her expert report regarding cleavage fragments. The court noted that Moline had "apparently cited to literature and different agencies" with regard to her opinions on cleavage fragments. Moreover, without further analysis, the court stated generally that there "are geological definitions that defendants point to and they have their experts in that regard, and there is a body of agencies and opinions relative ... toward the discussion of what does it all mean, in terms of medicine and ... the effect on the body."

At the outset of her testimony, Moline explained that asbestos is a fiber and that there are six regulated types of asbestos. She stated that she relied on a 2019 article from the Finnish Institute of Occupational Health entitled "Asbestos risk management guidelines for mines" (the 2019 Finnish article). She generally explained that the article supported her definition of asbestos as being any particle that has a minimum "length-to-thickness ratio" of 3:1. Moreover, she claimed without specificity that from an occupational medicine and public health point of view, fibers that are longer than they are wide are hazardous, cause cancer, and lead to pulmonary diseases.

Moline stated that she relied on a 2014 article by "Gordon, Fitzgerald, and Millette" entitled "Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in woman" (the 2014 Gordon article) to support her conclusion that exposure to talc, including defendants' talc, can cause mesothelioma. However, she did not discuss the details of the study, the data, or the results.

Later in her testimony, Moline again relied generally on the 2019 Finnish article when she concluded that all types of asbestos could cause mesothelioma. Without explaining the scientific basis for her theory, she stated that asbestos fibers that meet the size criteria pose a health risk regardless of how they are characterized by a geologist or mineralogist.

When discussing whether defendants' products caused plaintiffs' mesothelioma, Moline stated that she had reviewed "papers" showing that asbestos can become airborne when using talcum powders. She again briefly referred to the 2014 Gordon article, an untitled paper by "Rohl," and an unnamed study by "Mattenklott." At no point in Moline's testimony did she explain the details or specifics of the Rohl and Mattenklott studies. Rather, she would generally refer to these three papers throughout her testimony without describing the specific parameters of the studies to support her conclusion that billions of particles of asbestos can become airborne when small amounts of talcum powder were used.

On cross-examination, Moline admitted that she had never concluded that talcum powder caused mesothelioma prior to being hired by plaintiffs' attorneys. Moreover, she admitted that she issued her opinion that defendants' products caused plaintiffs' mesothelioma

prior to interviewing or examining Barden and Etheridge and, also, without interviewing or examining McNeill-George and Ronning.

**ii. The Lanzo court's analysis of Moline's prior trial testimony**

***9** In Lanzo, we concluded that Moline's expert testimony that non-asbestiform minerals can cause mesothelioma suffered from similar defects as Webber's opinions at trial. Lanzo, 467 N.J. Super at 511-12. We held that the trial court failed to assess Moline's methodology and the underlying data that she used to form her opinions. Id. at 513. Accordingly, we reversed and remanded for a new trial because the court failed to perform its gatekeeping function. Ibid.

For example, Moline relied on the 2006 EPA Region 9 Response when she concluded that there was no difference between asbestiform fibers and non-asbestiform cleavage fragments with the same dimensions and chemical compositions in terms of their ability to cause disease. Id. at 512. Moline failed to support her claims that there had been published literature and, also, studies to form the basis for her conclusions that non-asbestiform amphiboles cause mesothelioma. Ibid. Moreover, although she claimed that she reviewed additional studies and found information to support her statement that non-asbestiform minerals were carcinogenic, she failed to identify these studies. Id. at 512-13.

Moline's expert report stated, without support, that the EPA, Centers for Disease Control (CDC), and American Thoracic Society rejected the notion that there is biological significance to labeling anthophyllite or tremolite as either non-asbestiform or cleavage fragments. Id. at 512. She also failed to cite her sources for her claim that miners and millers of talc in New York had mesothelioma caused by talc containing approximately 50% non-asbestiform anthophyllite and tremolite. Ibid.

**iii. In the present case, the trial court erred by admitting Moline's expert testimony and the admission of this testimony was not harmless error**

Again, as in Lanzo, the trial court failed to perform its gatekeeping role in assessing the underlying reasonableness of Moline's methodology and underlying data in forming her opinion. Moline failed to identify the data she used to develop her opinion, did not discuss how the authorities she relied upon provided comparable data from other experts in the same field, and in some instances failed to adequately identify her sources. For example, she repeatedly cited to studies by Rohl and Mattenklott which may have had the effect of bolstering her statements to the jury as being more reliable despite Moline failing to discuss any details of such studies.

Further, Moline failed to explain her methodology or data as it related to her use

of the 2019 Finnish article to support her claim that from a public health point of view, fibers that are longer than they are wide are hazardous, cause cancer, and lead to pulmonary diseases. Similarly, she failed to explain the link between her theories about the causes of mesothelioma and the 2014 Gordon article because she did not explain the article including the data relied upon and the analysis.

As to the trial court's gatekeeping function, it again failed to hold an N.J.R.E. 104 hearing and made no legal determinations of reliability about Moline's methodology. The court also permitted the jury to make credibility determinations as to the quality of the expert testimony instead of first determining whether Moline's opinion was based on sound and adequately founded scientific methodology.

For the same reasons stated above regarding the admission of Webber's testimony, the trial court's failure to adequately perform its gatekeeping function was harmful error because it was "so wide off the mark that a manifest denial of justice resulted." Green, 160 N.J. at 492. Moline theorized that cleavage fragments could cause mesothelioma, but did not opine that cleavage fragments were in JBP or STS. However, her testimony bolstered plaintiffs' claims that they could have been exposed to substances that caused their mesothelioma. What is more, the jury could associate Moline's statements with Longo's testimony to conclude that all fibers could cause mesothelioma if either asbestiform fiber particles or fiber-shaped non-asbestiform cleavage fragments can cause cancer. Thus, via Moline's testimony, the jury heard unsupported theories that cleavage fragments could cause cancer. Because this error was "clearly capable of producing an unjust result," Velazquez, 447 N.J. Super. at 232, we reverse and remand for a new trial.

## D. DEFENDANTS' CHALLENGE TO LONGO'S EXTRAPOLATION TESTIMONY

***10** Defendants also raise several arguments concerning the trial court's admission of Longo's expert testimony. We will address defendants' contentions concerning Longo's extrapolation testimony because that testimony represents another occasion where the court failed to discharge its gatekeeping function as required by Accutane.

### i. The trial court's decision

After hearing oral argument, the trial court denied defendants' motion to hold an N.J.R.E. 104 hearing and exclude Longo's trial testimony concerning his "exposure calculations" where he extrapolated the number of ten-ounce containers of defendants' products that each plaintiff used in their lifetime. As to Longo's extrapolation testimony, the court merely stated that it was "something that Dr. Longo has done in this courtroom during the course of trials, where he takes the testimony ... of the plaintiff and he does an extrapolation." The court stated that it had seen Longo use data on "some" J&J documents previously. On the basis of

  

those statements, the court concluded that there would be no prejudice in allowing Longo to testify as to extrapolation because "he's done it on other trials." Instead of analyzing the matter further in accordance with the Accutane mandates, the court stated that any issues with Longo's testimony on this subject could be resolved on cross-examination.

**ii. Longo's testimony regarding extrapolation**

Longo explained that he reviewed the deposition testimony of McNeill-George, Etheridge, Barden, and Ronning. He believed that their description of how they used J&J's products was fair because based on J&J's own studies, most users of J&J's products used them after showering as plaintiffs had. Based on J&J's own studies, people used about eight grams per application.

Based upon that ambiguous data, Longo estimated that McNeill-George would have had 13,578 exposures to JBP and STS made with talc from the Vermont and Chinese mines and those exposures would have been substantial. He opined that Etheridge would have had approximately 8,180 applications of JBP, was exposed to substantial amounts of asbestos, and would have been exposed to the Vermont and Chinese talc.

According to Longo's analysis, Barden used JBP for approximately 23,449 applications, was exposed to substantial amounts of asbestos by virtue of his use of JBP, and that the talc came from the Italian and Vermont mines based on the timing of his usage. Finally, Longo told the jury that Ronning had approximately 6,787 applications of JBP with talc from the Vermont and Chinese mines, which would have represented a substantial exposure.

On cross-examination, Longo explained that he counted the number of applications, counted the amount of talcum powder used per person, and provided a potential range of exposure when he concluded that it was more likely than not that each plaintiff had substantial exposure to asbestos from defendants' products. He based his extrapolation data on a sample from a bottle of defendants' product that had been obtained on eBay. This bottle had the highest concentration of asbestos of any of the sample bottles Longo examined. Longo testified he used this unique sample bottle because the concentration of asbestos in it was similar to a published paper that had an analogous amount of asbestos and he wanted to compare the two.

***11** During cross-examination, defense counsel asked how Longo determined whether someone experienced "substantial exposure" to asbestos and alleged his testimony contradicted his expert testimony in other matters. In particular, in a prior case, Longo testified about an individual's use of crocidolite filters used in "Kent Micronite" brand cigarettes and, also, that same individual's possible asbestos exposure from mixing cement with asbestos. At the time of that case, Longo did not believe that the asbestos in the cement would cause significant asbestos exposure. He admitted that the asbestos in the mixing

  

cement was in excess of the asbestos found in JBP, but explained that the exposure to the asbestos in JBP was higher because it was being used as a hygiene product.

**iii. The trial court erred by admitting Longo's extrapolation testimony and the admission of this testimony was not harmless error**

As set forth above, Longo estimated the number of exposures McNeill-George, Etheridge, Barden, and Ronning each had to defendants' products based upon: their deposition testimony about the number of times they used defendants' products per day; J&J's own studies about the amount of talcum powder a person used per application; and the length of time each plaintiff used defendants' products as presented in their respective deposition testimony. In permitting this testimony without first conducting an N.J.R.E. 104 hearing and subjecting Longo's claims to the standards set forth in Accutane and Daubert, the trial court clearly erred in its judicial gatekeeping and abused its discretion.

There is insufficient evidence in the record to conclude that Longo's extrapolation methodology was based on a sound, adequately founded scientific methodology involving data reasonably relied upon by experts in the scientific field. Further, it is unclear if Longo's extrapolation method had been tested, subjected to peer review or publication, subjected to standards for controlling the technique, or accepted in the scientific community.

Tellingly, the trial court's analysis of the extrapolation method only consisted of recognizing that Longo had presented similar data in prior cases and had used J&J's documents in his analysis. This meager "finding" plainly did not comply with the strictures of Accutane and Daubert.

The trial court's admission of Longo's extrapolation testimony was harmful because it lent significant weight to plaintiffs' assertions that defendants' products were a substantial factor in causing plaintiffs' mesothelioma. This error was clearly capable of producing an unjust result. Therefore, the matter must be reversed and remanded for a new trial.

E. CONCLUSION

In sum, the trial court erred when it admitted Webber's and Moline's testimony about cleavage fragments, and Longo's extrapolation testimony. These errors, taken singularly or collectively, were harmful and require the reversal of the jury verdict. See Lanzo, 467 N.J. Super. at 517-18 (holding that trial court's failure to perform its gatekeeping function by allowing experts to testify concerning untested opinions is error clearly capable of producing unjust result). Therefore, we reverse the July 24, 2020, orders of final judgment and remand the matter for new trials.

In view of our decision, we need not address the other issues that defendants have raised on appeal, including their contentions that

the trial court erred by: striking their closing argument; consolidating the four matters for trial; committing other evidentiary and trial errors; empaneling a new jury for the punitive damages phase of the trial; denying their motion for a new trial on punitive damages; and failing to conduct an appropriate post-trial review of the punitive damages awards.

Reversed and remanded to the trial court for further proceedings in accordance with this opinion. We do not retain jurisdiction.

**All Citations**

Not Reported in Atl. Rptr., 2023 WL 6430088

## Footnotes

1 The four primary plaintiffs were D'Angela M. McNeill George, David Charles Etheridge, Douglas Barden, and William Ronning. Etheridge, Barden, and Ronning passed away during the course of the proceedings and their estates were substituted as plaintiffs.

2 Etheridge's, Barden's and Ronning's respective spouses also filed claims for loss of consortium.

3 The parties did not include the transcripts of the trial court's jury voir dire. As a result, the total number of trial days is unclear from the record on appeal.

4 The trial court later calculated prejudgment interest, which was added to each award.

5 The punitive damages phase of the trial lasted approximately sixteen non-consecutive days. Again, the total number of trial days is unclear from the appellate record.

6 Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593-95 (1993). Recently, in State v. Olenowski, 253 N.J. 133, 151-52 (2023), our Court adopted the Daubert principles in criminal cases.

  

[7] Longo testified he used a transmission electron microscope (TEM) to conduct his analysis.

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2024 WL 730342
Only the Westlaw citation is currently available.

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey, Appellate Division.

Thomas A. FREDELLA and Kelly A. Kearny, Plaintiffs-Appellants,
v.
TOWNSHIP OF TOMS RIVER, State of New Jersey Department of Transportation, and State of New Jersey Department of the Treasury-Fleet Management, Defendants-Respondents.

DOCKET NO. A-3196-21
|
Argued January 31, 2024
|
Decided February 22, 2024

On appeal from the Superior Court of New Jersey, Law Division, Ocean County, Docket No. L-3198-17.

**Attorneys and Law Firms**

Phillip C. Wiskow argued the cause for appellants (Gelman Gelman Wiskow & McCarthy, LLC, attorneys; Phillip C. Wiskow, on the briefs).

Thomas E. Monahan argued the cause for respondent Township of Toms River (Dasti, McGuckin, McNichols Connors Anthony & Buckley, attorneys; Thomas E. Monahan, of counsel; Patrick F. Varga, on the brief).

Before Judges Firko, Susswein, and Vanek.

**Opinion**

PER CURIAM

***1** This appeal arises out of a negligence lawsuit filed by plaintiffs Thomas A. Fredella (plaintiff)[1] and his now ex-wife, Kelly A. Kearney, against defendants Township of Toms River (the Township), State of New Jersey Department of Transportation (DOT), and State of New Jersey Department of the Treasury-Fleet Management arising out of a motor vehicle accident. On November 5, 2016, at 9:10 p.m., plaintiff struck a parked DOT truck that was responding to a call from the Toms River Police Department to remove a deer carcass from Route 37.

Plaintiff drove into the back of the DOT truck, resulting in severe injuries to his right leg. When emergency medical technicians (EMTs) arrived and had difficulty locating a vein to administer medication to plaintiff, he told them that he had used heroin earlier that day. The Township claimed plaintiff was contributorily negligent and a proximate cause of the accident because he was inattentive while driving and was under the influence of heroin.

Prior to trial, plaintiff and Kearny reached a settlement with the DOT and the Department of the Treasury (the DOT

 

settlement). A jury returned a verdict finding that all parties were responsible for the accident, allocating fault as follows: plaintiff sixty percent responsible; the Township twenty percent responsible; and the DOT twenty percent responsible. Based upon this verdict, plaintiff did not receive any award of damages.[2]

On appeal, plaintiff primarily challenges two trial court rulings, including the admission of the testimony of the Township's medical expert, Lawrence Guzzardi, M.D., without first holding a Frye/Daubert[3] hearing to determine whether the expert employed a reliable methodology. Dr. Guzzardi is an emergency room doctor and a toxicologist. Plaintiff filed three pre-trial motions objecting to Dr. Guzzardi testifying based on his expertise, arguing his opinion was an improper net opinion, and that the expert lacked the requisite expertise to offer testimony on the effect that heroin allegedly had on plaintiff's vision at the time of the accident. The trial court denied all of plaintiff's motions, finding Dr. Guzzardi had the requisite knowledge, training, and expertise to opine plaintiff was under the influence of heroin at the time of the accident. Plaintiff also contends the trial court erred in providing the Model Jury Charge on settling defendants.

For the reasons that follow, we remand for further proceedings and more detailed findings by the trial court addressing each of the discrete factors set forth in Daubert, as adopted with certain conditions by our Supreme Court in the matter of In re Accutane Litig., 234 N.J. 340 (2018). We affirm, however, the trial court's decision to use the Model Jury Charge to instruct the jury on settling defendants.

## I.

***2** We summarize the facts from the record most significant to the issues plaintiff has raised on appeal.

### A. The Accident

A motorist struck a deer while driving on Route 37 at approximately 7:00 p.m. on the day of plaintiff's accident. After the accident, its carcass lay across the right lane, with some innards and organs strewn into the center lane of the roadway. Officer Justin Lammer responded to the scene within five minutes, at 7:10 p.m. Lammer did not recall any details about the accident or seeing the deer and left the scene at approximately 7:54 p.m. At 8:12 p.m., DOT received a call from dispatch to remove the deer carcass.

At trial, Lammer agreed that per department policy, he was required to move animal carcasses to the side of the road if he could safely do so. Lammer stated if an officer could not move a carcass or any other type of obstruction from the road, the officer had to wait on the scene until the carcass was removed.

At 8:41 p.m. three DOT workers arrived—two in a pick-up truck with flashing lights and one in a safety truck with flashing lights and an arrow board—to direct

  

traffic. The record is unclear as to whether the arrow board was lit at the time of the accident. The DOT workers did not set up any additional safety precautions, such as cones or signs. The DOT trucks were initially parked on the shoulder lane of Route 37, but about a minute before the accident, they moved off the shoulder and parked in the right lane to begin the carcass removal process.

Plaintiff drove onto Route 37 from an exit ramp off the Garden State Parkway. He recalled seeing taillights driving about "two football fields" ahead of him. After merging onto Route 37, plaintiff moved to the center lane, then back to the right lane, when he struck the rear of the DOT safety truck.[4] Plaintiff testified he did not see any vehicles ahead of him before he hit the truck and did not see any lit signs or flashing lights.

Plaintiff sustained a severe open fracture in his lower right leg and had multiple breaks in the bone. Between November 2016 and February 2018, he underwent more than a dozen surgeries due to complications arising from infections and bone alignment. Ultimately, due to reoccurring risk of infection, plaintiff planned to have his leg amputated based on his doctor's recommendation.

B. Heroin Evidence

Plaintiff testified he told the EMTs he had used two bags of heroin the day of the accident, either late that morning or early that afternoon, because they had difficulty finding a vein to inject medication. According to plaintiff, the amount of heroin was the equivalent of drinking three beers and affected him for no more than thirty to forty-five minutes. Neither the police reports nor the EMT records noted plaintiff as being under the influence of any substance, but the EMT records noted that plaintiff had "pinpoint" pupils, measuring at two millimeters.[5] There were no laboratory tests confirming the levels of heroin in plaintiff's system at any time relevant to this matter.

***3** On March 30, 2021, plaintiff and Kearny reached the DOT settlement. That same day, plaintiff moved in limine to preclude Dr. Guzzardi from testifying that plaintiff was under the influence of heroin at the time of the accident, that the heroin impaired his vision and contributed to the accident. Plaintiff contended that Dr. Guzzardi's opinion should not be presented to the jury because he did not establish that plaintiff's heroin use was a substantial contributing factor to the accident.[6] Plaintiff also moved to bar the Township from advising the jury that he, Kearny, and DOT reached a settlement. The trial court denied both motions, finding Dr. Guzzardi's reports did not constitute a net opinion and that the Model Jury Charges expressly required such instruction.

Subsequently, Dr. Guzzardi was deposed. Dr. Guzzardi opined that at the time of the accident, plaintiff was "under the influence of heroin." The expert based his opinion on plaintiff's admission he had injected heroin earlier the day of the accident and the EMT's notation that he had pinpoint pupils, meaning his pupils measured only two millimeters. When assessing if someone is

  

under the influence of heroin, Dr. Guzzardi explained he looks at the patient's history, their clinical presentation, and laboratory tests.

Dr. Guzzardi testified that here, two of the three factors were satisfied because plaintiff had admitted to using heroin and presented with pinpoint pupils at the scene of the accident. Dr. Guzzardi stated morphine had a "half life of two to four hours," and that if plaintiff took heroin in the morning or early afternoon, it "would still be present in his body at the time of his accident and affecting the central nervous system." Dr. Guzzardi explained that heroin could affect alertness, judgment, reaction time, and night vision.

Dr. Guzzardi acknowledged there were unknown variables regarding plaintiff's level of intoxication, such as the exact time of the heroin injection, and whether any amount was in his system at the time of the accident, because no drug test was administered. A critical facet of Dr. Guzzardi's analysis was he did not know plaintiff's level of intoxication at the time of the accident and to what extent it had impacted his driving. However, Dr. Guzzardi stated that plaintiff's pinpoint pupils sufficiently demonstrated that he remained "adversely affected by heroin" and that his pupil size negatively impacted his vision, which "adversely affected" his driving.

Dr. Guzzardi testified there are four potential causes for pinpoint pupils: severe brain hemorrhage; pilocarpine—a drug used to treat glaucoma; exposure to high levels of organophosphate toxins (like insecticides); and narcotics. Dr. Guzzardi stated pupils can measure from two millimeters to eight-and-a-half millimeters, and that the average pupil measured from three-and-a-half millimeters to seven millimeters.[7]

The size of plaintiff's pupils recorded at the scene of the accident—two millimeters—was significant to Dr. Guzzardi because he felt it restricted plaintiff's ability to see light and limited his peripheral vision. Because the accident occurred at night, Dr. Guzzardi elaborated that regardless of whether the safety truck had its lights on, "if your eyes are made small, pinpoint, your eyes cannot get enough light in." Dr. Guzzardi stated that narcotics impact the eye's ability to adjust, and with pinpoint pupils, "you don't get enough light in." Dr. Guzzardi opined that the heroin impacted plaintiff's peripheral vision and might have been the reason why he did not notice the DOT truck directly ahead of him, especially in light of the fact plaintiff was changing lanes at the time.[8]

***4** Although Dr. Guzzardi offered an opinion, he conceded that he is not an ophthalmologist and could not explain or quantify to what extent plaintiff's vision was impacted. And without bloodwork, Dr. Guzzardi could not determine whether plaintiff's heroin use adversely impacted his judgment or reflexes at the time of the accident.

Following Dr. Guzzardi's deposition, plaintiff again moved to bar his testimony at trial because plaintiff's expert—who did not testify—disputed Dr. Guzzardi's opinion that two-millimeter pupils qualify as

pinpoint pupils. In addition, plaintiff argued that under New Jersey caselaw, a party's intoxication could not be introduced without supplementary evidence that the party's intoxication had contributed to the accident. The trial court denied plaintiff's motion, finding that any disagreement between the experts was a matter of weight, not admissibility, Dr. Guzzardi's testimony was sufficient to link plaintiff's admitted heroin use to his impaired driving, and the proffered testimony was not unduly prejudicial.

At his deposition, Dr. Guzzardi did not cite to any articles or studies in support of his opinion, which he stated was based on his clinical experience and review of plaintiff's medical records. When pressed on cross-examination on his failure to cite to any authority about heroin use and pupil size, Dr. Guzzardi answered this was "well known" to toxicologists and emergency physicians, and that "[e]very emergency physician knows that two-millimeter pupils are myotic pupils compatible with morphine abuse." When questioned whether this information was contained in a learned treatise, Dr. Guzzardi responded it was "such common knowledge that [he] did not cite it." Dr. Guzzardi added that he had "published ... on the effect of morphine and opiates on pupil size" and had "testified about this [issue] before our Supreme Court."

In his second motion, plaintiff again argued that his expert disputed Dr. Guzzardi's definition of pinpoint pupils as measuring two millimeters. And, plaintiff asserted that regardless, his heroin use could not be introduced without supplemental evidence that he was intoxicated at the time of the accident, and his intoxication impaired his driving. The trial court denied the motion and again held that any dispute about pupil size went to the weight of the testimony, not its admissibility. In addition, the trial court disagreed with plaintiff's interpretation of the caselaw, holding Dr. Guzzardi's testimony was sufficient to link plaintiff's admitted heroin use to his impaired driving. The trial court reiterated its prior finding that Dr. Guzzardi's opinion was not a net opinion and determined his testimony was not excludable under N.J.R.E. 403 because its probative value was not substantially outweighed by the risk of undue prejudice.

On April 21, 2022, plaintiff sent a letter to the trial court making his third motion requesting a Frye/Daubert hearing to ascertain the admissibility of Dr. Guzzardi's testimony. The trial court heard oral argument on the request that day and reserved decision. A week later, on April 28, 2022, the trial court issued an order accompanied by a written decision denying plaintiff's request for a Frye/Daubert hearing and concluding a pre-trial hearing was unnecessary because Dr. Guzzardi had the requisite knowledge, training, or expertise to opine that plaintiff was under the influence of heroin at the time of the accident, which impaired his ability to operate a motor vehicle.

***5** The trial court found Dr. Guzzardi had the "appropriate credentials to offer the opinions expressed in his report," and he provided "sufficient 'whys and wherefores' in support of his opinion." The trial court noted plaintiff could raise timely objections at trial about Dr. Guzzardi's "qualifications,

foundation, scope," and the court's N.J.R.E. 403 ruling. The trial court further stated that an expert's opinion need not be based on "treatises or any type of documentary support but may include what the witness has learned from personal experience." The trial court did not make findings about Dr. Guzzardi's ability to testify as to the impact of opioids on vision. However, during trial, the trial court ruled, consistent with its prior decision, that Dr. Guzzardi's inability to quantify the extent to which plaintiff's pinpoint pupils impacted his vision went to the weight of his testimony, not its admissibility. This appeal followed.

II.

Our Supreme Court has instructed that in determining the admissibility of scientific expert testimony in civil, and now criminal cases, our trial courts must utilize a "methodology-based test for reliability" similar to the standard set forth by the United States Supreme Court in Daubert. In re Accutane, 234 N.J. at 397. This standard is as follows:

> Our view of proper gatekeeping in a methodology-based approach to reliability for expert scientific testimony requires the proponent to demonstrate that the expert applies his or her scientifically recognized methodology in the way that others in the field practice the methodology. When a proponent does not demonstrate the soundness of a methodology, both in terms of its approach to reasoning and to its use of data, from the perspective of others within the relevant scientific community, the gatekeeper should exclude the proposed expert testimony on the basis that it is unreliable.
>
> [Id. at 399-400.]

Applying this standard, our courts must consider "whether an expert's reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to facts in issue." Id. at 397 (citing Daubert, 509 U.S. at 591, 594-95; Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991)).

The trial court's role is not to "substitute its judgment for that of the relevant scientific community," but "to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." Id. at 414. Thus, experts "must be able to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are scientifically reliable." Id. at 417. Moreover, when an expert relies on scientific or medical studies, "the trial court should review the studies, as well as other information proffered by the parties, to determine if they are of a kind on which such experts ordinarily rely," and if they are "derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." Ibid.

When applying this standard, our judges should now address the multiple Daubert

factors, a " 'helpful—but not necessary or definitive—guide' for trial courts in New Jersey" to follow when assessing the reliability of scientific or technical expert testimony. State v. Olenowski, 253 N.J. 133, 149 (2023) (quoting In re Accutane, 234 N.J. at 398). These factors are as follows:

> (1) Whether the scientific theory can be, or at any time has been, tested;
>
> (2) Whether the scientific theory has been subjected to peer review and publication, noting that publication is one form of peer review but is not a "sine qua non";
>
> (3) Whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the technique's operation; and
>
> (4) Whether there does exist a general acceptance in the scientific community about the scientific theory.
>
> ***6** [In re Accutane, 234 N.J. at 398 (citing Daubert, 509 U.S. at 593-95).]

The first enumerated Daubert factor—testability—relates closely to the dual components of the third factor, error rate and standards. Testability is "a key question" that entails whether a theory or technique "can be (and has been) tested." Daubert, 509 U.S. at 593.

The second Daubert factor—peer review and publication—is significant because submission of a methodology "to the scrutiny of the scientific community is a component of 'good science' " and "increases the likelihood that substantive flaws in methodology will be detected." Ibid.

The third Daubert factor concerns both the known or potential rate of error in testing the methodology as well as any standards for maintaining or controlling the methodology's operation. Id. at 594. As the Court noted in Daubert, a trial court "ordinarily" should account for the "known or potential rate of error" of a methodology. Ibid. In addition, a methodology is more reliable if it is governed by well-established standards for operation. Ibid. See also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 154-57 (1999) (rejecting as inadmissible an expert who had not consistently adhered to a protocol with appropriate standards).

Lastly, the fourth Daubert factor—general acceptance—(the former test of Frye is no longer the dispositive test since the Court has adopted the multifactor Daubert approach) is still pertinent. Daubert, 509 U.S. at 594-96; In re Accutane, 234 N.J. at 398.

As the Supreme Court stated in In re Accutane, 234 N.J. at 398, and again in Olenowski, these specific factors are not a rigid set of considerations for ascertaining the reliability of a proffered expert's methodology. 253 N.J. at 149. Nonetheless, they provide an important framework for guiding the analysis. The trial court's consideration of each of these factors is integral to the appellate court's review of whether the trial court abused its discretion in concluding whether an expert's methodology was sufficiently reliable to be admitted to a jury. In re Accutane, 234 N.J.

  

at 391.

In the matter under review, plaintiff contends that the trial court erred in admitting Dr. Guzzardi's testimony without first determining whether his opinion satisfied the Frye standard. Plaintiff also challenges the accuracy of the measurement of his pupils—and the definition of pinpoint pupils—arguing that this undermines Dr. Guzzardi's basis for concluding the pupil size meant plaintiff was under the influence of heroin at the time of the accident.

Plaintiff maintains an evidentiary hearing was necessary first to establish that Dr. Guzzardi correctly defined pinpoint pupils as measuring two millimeters, and second to determine whether there was scientific support for the proposition that pinpoint pupils are a sign the person is under the influence of opiates. Relatedly, plaintiff argues that Dr. Guzzardi's testimony was inadmissible because he could not quantify plaintiff's level of impairment and, thus, could not determine whether his impairment was a substantial contributing factor for the accident.

***7** In reviewing a trial court's decision on admission of expert testimony in a civil action, we apply an abuse of discretion standard. In re Accutane Litig., 234 N.J. at 392. This standard extends to the decision to conduct a pre-trial evidentiary hearing. Kemp by Wright v. State, 174 N.J. 412, 432 (2002). The trial court's ruling should be reversed "only if it 'was so wide off the mark that a manifest denial of justice resulted.' " Rodriguez v. Wal-Mart Stores, Inc., 237 N.J. 36, 57 (2019) (quoting Griffin v. City of E. Orange, 225 N.J. 400, 413 (2016)).

The admission of expert testimony is generally governed by N.J.R.E. 702, which provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise." To satisfy this standard, the proponent of expert testimony must establish that: (1) the subject matter of the testimony is "beyond the ken of the average juror"; (2) the field of inquiry is "at a state of the art such that an expert's testimony could be sufficiently reliable"; and (3) the witness has "sufficient expertise" to offer the testimony. In re Accutane Litig., 234 N.J. at 349 (quoting State v. Kelly, 97 N.J. 178, 223 (1984)). This is "the baseline for the admissibility of expert testimony." Ibid.

Here, the first prong of N.J.R.E. 702 is satisfied because there is no dispute that the impact of opiates on vision is beyond the ken of the average juror. The third prong of N.J.R.E. 702 was addressed by the trial court's finding that Dr. Guzzardi had sufficient expertise to opine that plaintiff was under the influence at the time of the accident. But the trial court did not address the second prong of N.J.R.E. 702—whether Dr. Guzzardi's opinion was based on a reliably sound methodology—and instead focused on whether his testimony amounted to an impermissible net opinion.

On appeal, plaintiff does not dispute that heroin use causes pinpoint pupils but rather he challenges the definition of pinpoint

pupils, whether his presentation fit this definition, whether the presence of pinpoint pupils was an accurate estimator that he remained under the influence of heroin, and whether his pinpoint pupils impacted his vision. Our review of the record reveals the trial court did not consider these arguments, all of which challenge the reliability of Dr. Guzzardi's opinion.

We have an overarching concern that the trial court's analysis failed to sufficiently adhere to the Daubert standard and the principles set forth by our Supreme Court more recently in Accutane and Olenowski. Put succinctly, Dr. Guzzardi opined that because plaintiff had admitted to using heroin earlier in the day, and because he presented with pinpoint pupils at the time of the accident, he was still under the influence of heroin at the time of the accident.

Dr. Guzzardi did not claim that plaintiff's heroin use impaired his judgment or reaction time; he conceded that he could not make those determinations because he did not know how much heroin was in plaintiff's system. Nonetheless, Dr. Guzzardi opined that plaintiff's pinpoint pupils impaired his peripheral vision and ability to see at night. This conclusion is salient because the only adverse effect of plaintiff's heroin use according to Dr. Guzzardi, was its impact on plaintiff's vision. The trial court never determined that Dr. Guzzardi was qualified to testify about vision under N.J.R.E. 702.

***8** Moreover, there is no real dispute that heroin can cause pinpoint pupils, and that Dr. Guzzardi, having expertise in toxicology, can opine as to that fact. But, Dr. Guzzardi's opinion went beyond this point, opining about how pinpoint pupils, in turn, impact one's peripheral vision and ability to see at night. While our Supreme Court has taken a liberal approach when assessing an individual's qualifications to testify on a topic as an expert witness, State v. Jenewicz, 193 N.J. 440, 454 (2008), the trial court did not address whether Dr. Guzzardi's expertise—as a toxicologist and emergency room physician—extended to how opioids impact one's vision, despite his lack of qualifications as an ophthalmologist. In this respect, Dr. Guzzardi's lack of expertise in the area of ophthalmology may constitute a flawed analysis, and the trial court failed to properly assess Dr. Guzzardi's qualifications to testify on this point. We add that Dr. Guzzardi's testimony to the jury that plaintiff's heroin use adversely impacted his vision, without being able to quantify to what extent it impacted plaintiff's vision, may constitute speculation and a net opinion.

The net opinion rule "is a 'corollary of [N.J.R.E. 703] ... which forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data.' " Townsend v. Pierre, 221 N.J. 36, 53-54 (2015) (quoting Polzo v. Cnty. of Essex, 196 N.J. 569, 583 (2008)). It "mandates that experts 'be able to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are reliable.' " Id. at 55 (quoting Landrigan, 127 N.J. at 417). An expert's conclusion may be excluded "if it is based merely on unfounded speculation and unquantified possibilities." Ibid. (quoting Grzanka v. Pfeifer, 301 N.J. Super. 563, 580 (App. Div. 1997)). Such an opinion is

excluded because "when an expert speculates, 'he [or she] ceases to be an aid to the trier of fact and becomes nothing more than additional juror." Ibid. (quoting Jimenez v. GNOC, Corp., 286 N.J. Super. 533, 540 (App. Div. 1996), overruled on other grounds, Jerista v. Murray, 185 N.J. 175 (2005)). The net opinion rule also "focuses upon 'the failure of the expert to explain a causal connection between the act or incident complained of and the injury or damage allegedly resulting therefrom.' " Kaplan v. Skoloff & Wolfe, P.C., 339 N.J. Super. 97, 102 (App. Div. 2001) (quoting Buckelew v. Grossbard, 87 N.J. 512, 524 (1981)).

Plaintiff also maintains that Dr. Guzzardi's opinion should have been excluded because he could not conclusively determine whether plaintiff's heroin use was a significant contributing factor for the accident. In Gustavson v. Gaynor, 206 N.J. Super. 540, 545-46 (App. Div. 1985), we addressed admissibility of intoxication evidence and its potential for prejudice in a personal injury action where a party purportedly drank alcohol prior to his car accident. We held that a party's consumption of alcohol could not be admitted unless there was "supporting evidence" that the driver was unfit to drive due to his or her intoxication at the time of the accident. Id. at 545. Such evidence may include proof of excessive drinking or erratic driving. Ibid. Similarly, our Supreme Court recently commented that where a driver's ingestion of drugs is alleged to have caused the driver's impairment, the impairment "must be proven by the State with independent evidence." State v. Olenowski, 255 N.J. 529, 609 (2023) (Olenowski II) (citing State v. Bealor, 187 N.J. 574, 577 (2006)). Such independent evidence may include factual observations of intoxication by the arresting officer, a driver's admission, or drug paraphernalia found in the car. Id. at 610. Plaintiff also questions whether there is medical support for Dr. Guzzardi's opinion that pinpoint pupils mean one is still under the influence of heroin and whether the probative value of the heroin evidence is outweighed by the potential for undue prejudice.[9]

***9** Although we do not resolve these questions here, we are persuaded the best course is to remand this matter to the trial court for a more fulsome analysis of the Dauber factors. We accordingly remand this matter to the trial court to conduct a Daubert hearing and to provide a more detailed and complete factorby-factor Daubert analysis.

For the benefit of the trial court, the parties shall provide the trial court, within twenty days of this opinion, their appellate briefs, and appendices. The trial court has the discretion to require supplemental briefing. If the trial court determines that Dr. Guzzardi offered a proper expert opinion, and that the heroin evidence was not unduly prejudicial, the verdict should stand, otherwise, a new trial will be necessary. The remand shall be concluded by April 26, 2024. We intimate no views on the appropriate outcome.

III.

Next, plaintiff argues the trial court erred in following the Model Jury Charge on settling

defendants. Plaintiff contends the trial court should have rejected use of the Model Jury Charge, as the trial court did in the case of Hernandez v. Chekenian, 447 N.J. Super. 355 (Law Div. 2016), because the settlement was irrelevant to the jury's deliberations. We disagree.

Appropriate and proper jury instructions are essential for a fair trial. Prioleau v. Ky. Fried Chicken, Inc., 223 N.J. 245, 256 (2015). "A jury is entitled to an explanation of the applicable legal principles and how they are to be applied in light of the parties' contentions and the evidence produced in the case." Ibid. (quoting Viscik v. Fowler Equip. Co., 173 N.J. 1, 18 (2002)). Thus, "[j]ury charges 'must outline the function of the jury, set forth the issues, correctly state the applicable law in understandable language, and plainly spell out how the jury should apply the legal principles to the facts as it may find them[.]' " Ibid. (quoting Velazquez v. Portadin, 163 N.J. 677, 688 (2000)).

Instructions given in accordance with the Model Jury Charges, or which closely track the Model Jury Charges, are generally not considered erroneous. Mogull v. CB Com. Real Estate Grp., Inc., 162 N.J. 449, 466 (2000). "As a general matter, [appellate courts] will not reverse if an erroneous jury instruction was 'incapable of producing an unjust result or prejudicing substantial rights.' " Prioleau, 223 N.J. at 257 (quoting Mandal v. Port Auth. of N.Y. & N.J., 430 N.J. Super. 287, 296 (App. Div. 2013)).

At trial, plaintiff moved to exclude any mention of the DOT settlement to the jury, arguing it was irrelevant and would result in undue speculation by the jury as to the amount of the settlement, and thus adversely influence any award to him. The trial court disagreed, stating the jury would learn of DOT's role in the accident during trial, and during deliberations would consider whether DOT was negligent and a proximate cause of the accident, making it "the elephant in the room with the jury free to speculate in any direction to the unfair detriment to either party because ... DOT was not a participant at trial."

At the start of trial and following counsels' summations, the trial court instructed the jury that DOT was a named defendant in this case, but "[b]efore the trial started, ... plaintiff and ... DOT ... resolved their differences." The trial court directed the jury "not to speculate as to the reasons why ... plaintiff and ... DOT settled this dispute," or what amount, if any, was paid to resolve the claim. The trial court then instructed the jury to consider whether the Township was negligent, and if it was, whether its negligence was a proximate cause of the accident. Next, the trial court instructed the jury to consider whether DOT was negligent, and if so, whether its negligence was a proximate cause of the accident.

***10** On appeal, plaintiff reprises the argument he made before the trial court that it should have followed the holding in Hernandez, 447 N.J. Super. at 358-59, and departed from the Model Jury Charge because the charge contains irrelevant information regarding a settlement and highlighting the settlement invited speculation. Plaintiff further argues that since the jury had to consider DOT's level of culpability anyway, the settlement terms

  

were irrelevant, comparing the situation to cases where parties are barred from addressing a related worker's compensation claim in a third-party lawsuit based on the theory the jury may be influenced to give the plaintiff's claim less consideration if it thinks plaintiff has other avenues of redress. We are unpersuaded.

Pertinent here is the language contained in Model Jury Charges 1.11G and 1.17 on "Settling Defendants," given by the trial court at the beginning and end of the trial. The preliminary charge advises the jury that the plaintiff had raised a claim against another party, and before the trial started, the other party and plaintiff had settled and the other party "will no longer be involved in this trial." Model Jury Charges (Civil), 1.11G, "Settling Defendants" (rev. Apr. 2018).

The Model Jury Charge given before deliberations is more detailed, notifies the jury that there was another defendant in the case; that plaintiff and the other defendant reached a settlement; and instructs the jury not to speculate as to the reasons for the settlement or the amount, if any, of the settlement. Model Jury Charges (Civil), 1.17, "Instructions to Jury in Cases in Which One or More Defendants Have Settled with the Plaintiff" (rev. Apr. 2018). The charge continues that the jury must first determine if the remaining defendant was negligent and the proximate cause of the accident, and then if the settling defendant also was negligent and a proximate cause of the accident. Ibid.

However, the Model Jury Charges include a "Note to Judge," which reads as follows:

> In Hernandez v. Chekenian, 447 N.J. Super. 355 (Law Div. 2016), Judge Rea held that Model Civil Jury Charges 1.11G and 1.17 should only be used in cases where the defendant settles during trial. It should not be given when defendants settle before the trial begins because it is irrelevant and unduly prejudicial. In dicta, he questioned the use of the terms "settlement" and "settled" as being irrelevant as well as prejudicial. This case, while published, has not been the subject of appellate review. The Supreme Court Committee for Model Civil Jury Charges is providing this for informational purposes for the trial judge.
>
> [Model Jury Charges (Civil), 1.11G; Model Jury Charges (Civil), 1.17.]

Plaintiff relies on the holding in Hernandez, 447 N.J. Super. at 357, where the trial court held that the settling defendant jury charge should not be given if the party in question settled the case before trial began. The case involved a three-car accident, where one of the defendants settled with the plaintiff through his insurance carrier. Id. at 356. There, the trial court declined to read the settling defendants jury charge, finding that there was "no legitimate reason that a jury needs to be told that there was another defendant(s) who settled their dispute(s) by paying an amount of money." Id. at 357.

The trial court in Hernandez questioned the language of the Model Jury Charge, stating that it raised an issue that was not relevant to the deliberations process, and then immediately told the jury to disregard it. Id. at 358. The trial court there noted that the settling defendant charge was combined

with the language about comparative negligence, where a settling party appears on the verdict sheet to determine the percentage of negligent conduct attributable to that party. Id. at 358-59. The trial court added that this does not mean, however, that the jury should also be told that the settling party paid money to the plaintiff. Id. at 359. We note the trial court's decision in Hernandez did not result in any substantive changes to Model Jury Charges (Civil) 1.116 and 1.17. The "Note to Judge" specifies the Hernandez decision is provided for informational purposes for the trial judge and has not been the subject of appellate review.

***11** Here, the trial court's jury instructions correctly adhered to the Model Jury Charges. "[A] jury charge is presumed to be proper when it tracks the [M]odel [J]ury [C]harge because the process to adopt [M]odel [J]ury [C]harges is 'comprehensive and thorough.' " State v. Cotto, 471 N.J. Super. 489, 543 (App. Div. 2022) (quoting State v. R.B., 183 N.J. 308, 325 (2005)). See also Mogull, 162 N.J. at 44 ("It is difficult to find that a charge that follows the Model Jury Charge so closely constitutes plain error."). However, the Model Jury Charges "are not binding authority," State v. Bryant, 419 N.J. Super. 15, 28 (App. Div. 2011), and may be reviewed on appeal. Morlino v. Med. Ctr., 152 N.J. 563, 590 (1998) (although the Court concluded that the disputed Model Jury Charge did not have the capacity to mislead the jury, it nevertheless remanded the charge to the Supreme Court Committee on Model Jury Charges, Civil, to reconsider and rework the charge in consideration of the Court's findings).

The jury in this case was advised in a straightforward manner that plaintiff and DOT "resolved their differences" prior to trial, and the jury was not to speculate about what the resolution was. Moreover, it has long been the practice in New Jersey that,

> where multiple tort-feasors are or may be jointly responsible for an individual's injuries and losses, and one or more of them effect a settlement in exchange for a covenant not to sue, the fact of the settlement, but not the amount paid, is generally brought to the attention of the jury at the trial.
>
> [Theobold v. Angelos, 40 N.J. 295, 303-04, 191 A.2d 465 (1963).]

Essentially, jurors have to be told the facts of a settlement in order to avoid juror speculation. Theobold, 40 N.J. at 304. The danger of this speculation arises whenever a jury is asked to make a liability determination regarding an absent party, regardless of whether that party appeared for any portion of the trial.

Finally, a reviewing court is concerned with the "overall effect" of a jury charge rather than allegedly erroneous words "in isolation." State v. Savage, 172 N.J. 374, 387 (2002). In this case, the trial court was not bound to follow the dicta in Hernandez, and it clearly was appropriate to use the Model Jury Charges as given, which complied with well-established precedent, and in these circumstances, did not create prejudice.

Affirmed in part, and remanded in part for a

  

Daubert hearing. We do not retain jurisdiction.

Not Reported in Atl. Rptr., 2024 WL 730342

## All Citations

## Footnotes

1 In our opinion, "plaintiff" refers to Thomas A. Fredella.

2 Pursuant to New Jersey's comparative negligence statute, as set forth in N.J.S.A. 2A:15-5.1, "a plaintiff who is found to be more than fifty percent at fault is entitled to no recovery." Brodsky v. Grinnel Haulers, 181 N.J. 102, 109 (2004).

3 Frye v. United States, 293 F. 1013 (D.C. Cir. 1923); Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

4 Plaintiff presented testimony from an accident reconstruction expert who testified that regardless of plaintiff's lane changes or whether the arrow board was on, he did not have sufficient time to stop his vehicle and avoid the collision.

5 The EMT records are contained in plaintiff's appendix but are difficult to read due to the poor quality of the copy. Thus, our summary of the EMT's findings is based on Dr. Guzzardi's testimony. Dr. Guzzardi testified that plaintiff's pupil size gradually increased to four millimeters when measured at the hospital.

6 While plaintiff requested a Frye/Daubert hearing, his arguments on appeal center on the Frye standard for admissibility, i.e., that of general acceptance by the relevant scientific community. Frye, 293 F. at 1013-14. Regardless, now on appeal and at the time of trial, New Jersey utilizes a "methodology-based test for reliability" similar to the standard set forth by the United States Supreme Court in Daubert. In re Accutane Litig., 234 N.J. at

397.

7 Plaintiff's counsel cross-examined Dr. Guzzardi with the American Ophthalmological Society's definition of pinpoint pupils as measuring less than two millimeters, and normal pupils as measuring between two and eight millimeters.

8 Plaintiff testified that he used mirrors to change lanes because he drove a van for years and came to rely on mirrors when driving. Dr. Guzzardi commented that he did not know if plaintiff used mirrors out of habit or because he was a "chronic heroin user" and relied on mirrors because he always had pinpoint pupils.

9 As discussed in Olenowski II, 255 N.J. at 549, under the influence means "a substantial deterioration or diminution of the mental faculties or physical capabilities of a person whether it be due to intoxicating liquor, narcotic, hallucinogenic or habit-producing drugs." (quoting State v. Tamburro, 68 N.J. 414, 420-21 (1975)). Yet in terms of criminal liability, unlike with alcohol consumption, there is no designated blood level that constitutes a "per se violation" of driving under the influence of drugs. Id. at 545, 548. Consequently, while a toxicology report can corroborate the presence of drugs in the driver's system, it "cannot prove that the driver was actually impaired by drugs while behind the wheel," and it is unclear what "drug level ... establishes impairment per se." Id. at 608. While this language refers to criminal culpability, it also relates to the lack of clarity as to what constitutes drug-impaired driving.

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UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey, Appellate Division.

Valerie SEGAR, Plaintiff-Appellant,
v.
CONSOLIDATED RAIL CORPORATION, a/k/a Conrail Corporation, Defendant-Respondent,
and
Norfolk Southern Railway Company, a/k/a Norfolk Southern Corporation, CSX Transportation, Inc., CSX Corporation, Jerry Kaminski, Ryan Keating, Ryan Hill, Jon A. Havlicek, Wilbert Den Ouden, and Mark Mather, Defendants.

DOCKET NO. A-1420-21
|
Argued September 26, 2023
|
Decided October 13, 2023

On appeal from the Superior Court of New Jersey, Law Division, Gloucester County, Docket No. L-1241-15.

**Attorneys and Law Firms**

Thomas N. Sweeney argued the cause for appellant (Messa & Associates, PC, attorneys; Thomas N. Sweeney, on the briefs).

Ira L. Podheiser (Burns White LLC) of the Pennsylvania bar, admitted pro hac vice, argued the cause for respondent (Burns White LLC and Ira L. Podheiser, attorneys; Brian D. Pagano, of counsel and on the brief).

Before Judges Sabatino, Mawla, and Marczyk.

**Opinion**

PER CURIAM

***1** This lawsuit arises out of a derailment of a freight train in Paulsboro on November 30, 2012. The railroad, defendant Consolidated Rail Corporation a/k/a Conrail Corporation ("Conrail"), stipulates to its liability for the occurrence of the derailment. The derailment caused vinyl chloride to leak into the atmosphere from four freight cars that toppled off the tracks.

Plaintiff Valerie Segar, a resident of Paulsboro, lived a short distance from the derailment site. After the derailment, she noticed a fog in the air and sweet-smelling odor, which is characteristic of vinyl chloride. She started to feel sick and went to a local hospital emergency room a few days later.

The emergency room medical staff diagnosed a thrombosis (i.e., blood clotting) in plaintiff's right foot. Plaintiff was overweight, a diabetic, and a smoker, although she had no leg ulcers. Her serious condition required her right leg to be

 

amputated below the knee in late December 2012, less than a month after the derailment.

The New Jersey Department of Health ("NJDOH") investigated the derailment and issued a report to the federal government. It found that numerous residents of Paulsboro, in addition to plaintiff, had likewise reported various symptoms and had sought treatment at the emergency room following the leakage of the vinyl chloride.

Plaintiff sued Conrail and several other parties,[1] alleging that the vinyl chloride leakage caused her to sustain the thrombosis and subsequent amputation. She retained as a medical causation expert Philip Levin, M.D. Dr. Levin, a board-certified endocrinologist and internist, is an assistant professor at Johns Hopkins Medical School. His credentials include a medical degree from the University of Maryland, residencies at Yale and Georgetown Medical Schools, and a fellowship at Ohio State Medical School. Dr. Levin has treated patients with diabetes and vascular conditions for several decades. He has authored and co-authored numerous professional articles about vascular disease and diabetes. He is not a toxicologist.

Dr. Levin opines that plaintiff's exposure to the dispersed vinyl chloride caused her to develop blood clotting, which led to the amputation. He explains how vinyl chloride, at the molecular level, affects the blood serum and causes arterial blockages. In this regard, Dr. Levin has detailed how vinyl chloride narrows the vascular lumen to cause a complete occlusion, how it inflames or irritates the wall of the artery to reduce blood flow, how it elevates lipoprotein (a)—which is associated with hypovascular coagulability—and how it impairs capillary microcirculation.

Defendant counters Dr. Levin's opinions on medical causation with its own expert, Michael I. Greenberg, M.D. Dr. Greenberg is board certified in toxicology and other fields of medicine. He received his medical degree from Temple Medical School. He also has a master's degree in public health and occupational medicine from the University of Wisconsin, as well as a master's degree in forensic toxicology from the University of Florida. He has taught medical students for many years and, as of the time of the proceedings below, was on the faculty of Drexel University College of Medicine. Like Dr. Levin, he too has authored and co-authored dozens of professional articles. He is not an endocrinologist.

***2** Dr. Greenberg contends plaintiff's leg clotting was solely the result of her longstanding diabetes and underlying poor health. He opines that plaintiff's short-term ingestion of vinyl chloride was not the medical cause of her thrombus and her ensuing leg amputation.

Initially, plaintiff submitted in discovery a two-page expert report from Dr. Levin. Defendant moved to bar Dr. Levin's testimony as unreliable under the applicable criteria of N.J.R.E. 702, and as an inadmissible net opinion. After reviewing the parties' submissions, the trial court scheduled a "Kemp hearing"[2] to evaluate the admissibility of Dr. Levin's testimony. Both Dr. Levin and Dr. Greenberg testified at the hearing, and were questioned by counsel and

the trial court.

Two days before the Kemp hearing, plaintiff served on the defense an eight-page supplemental expert report from Dr. Levin, which bolstered his previous opinions. The supplemental report accompanied over 500 pages of professional studies, medical literature, and other materials, including the NJDOH investigation report.

The defense moved to exclude the court's consideration of Dr. Levin's supplemental report as untimely. The motion judge instead adjourned the Kemp hearing and allowed the defense to conduct a second deposition of Dr. Levin.

The court thereafter conducted the Kemp hearing and heard Dr. Levin's testimony explaining his methodology. His methodology is based on what Dr. Levin characterizes as a differential diagnosis, ruling out other possible causes of the thrombosis. A critical facet of his analysis is that, unlike most other diabetic patients he has seen in over thirty years of practice who required amputations, plaintiff had no ulcers, cuts, or preexisting swelling.

At the end of the hearing, the motion judge issued an oral ruling on December 6, 2021, concluding that Dr. Levin's methodology was not sufficiently reliable to present to a jury. Among other things, the judge noted that Dr. Levin had never treated a patient with vinyl chloride exposure. The judge further noted that the published studies linking vinyl chloride exposure to circulatory conditions generally involve occupational exposure over long periods of time, not the short-term exposure as in this case. In particular, the judge stated in his oral ruling that he did not find in the motion record "any evidence that vinyl chloride causes a thrombus in the femoral artery" (emphasis added).

After excluding Dr. Levin's testimony, on March 22, 2022, the judge awarded defendant $15,380 in counsel fees as a sanction for necessitating the defense to incur additional attorney time to address Dr. Levin's late expert report. Since plaintiff could not proceed with her case without a medical causation expert, the judge then entered summary judgment in favor of Conrail, dismissing the lawsuit.

Plaintiff now appeals the exclusion of Dr. Levin's expert testimony, the ensuing entry of summary judgment, and the counsel fee sanction. For the reasons that follow, we remand for further proceedings and more detailed findings by the trial court addressing each of the discrete factors set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) as adopted with certain conditions by the New Jersey Supreme Court in In re Accutane Litigation, 234 N.J. 340 (2018). We affirm, however, the monetary sanction imposed.

***3** Our Supreme Court has instructed that in determining the admissibility of scientific expert testimony in civil (and now criminal) cases, our trial courts must utilize a "methodology-based test for reliability" similar to the standard set forth by the United States Supreme Court in Daubert. In re Accutane, 234 N.J. at 397. This standard is as follows:

> Our view of proper gatekeeping in a methodology-based approach to reliability for expert scientific testimony requires the proponent to demonstrate that the expert applies his or her scientifically recognized methodology in the way that others in the field practice the methodology. When a proponent does not demonstrate the soundness of a methodology, both in terms of its approach to reasoning and to its use of data, from the perspective of others within the relevant scientific community, the gatekeeper should exclude the proposed expert testimony on the basis that it is unreliable.
>
> [Id. at 399-400.]

Applying this standard, our courts must consider "whether an expert's reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to facts in issue." Id. at 397 (citing Daubert, 509 U.S. at 591, 594-95; Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991)).

Such an approach is appropriate when dealing with "the issue of causation in toxic-tort litigation concerning diseases of indeterminate origin," where "[m]any such injuries remain latent for years, are associated with diverse risk factors, and occur without any apparent cause." Landrigan v. Celotex Corp., 127 N.J. 404, 413 (1992).

The trial court's role is not to "substitute its judgment for that of the relevant scientific community," but "to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." Id. at 414. Thus, experts "must be able to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are scientifically reliable." Id. at 417. Moreover, when an expert relies on scientific or medical studies, "the trial court should review the studies, as well as other information proffered by the parties, to determine if they are of a kind on which such experts ordinarily rely," and if they are "derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." Ibid.

When applying this standard, our judges should now address the multiple Daubert factors, a " 'helpful—but not necessary or definitive—guide' for trial courts in New Jersey" to follow when assessing the reliability of scientific or technical expert testimony. State v. Olenowski, 253 N.J. 133, 149 (2023) (quoting In re Accutane, 234 N.J. at 398). These factors are as follows:

> (1) Whether the scientific theory can be, or at any time has been, tested;
>
> (2) Whether the scientific theory has been subjected to peer review and publication, noting that publication is one form of peer review but is not a "sine qua non";
>
> (3) Whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the technique's operation; and

> (4) Whether there does exist a general acceptance in the scientific community about the scientific theory.
>
> ***4** [In re Accutane, 234 N.J. at 398 (citing Daubert, 509 U.S. at 593-95).]

The first listed Daubert factor—testability—relates closely to the dual components of the third factor, error rate and standards. Testability is "a key question" that entails whether a theory or technique "can be (and has been tested)." Daubert, 509 U.S. at 593.

The second Daubert factor—peer review and publication—is significant because submission of a methodology "to the scrutiny of the scientific community is a component of 'good science' " and "increases the likelihood that substantive flaws in methodology will be detected." Ibid.

The third Daubert factor concerns both the known or potential rate of error in testing the methodology as well as any standards for maintaining or controlling the methodology's operation. As the Court noted in Daubert, a trial court "ordinarily" should account for the "known or potential rate of error" of a methodology. Id. at 594. In addition, a methodology is more reliable if it is governed by well-established standards for operation. Ibid. See also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 154-57 (1999) (rejecting as inadmissible an expert who had not consistently adhered to a protocol with appropriate standards).

Lastly, the fourth Daubert factor—general acceptance—(the former test of Frye v. United States, 293 F. 1013 (D.C. Cir. 1923)) is no longer the dispositive test since the Court has adopted the multifactor Daubert approach, but it is still pertinent. Daubert, 509 U.S. at 594-96; In re Accutane, 234 N.J. at 398.

As the Court stated in In re Accutane and again in Olenowski, these specific factors are not a rigid set of considerations for ascertaining the reliability of a proffered expert's methodology. Nonetheless, they provide an important framework for guiding the analysis. The trial court's consideration of each of these factors is integral to the appellate court's review of whether the trial court abused its discretion in concluding whether an expert's methodology was sufficiently reliable to be admitted to a jury. In re Accutane, 234 N.J. at 391.

Here, the brief oral opinion the court issued immediately after hearing the testimony of Dr. Levin and Dr. Greenberg did not fully analyze, one by one, each of the Daubert factors. The opinion correctly recited the factors in its general overview of the law. Unfortunately, its analysis of the factors was incomplete and seemingly inconsistent in some respects.

To begin with, the opinion did not analyze testability (Daubert factor one) or error rate (a component of factor three).

The opinion referred to some of the published literature (Daubert factor two) about vinyl chloride exposure, including several peer reviewed articles supplied and relied upon by Dr. Levin. It noted the studies addressing long-term exposure to the

  

chemical in occupational settings and contrasted it to plaintiff's short-term exposure. In colloquy with counsel, the court criticized Dr. Levin's analysis because "he didn't find any medical literature that a thrombus was caused by an inhalation [of] vinyl chloride."

***5** On the other hand, the judge did find "there is compelling evidence that such a [medical cause-effect] relationship exists between the inhalation of vinyl chloride and some effect on the vascular system based on what I've heard." The judge also found that "accepting the studies that were sent by Dr. Levin, there does seem to be an association between the inhalation of vinyl chloride and some effect on vascular structures." The judge characterized the studies, however, as "limited," noting that "there wasn't a particular study about the effect of vinyl chloride on diabetes."

With respect to standards (part of Daubert factor three), the court recognized that the methodology of differential diagnosis is a judicially approved methodology. See Creanga v. Jardal, 185 N.J. 345, 357-58 (2005). However, the court was "troubled by the way Dr. Levin concluded his differential diagnosis," observing that it was not sure that he provided "sufficient reasons why other causes were [not] just as likely to cause this [injury] as vinyl chloride." The court noted that Dr. Levin "used a lot of generalities," and "went through study after study that talked about cardiac issues, that talked about vascular issues, but they weren't very specific." The court further observed that it "had trouble understanding [Dr. Levin's] methodology."

Finally, with respect to Daubert factor four—general acceptance—the judge noted it "had no evidence about whether other experts would rely on this evidence [the studies cited by Dr. Levin]," and that "it's very difficult for me to ... make that comparison."

These and other observations within the court's oral opinion reflect the court's earnest attempt to perform the factor-based analysis prescribed by Daubert, In re Accutane, and Olenowski. Even so, our appellate review is hindered by the omission of a discussion of factor one and part of factor three (respectively, testability and error rate),[3] and the occasional non-definitive and inconsistent language used by the court in discussing some of the other factors.

We also have an overarching concern that the trial court's analysis at times appears, at least in how it was expressed, to have failed to sufficiently adhere to the Supreme Court's guidance in Rubanick, 125 N.J. at 449, concerning the specific difficulties inherent in toxic tort litigation. The Court recognized in Rubanick that "toxic-tort litigation does not frequently encounter well-established and widely accepted scientific theories of causation that can, at the level demanded by the scientific method, precisely delineate the causal path between the toxin and the pathology." Id. at 449. "Nevertheless, in such litigation there is often available data and information of a type that that is used and relied on by experts in the field." Ibid. "[F]urther, there are reputable and highly qualified experts who, drawing on such data and information, have the proficiency to apply sound

scientific methods sufficient to reach creditable opinions with respect to causation." Ibid.

Hence, the Court in Rubanick was "strongly persuaded that a standard that accounts for those considerations should be employed to determine the reliability of expert opinion testimony relating to causation in toxic-tort litigation." Ibid. The Court held that "in toxic-tort litigation, a scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately founded scientific methodology involving data and information of the type reasonably relied upon by experts in the scientific field." Ibid. In essence, the Court has prescribed a contextualized standard for the admission of expert methodologies in toxic tort cases.

***6** Here, the trial court acknowledged Rubanick, but focused its comments substantially upon (1) the absence of published studies that explicitly address whether short-term exposure to vinyl chloride can impair a person's vascular system, and (2) the soundness of Dr. Levin's differential diagnosis in ruling out other more common causes of arterial thrombus in persons with diabetes. The former may be reasonably accounted for by the (fortunate) rarity in which a short-term escape of high concentrations of vinyl chloride occurs. The court's opinion does not explain sufficiently why the medical explanations posited by Dr. Levin, in drawing comparisons with the published studies of long-term exposures, are not plausible and reliable enough to be considered by a jury.

In addition, the court's critique of Dr. Levin's application of a differential diagnosis methodology may be suitable fodder for cross-examination, but that does not make the methodology itself an inherently unreliable technique. See Creanga, 185 N.J. at 357-58 (deeming a differential diagnosis an appropriate methodology); see also Hisenaj v. Kuehner, 194 N.J. 6, 25 (2008) (reversing the appellate court's conclusion of inadmissibility and allowing a defense biomechanical engineer's expert testimony to be presented to a jury, despite flaws in his analysis that could be impeached on cross-examination).

The court did not address case law recognizing that in conducting a differential diagnosis, a physician is "not required to rule out all alternative possible causes of [the plaintiff's] illness. Rather, only 'where a defendant points to a plausible alternative cause and the doctor offers no explanation for why [the doctor] has concluded that was not the sole cause, that doctor's methodology is unreliable.' " Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 n.27 (3d Cir. 1994)).[4] Further, the Third Circuit has observed that "a physician need not conduct every possible test to rule out all possible causes of a patient's illness, 'so long as [the doctor] employed sufficient diagnostic techniques to have good grounds for [their] conclusion.' " Ibid. (quoting In re Paoli, 35 F.3d at 761). In this respect, Dr. Levin's alleged failure to apply the methodology correctly, including the so-called "Bradford Hill" factors for a differential diagnosis, should be analyzed more fully by the trial

court.

Although we do not resolve these questions here, we are persuaded the best course is to remand this matter to the trial court for a more fulsome analysis of the discrete Daubert factors, viewed through the prism of Rubanick. In all fairness to the motion judge (who has since retired), it does not appear that the parties' briefing before the Kemp hearing focused heavily on the discrete Daubert factors, which may well explain why the court's oral opinion was conveyed in the manner it was delivered.

We accordingly remand this matter for further consideration by a successor judge in the Law Division and ask the judge to provide a more detailed and complete factor-by-factor Daubert analysis, bearing in mind the Court's guidance in Rubanick about the special constraints of toxic tort cases. For the benefit of the successor judge, the parties shall provide the trial court within twenty days of this opinion, their appellate briefs and appendices and a transcript of the Kemp hearing testimony (which the original motion judge never saw). The successor judge has the discretion to require additional briefing and a supplemental Rule 104 hearing if that judge deems it helpful. In the meantime, summary judgment is vacated without prejudice, abiding the outcome of the remand on admissibility.[5] We intimate no views on the appropriate outcome.

***7** The remand shall be concluded by January 31, 2024. After the trial court issues its ruling, either side may pursue timely appellate review with a new notice of appeal or motion for leave to appeal.

Lastly, we briefly note that we affirm the trial court's monetary sanction as being within the court's range of discretion. Salazar v. MKGC + Design, 458 N.J. Super. 551, 558-59 (App. Div. 2019). The court could have imposed a more drastic sanction under the circumstances, including total exclusion of the supplemental report tendered two years after the discovery deadline had passed. R. 4:23-1. In addition, our courts must encourage adherence to discovery deadlines and discourage last-minute voluminous submissions that are disruptive and discourteous to the court and opposing counsel. Seoung Ouk Cho v. Trinitas Reg'l Med. Ctr., 443 N.J. Super. 461, 468-72 (App. Div. 2015).

Affirmed in part and remanded in part. We do not retain jurisdiction.

**All Citations**

Not Reported in Atl. Rptr., 2023 WL 6784978

## Footnotes

1 The other named defendants are no longer involved in this litigation.

[2] See Kemp ex rel. Wright v. State, 174 N.J. 412, 432-33 (2002) (prescribing testimonial hearings for trial courts to assess the admissibility of expert testimony).

[3] It is unclear from the submissions whether the parties agree that a differential diagnosis methodology, when used for purposes of medical causation in civil litigation, is testable, and if so, whether there is a potential or known error rate in using such a methodology.

[4] We cite this federal case law only for its persuasive value recognizing we are not strictly bound by federal Daubert decisions. In re Accutane, 234 N.J. at 399.

[5] For the sake of completeness, the trial court on remand shall adjudicate the "net opinion" argument made by defendant but not resolved in the court's December 2021 opinion.

End of Document

2025 WL 1903760
Only the Westlaw citation is currently available.



Supreme Court of Delaware.

IN RE ZANTAC (RANITIDINE) LITIGATION

No. 255, 2024
|
Submitted: April 16, 2025
|
Decided: July 10, 2025

**Synopsis**

**Background:** Consumers brought personal injury action against manufacturers of medication used to treat heartburn and other gastrointestinal disorders, which had been recalled due to N-Nitrosodimethylamine (NDMA), a likely carcinogen, being found in some samples of medication, alleging medication caused them to develop cancer. The Superior Court, Vivian L. Medinilla, J., 2024 WL 2812168, denied manufacturers' motion to exclude expert testimony. Order was certified for interlocutory appeal

**Holdings:** The Supreme Court, Abigail M. LeGrow, J., held that:

trial court's admission of expert testimony that was excluded from related federal multi-district litigation (MDL) proceedings was based on erroneous conclusion that Delaware applied different standard for admissibility than federal courts;

trial court applied incorrect standard in admitting consumers' expert testimony on question of whether medication caused consumers' cancers by passing crucial questions of sufficiency and reliability of experts' testimony onto the jury, rather than making such determinations itself; and

trial court erred in defining general causation question as whether the allegedly toxic agent in medication could have caused consumers' cancers, rather than whether the medication itself could have caused their cancers.

Reversed and remanded.

**Procedural Posture(s):** On Appeal; Motion to Exclude Expert Report or Testimony.

Court Below: Superior Court of the State of Delaware, C.A. No. N22C-09-101

Upon appeal from the Superior Court of the State of Delaware. **REVERSED.**

**Attorneys and Law Firms**

Colleen Shields, Esquire, Patrick M. Brannigan, Esquire, ECKERT SEAMANS CHERIN & MELLOTT, LLC, Wilmington, Delaware, Jay P. Lefkowitz, Esquire, KIRKLAND & ELLIS LLP, New York,

New York, Cole T. Carter, Esquire, KIRKLAND & ELLIS LLP, Chicago, Illinois, Mark S. Cheffo, Esquire, Hayden A. Coleman, Esquire, Bert L. Wolff, Esquire, DECHERT LLP, New York, New York, Will Sachse, Esquire, DECHERT LLP, Philadelphia, Pennsylvania, Lindsey Cohan, Esquire, DECHERT LLP, Austin, Texas, for Defendant-Below, Appellant GlaxoSmithKline LLC.

Daniel J. Brown, Esquire, MCCARTER & ENGLISH, Wilmington, Delaware, Joseph G. Petrosinelli, Esquire, Amy M. Saharia, Esquire, M. Elaine Horn, Esquire, WILLIAMS & CONNOLLY LLP, Washington, District of Columbia, for Defendant-Below, Appellant Pfizer Inc.

Joseph S. Naylor, Esquire, SWARTZ CAMPBELL, Wilmington, Delaware, Andrew T. Bayman, KING & SPALDING LLP, Atlanta, Georgia, Paul A. Mezzina, Esquire, (argued), KING & SPALDING LLP, Washington, District of Columbia, for Defendants-Below, Appellants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim U.S.A. Corporation.

Nancy Shane Rappaport, Esquire, DLA PIPER LLP, Wilmington, Delaware, Frederick L. Cottrell, III, Esquire, RICHARDS, LAYTON, & FINGER, P.A., Wilmington, Delaware, Loren H. Brown, Esquire, DLA PIPER LLP, New York, New York, Ilana Eisenstein, Esquire, DLA PIPER LLP, Philadelphia, Pennsylvania, for Defendants-Below, Appellants Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC, and Chattem, Inc.

Sean T. O'Kelly, Esquire, Gerard M. O'Rourke, Esquire, O'KELLY & O'ROURKE, LLC, Wilmington, Delaware, Christopher R. Carton, Esquire, BOWMAN AND BROOKE LLP, New Brunswick, New Jersey, John D. Garrett, Esquire, David J. Duke, Esquire, Melissa Ferrell, Esquire, BOWMAN AND BROOKE LLP, Austin, Texas, Edward L. O'Toole, Esquire, BOWMAN AND BROOKE LLP, New York, New York, for Defendant-Below, Appellant Patheon Manufacturing Services, LLC.

Raeann Warner, Esquire, COLLINS PRICE & WARNER, Wilmington, Delaware, Bernard G. Conaway, Esquire, CONAWAY-LEGAL LLC, Wilmington, Delaware, Joseph J. Rhoades, Esquire, Stephen T. Morrow, Esquire, RHOADES & MORROW LLC, Wilmington, Delaware, R. Brent Wisner, Esquire, (argued) WISNER BAUM, LLP, Los Angeles, California, Jennifer A. Moore, Esquire, MOORE LAW GROUP, PLLC, Louisville, Kentucky, for Appellees.

Before SEITZ, Chief Justice; VALIHURA, TRAYNOR, LEGROW, and GRIFFITHS, Justices, constituting the Court en Banc.

**Opinion**

LEGROW, Justice:

***1** This Court accepted an interlocutory appeal from the Superior Court's decision denying a series of motions that sought to exclude several expert reports proffered by the plaintiffs in support of their position that

  

Zantac containing ranitidine—or its generic—is capable of causing the ten types of cancers at issue in this case. In their motions, the defendants raised several objections to the methodologies that the plaintiffs' experts employed to support their general causation conclusions. The Superior Court, however, concluded that all those objections amounted to disputes that were questions for the jury, not the trial judge. In so doing, the court referred to the "liberal thrust" of Delaware's evidentiary rules as favoring the admissibility of expert testimony, concluded that Delaware's rule is distinct from the analogous federal rule, and held that the expert's general causation conclusions could be based on the alleged disease-causing agent, rather than the product at issue in this case.

We reverse. First, the Superior Court erred in adopting a standard that favored or presumed the admissibility of expert testimony. Under our rules and existing precedent, the proponent of an expert opinion bears the burden of establishing that the opinion is based on sufficient facts or data and on dependable principles and methods that are reliably applied to the facts of the case. Unless these sufficiency and reliability elements are established by a preponderance of the evidence, the opinion is not admissible. Delaware's evidentiary rules governing expert testimony are consistent with federal law. A trial judge must act as the gatekeeper of expert testimony and should not dismiss challenges to the sufficiency or reliability of an expert opinion by viewing the disputes as questions for the jury to weigh.

Second, the trial court erred in framing the general causation question at issue in this case. General causation addresses whether the substance at issue is capable of causing the harm alleged. The court concluded that the experts could base their conclusions on studies regarding the alleged disease-causing agent rather than the product at issue in the case, without establishing a reliable bridge between the product at issue and the scientific data regarding the toxic agent. In so holding, the trial court failed to require the experts to apply a reliable scientific methodology to reach their conclusion that the exposure to the toxic agent in the studies on which the experts relied was comparable to the exposure to the toxic agent caused by the product. That holding was inconsistent with Delaware law.

## I. FACTUAL AND PROCEDURAL BACKGROUND[1]

This interlocutory appeal arises out of personal injury claims filed in the Superior Court. Nearly 75,000 plaintiffs (the "Plaintiffs") alleged that their ingestion of the molecule ranitidine, marketed under the brand name Zantac—in which N-Nitrosodimethylamine ("NDMA"), a likely carcinogen, may be found—caused the cancer with which they were diagnosed (the "Zantac Litigation").[2]

### A. Zantac's History

***2** The Defendants-below, Appellants are GlaxoSmithKline LLC ("GSK"); Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and

Ingelheim U.S.A. Corporation (collectively, "B.I."); Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and Chattem, Inc. (collectively, "Sanofi"); Pfizer Inc. ("Pfizer") (together with GSK, B.I., and Sanofi, the "Brand Defendants"); and Patheon (together with the Brand Defendants, the "Defendants").

Ranitidine is a histamine-2 receptor blocker used to "treat heartburn and many other gastro-intestinal disorders, including duodenal ulcers, gastroesophageal reflux disease ("GERD") and esophagitis."[3] In 1983, the FDA approved ranitidine for prescription use to treat ulcers and later approved it to treat other stomach and esophageal conditions. In 1995, the FDA approved ranitidine for low dose over-the-counter ("OTC") use, and by 2004, the FDA had approved higher doses of ranitidine for OTC use.

During the more than 35 years that ranitidine was on the market, four brand pharmaceutical companies and generic manufacturers sold versions of the product.[4] GSK developed the medication and initially marketed it in prescription form. In 1995, GSK marketed it as an OTC medication in a joint venture with a predecessor of Pfizer. In 1998, GSK transferred its rights to sell OTC Zantac in the U.S. to that Pfizer predecessor. In 2006, B.I. acquired the rights to sell OTC Zantac. In 2017, Defendant Sanofi began selling OTC Zantac after acquiring the brand from B.I.

In September 2019, a citizen petition submitted to the FDA sparked a recall of ranitidine. A private company and online pharmacy called Valisure theorized that ranitidine had the potential to degrade into NDMA. To evaluate this theory, Valisure tested batches of ranitidine under various conditions and found high levels of NDMA. Based on those findings, Valisure submitted a citizen petition to the FDA asserting that ranitidine contains "extremely high levels of [ ] NDMA."[5] Valisure reported that its study found NDMA at levels in excess of three million nanograms per tablet, exceeding the limit of 96 nanograms per day that the FDA had set for NDMA ingestion in the context of an unrelated class of medications.

"NDMA is an N-nitrosamine impurity," and multiple health agencies in the United States and other countries "consider NDMA to be [either] a probable human carcinogen" or "a reasonably anticipated human carcinogen."[6] But "NDMA is a ubiquitous substance found in trace amounts in air, water, and food."[7] "Studies have [ ] shown that NDMA increases the risk of cancer in humans and animals. As a result of findings like these, the FDA had set an acceptable daily intake ("ADI") limit for NDMA at 96 nanograms."[8]

After reviewing Valisure's petition, the FDA raised concerns about the study's testing methodology.[9] The FDA also voiced concerns with Valisure's findings which, when replicated, did not produce the same results.[10] Despite those inconsistencies, the FDA and ranitidine manufacturers studied NDMA in ranitidine and examined whether ranitidine use increased cancer risks in patients. Over the next month, tests revealed NDMA amounts lower than what Valisure reported. Some of the lots tested contained amounts below the acceptable daily intake ("ADI"). "Some ranitidine pills did show NDMA above 96 ng, but even the

highest-tested pill showed NDMA at a tiny fraction of the level reported by Valisure."[11]

***3** In the fall of 2019, the manufacturers who were then selling ranitidine voluntarily recalled their products.[12] By April 2020—after further testing confirmed that the NDMA levels in some samples continued to exceed the ADI—the FDA requested that manufacturers initiate a withdrawal of all remaining batches on the market.

**B. Procedural History**

After the ranitidine recall, litigation ensued nationwide. The plaintiffs in those cases allege that the ranitidine they consumed degraded into NDMA and caused them to develop various types of cancer. Before the claims in Delaware were filed, a Multidistrict Litigation in Florida was formed to address similar claims that ranitidine caused the plaintiffs to develop cancer.

*i. National Procedural History—The "MDL"*

To address the claims filed in federal court, the United States Judicial Panel on Multidistrict Litigation established a multidistrict litigation process (the "MDL") in February 2020 in the U.S. District Court for the Southern District of Florida in West Palm Beach for all pretrial purposes. The Judicial Panel ordered federal lawsuits for personal injury and economic damages from the purchase or use of Zantac to be transferred to the MDL.

The claims in the MDL narrowed over time. First, the plaintiffs notified the MDL court that they had decided not to pursue general causation expert reports for breast and kidney cancers and had narrowed their initial list of cancers purportedly caused by ranitidine ingestion from ten to eight. In January 2022, the MDL plaintiffs again notified the court that they were not pursuing claims related to certain cancers, and further narrowed the list of associated cancers to five. Shortly after the MDL plaintiffs notified the MDL court that they would not provide general causation opinions for five cancers,[13] many of the MDL claimants with those cancers refiled their claims in Delaware.

In early 2022, the MDL court held a *Daubert* hearing to examine plaintiffs' experts' general causation opinions that Zantac caused five types of cancer in the patients who ingested it. On December 6, 2022, the MDL court issued its opinion on the pending *Daubert* and summary judgment motions ("MDL Order"). In its 200-page opinion, the MDL court, in pertinent part, excluded the plaintiffs' experts' general causation opinions and granted summary judgment for Defendants. The court found that the MDL plaintiffs' experts improperly supported their general causation opinions by extrapolating data "not on the conclusions of any ranitidine-based study author, but instead (for the most part) upon the raw data found in studies that analyzed NDMA-rich food and NDMA-rich air ...

  

[including] studies focused on the consumption of processed meats and the inhalation of fumes in rubber factories."[14]

***4** The MDL court made three findings of significance to the issues before us on appeal, each of which formed the bases for its *Daubert* ruling. First, the court addressed the issue of threshold dose and held that "Plaintiffs must identify a threshold dose range at which ranitidine can cause cancer ...."[15] The MDL court reasoned that case law in that circuit requires a plaintiff to identify either a threshold dose or a range of doses, and "the Plaintiffs minimize the importance of the concept of the amount of any potential risk from ranitidine consumption."[16] The MDL court noted that "[t]he question of general causation is not satisfied simply because an infinitesimal risk of cancer is more than zero risk."[17]

Second, the MDL court addressed the experts' reliance on NDMA studies to form their opinions about ranitidine. The MDL court held that a general causation inquiry must focus on ranitidine, not extrapolations from studies about an allegedly harmful component of the medication.[18] The MDL court held that "the Plaintiffs must show that ranitidine consumption can result in sufficient NDMA ingestion to cause their alleged injuries."[19] The court went on to admonish the MDL plaintiffs' experts' focus on NDMA because, among other reasons, "[t]he amount of NDMA in ranitidine is uncertain" and "[a] critical, important benefit of the ranitidine epidemiology is that it removes this question from the estimate of cancer risk."[20] The MDL court noted that a focus on epidemiological studies on ranitidine was essential, explaining that

> Regardless of how much NDMA was formed in ranitidine products through exposure to heat in the supply chain, people consumed them. Did that consumption, regardless of how much NDMA was in the ranitidine over time, result in cancer? Relatedly, did anyone who consumed ranitidine get cancer, regardless of how long their ranitidine consumption lasted? These are the narrowed (and highly relevant) questions that ranitidine epidemiology attempts to answer.[21]

Third, the MDL court discussed its gatekeeping function "to ensure that speculative and unreliable opinions do not reach the jury."[22]

The MDL court focused its analysis on whether the plaintiffs' general causation opinions on ranitidine could be submitted to the jury despite there being "no published conclusion or finding, outside of this litigation, that concludes that ranitidine causes cancer of any kind."[23] In contrast, the court noted, "there is a large amount of evidence for the Defendants' position—evidence that there is no link between ranitidine consumption and cancer."[24] Further, the MDL court noted that the plaintiffs' "lack of independent scientific support is a valid ground for the Court to grant the Defendants' Epidemiology [*Daubert*] Motion because it is a valid

ground for the Court to question the reliability of the Plaintiffs' experts' methodologies."[25]

*ii. The Superior Court Action*

In September 2022, nearly 75,000 ranitidine-related personal injury complaints were filed in the Delaware Superior Court. Plaintiffs allege that Defendants collectively bear responsibility for their cancer and the related injuries or deaths allegedly caused from their ingestion of ranitidine. The Plaintiffs' claims relate to ten specific types of cancer: bladder, esophageal, gastric, liver, pancreatic, breast, colorectal, kidney, lung, and prostate. Almost 80% of the Delaware Plaintiffs originally registered their claims in the MDL, and almost 90% of the Delaware Plaintiffs allegedly suffered from one of the five types of cancer for which the MDL plaintiffs acknowledged there was insufficient evidence of causation.[26]

***5** Under a Superior Court case management order, the Zantac Litigation is proceeding simultaneously on two tracks. The first track is intended to address "general causation"—that is, whether the ingestion of Zantac is capable of causing the types of cancer alleged by Plaintiffs. To carry their burden under this first track, Plaintiffs retained ten experts to offer general causation opinions for each of the ten cancers at issue in the case. The second track is designed to identify representative cases for bellwether discovery and trial.

*a. Plaintiffs' Experts*

In the Superior Court action, Plaintiffs proffered a new slate of experts, who were not presented in the MDL; eight of those experts opined that ranitidine causes ten types of cancer. In November 2023, Defendants moved to exclude the general causation experts' testimony under Delaware Uniform Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[27] Defendants argued to the Superior Court that all Plaintiffs' experts' reports and conclusions suffered from the same methodological flaws identified by the MDL court in its decision to exclude the expert reports in that litigation. The Delaware Defendants contended that those flaws should command the same result in this case. Specifically, Defendants argued that Plaintiffs' experts did not opine on threshold dose—most asserted that NDMA is unsafe at any level. Further, Defendants posited that the methodologies used by Plaintiffs' experts were outcome-driven and unreliable and therefore could not satisfy *Daubert* and Rule 702.

Plaintiffs' ten experts are doctors and scientists whose education and qualifications were not challenged in the Superior Court or on appeal. To help contextualize the *Daubert* motions resolved by the Superior Court, we briefly summarize the experts' proffered opinions.

(1) Dr. Charles Jameson opined that ranitidine produces NDMA both exogenously (outside the body) and endogenously (inside the body); that NDMA meets five characteristics of the generally accepted characteristics of a

carcinogen; and that it is generally accepted among cancer science researchers that NDMA is capable of causing cancer in animals and humans.[28]

(2) Dr. William Sawyer opined on a single issue: that an inhaled dose of NDMA observed in a particular study (the Hidajat study)[29] was equivalent to an oral dose of NDMA. Sawyer relied on a study that followed rubber workers. He did not opine on ranitidine.[30]

(3) Dr. Alfred I. Neugeut looked at peer-reviewed literature on NDMA, ranitidine, and bladder cancer; prepared a forest plot synthesizing the studies; and opined that there is a causal association between ranitidine and urinary bladder cancer.[31]

(4) Dr. Vinod K. Rustgi was asked by Plaintiffs to provide an expert opinion regarding the role of high levels of NDMA found in ranitidine in the risk of developing of Hepatocellular carcinoma ("HCC"), a type of liver cancer. In conducting his analysis, Dr. Rustgi relied on in-vitro data, in-vivo data, tissue culture and animal models, as well as epidemiological evidence in humans. Dr. Rustgi conceded, however, that ranitidine or NDMA is not generally accepted by the community of liver specialists as a cause of liver cancer.[32]

(5) Dr. Ioannis Hatzaras was designated by Plaintiffs to evaluate whether NDMA exposure from ranitidine can cause esophageal, stomach, and colorectal cancer. Dr. Hatzaras reviewed studies demonstrating that NDMA is a carcinogen and looked into the relationship between ranitidine-containing NDMA and development of foregut/colorectal cancer.[33]

***6** (6) Dr. Dan J. Raz was asked by Plaintiffs to opine as to the causal relationship between ranitidine and lung cancer. Dr. Raz used a review of electronic databases to provide sources for his opinions and also looked to public health authorities, including the FDA, WHO, and IARC. Dr. Raz's ultimate opinion relied primarily on two studies and data points to support his opinion.[34]

(7) Dr. Pablo Leone was asked by Plaintiffs to offer a general causation opinion as to whether NDMA exposure from ranitidine causes breast cancer based upon epidemiological evidence. Dr. Leone acknowledged that medical and scientific associations do not identify a link between ranitidine and breast cancer. Dr. Leone considered studies of ranitidine epidemiology, NDMA dietary studies, draft and non-peer reviewed studies, and animal studies, and gave all the sources he considered equivalent weight.[35]

(8) Dr. Vitaly Margulis prepared a report that discussed how ranitidine breaks down into NDMA, how NDMA metabolizes in the body, and the mechanism by which NDMA can cause kidney cancer. Based on his review of data and studies, including dietary and occupational studies of NDMA, Dr. Margulis concluded that NDMA in ranitidine likely causes kidney cancer.[36]

(9) Dr. George Miller provided an opinion regarding whether NDMA exposure from ranitidine causes

pancreatic cancer. In preparing that opinion, Dr. Miller first analyzed whether ranitidine contains a cancer-causing agent and found that NDMA is a toxic degeneration byproduct of ranitidine. Dr. Miller also relied upon testing outlined in the expert report by Emery Pharma—discussed below—and he analyzed studies that showed a link between dietary sources of NDMA and pancreatic cancer. Dr. Miller then compared the studies with others that did not show an association between ingestion of nitrates and pancreatic cancer, finding flaws with those that did not show an association. Dr. Miller also analyzed studies showing a link between occupational exposure to NDMA and pancreatic cancer.[37]

(10) Dr. Bruce J. Trock was asked to give a general causation opinion regarding whether NDMA exposure from ranitidine causes prostate cancer. Dr. Trock relied on evidence from animal and occupational studies of NDMA in reaching his opinion.[38]

Additionally, Plaintiffs retained Emery Pharma (hereinafter "Emery") to (i) conduct further testing on the levels of NDMA in ranitidine provided by Defendants and specifically the levels in Plaintiffs' own pills, and (ii) opine on ranitidine's ability to degrade and transform into NDMA. Defendants offered nine challenges to the admissibility of the Emery Pharma Opinion.[39]

*b. The Superior Court's Order*

On May 31, 2024, the Superior Court denied Defendants' motions to exclude the experts' testimony (the "Order"). The court addressed Defendants' challenges to each of Plaintiffs' ten experts and reached legal conclusions applicable to all the experts. Relevant to the claims on appeal, the Superior Court found that: (1) the "general causation" question in the case "focuses on NDMA,"[40] and the experts' general causation opinions therefore could be based on studies relating to the ingestion of NDMA, rather than ranitidine itself;[41] (2) Delaware law does not "recognize a 'threshold dose' requirement as part of the general causation analysis";[42] and (3) in performing its role as a gatekeeper and conducting a *Daubert* analysis, the trial court should rule "with a 'liberal thrust' favoring admission."[43] Consistent with its "liberal thrust" standard, the court repeatedly dismissed each of Defendants' legal arguments by stating that they went to weight rather than admissibility, concluding that the issues Defendants raised were questions for a jury.

*c. Interlocutory Appeal*

***7** Defendants asked the Superior Court to certify its order for an interlocutory appeal. The Superior Court denied certification, but this Court reviewed Defendants' application and granted the request.[44] Although evidentiary rulings are rarely appropriate for interlocutory review, this Court noted that: "a ruling on the issues regarding the

Plaintiffs' general causation experts could be dispositive for some or all of the almost 75,000 claims filed in Delaware ... and, importantly, the Superior Court's decision raises substantial issues regarding the *Daubert* standard generally and mass tort litigation specifically[.]"[45] The two guiding questions this Court identified in its order were "whether (i) experts may base their causation opinions on studies regarding the cancer-causing agent or must focus on the product at issue in the litigation, and (ii) Delaware law requires experts to identify a threshold dose for purposes of establishing general causation."[46]

*d. Parties' Contentions on Appeal*

Appellants raise three claims on appeal. First, they argue that the Superior Court erred in holding that Plaintiffs' experts did not need to identify the threshold dose required to cause the cancers at issue.[47] Appellees argue in response that threshold dose is not required to reach an opinion on general causation.[48] Specifically, Appellees contend that threshold dose is not applicable to a carcinogen and as such is not relevant to the claims in this case.[49] Further, Appellees maintain that "there is no legal basis to disturb the Superior Court's holding that 'threshold dose' is one non-dispositive consideration under *Daubert*."[50]

Next, Appellants contend that the Superior Court erred in focusing its general causation analysis on NDMA, rather than ranitidine.[51] Appellants argue that "[t]he Court gave no tenable justification for [its] holding, which takes an approach contrary to that of every independent scientist who has investigated whether there is a relationship between ranitidine and cancer."[52] Appellees respond that the Superior Court correctly considered each expert's reliance on NDMA and ranitidine data in assessing admissibility.[53] Appellees contend that "[w]hether [ ] exposure [to NDMA] comes from food, or from taking a pill every day, does not matter."[54] Further, Plaintiffs argued in the Superior Court that because it is "undisputed that [ ] NDMA is found in ranitidine *and* that NDMA causes cancer ... it would seem obvious then, that if a person ingested ranitidine with NDMA, they could develop cancer."[55]

Finally, Appellants contend that the Superior Court applied an unduly lenient standard and wrongly held that all methodological critiques went to weight, not admissibility.[56] Specifically, Appellants argue that an analysis under Delaware Uniform Rule of Evidence ("DRE") 702 should not be conducted with a "liberal thrust favoring admission" and that it is a trial court's duty to ensure that an expert applies his or her methodology reliably.[57]

Appellees respond that the Superior Court applied the correct *Daubert* standard in reviewing the admissibility of Appellees' general-causation experts.[58] They note that after finding each expert's opinion methodologically reliable and reasonable under *Daubert*, the Superior Court was right to leave challenges to the "correctness" of those opinions to the jury.[59]

  

## II. STANDARD OF REVIEW

We review questions of law, including a trial court's interpretations of rules of evidence or burdens of proof, *de novo*.[60] We review a trial court's decision to admit or exclude evidence for abuse of discretion.[61] "To find an abuse of discretion, there must be a showing that the trial court acted in an arbitrary and capricious manner."[62] "That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion."[63]

## III. ANALYSIS

***8** DRE 702 governs the admissibility of expert opinion testimony. The Rule allows a party to rely on expert testimony that will assist the trier of fact, provided that the opinion meets the Rule's express admissibility requirements: the opinion must have a sufficient basis and be based on reliable principles and methods that are applied reliably to the facts of the case. Specifically, the Rule 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 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.[64]

The United States Supreme Court's holding in *Daubert* further explains the standard governing the admissibility of expert testimony. Delaware has adopted *Daubert*, and a well-developed body of caselaw explains how DRE 702 and *Daubert* are to be applied. This Court explained in *Tumlinson v. Advanced Micro Devices, Inc.*:

> In *Daubert*, the United States Supreme Court held that Federal Rule of Evidence 702—the nearly identical federal counterpart to [DRE] 702—displaced *Frye v. United States's* "general acceptance" test for determining the admissibility of expert opinion testimony. This Court, in *M.G. Bancorporation, Inc. v. Le Beau*, adopted *Daubert* and its progeny, as the "correct interpretation of Delaware Rule of Evidence 702."[65]

More specifically, under *Daubert*, "[i]n order for expert testimony to be admissible, the trial judge must act as a gatekeeper and determine that the evidence is both (1) reliable and (2) relevant."[66] To determine reliability under *Daubert*, a trial court may consider a non-exhaustive list of factors,

including: (1) whether the expert opinion testimony "can be (and has been) tested"; (2) whether it "has been subjected to peer review and publication"; (3) its "known or potential rate of error"; and (4) whether it has attracted widespread acceptance within the scientific community.[67] "The inquiry is a flexible one, and its focus must be solely on principles and methodology, not on the conclusions that they generate."[68] "The party seeking to introduce the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence."[69]

We have interpreted DRE 702 to be consistent with its analogue, Federal Rule of Evidence ("FRE") 702, and we look to the federal rule and judicial application of it as persuasive authority.[70] Because Delaware follows FRE 702 and views the official comments to the rule as helpful authority in construing DRE 702,[71] Delaware courts appropriately look to federal caselaw and commentary in discharging their gatekeeping function regarding expert testimony.

***9** FRE 702 was recently amended to clarify the rule without changing its substance. The 2023 amendments to the federal rule confirmed that trial courts are required to vigorously exercise their gatekeeping function.[72] In a May 2022 report, the Judicial Conference Advisory Committee on Evidence Rules (the "Advisory Committee") wrote that judicial decisions treating expert opinions as presumptively admissible and dismissing challenges to the sufficiency or reliability factors as questions of "weight" rather than "admissibility" consistently misapplied the rule and failed to perform the court's gatekeeping function with fidelity. Specifically, the Advisory Committee stated:

> the Committee resolved to respond to the fact that many courts have declared that the reliability requirements set forth in Rule 702(b) and (d) --- that the expert has relied on sufficient facts or data and has reliably applied a reliable methodology --- are questions of weight and not admissibility, and more broadly that expert testimony is presumed to be admissible. These statements misstate Rule 702, because its admissibility requirements must be established to a court by a preponderance of the evidence. The Committee concluded that in a fair number of cases, the courts have found expert testimony admissible even though the proponent has not satisfied the Rule 702(b) and (d) requirements by a preponderance of the evidence --- essentially treating these questions as ones of weight rather than admissibility ....[73]

The Advisory Committee further explained that the change to FRE 702 emphasized the preponderance-of-the-evidence standard and

  

"specifically was made necessary by the courts that have failed to apply correctly the reliability requirements of [Federal Rule 702]."[74] The Advisory Committee explained that this change would confirm that FRE 104(a) applies to FRE 702, noting that

> [U]ltimately the Committee unanimously agreed that explicitly weaving the Rule 104(a) standard into the text of Rule 702 would be a substantial improvement that would address an important conflict among the courts. While it is true that the Rule 104(a) preponderance of the evidence standard applies to Rule 702 as well as other rules, it is with respect to the reliability requirements of expert testimony that many courts are misapplying that standard. Moreover, it takes some effort to determine the applicable standard of proof --- Rule 104(a) does not mention the applicable standard of proof, requiring a resort to case law.[75]

The Advisory Committee went on to reiterate that "many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a)."[76] In other words, the Advisory Committee eschewed a presumption of admissibility in favor of a carefully applied gatekeeping function.

***10** DRE 702 has not been amended at the present time to mirror the 2023 amendments to FRE 702. But, because the Advisory Committee has explained that the 2023 amendments are not substantive and instead only clarified the existing federal standard, we view the committee's recent guidance as important material to consider in reviewing our trial courts' decisions and providing guidance to litigants.[77] Nothing in the recent amendments conflicts with our existing precedent, and the commentary accompanying those amendments offers additional guidance as trial courts confront the difficult task of evaluating the admissibility of an expert opinion.[78]

**A. The trial court erred in interpreting DRE 702 as liberally favoring admissibility and adopting a standard distinct from FRE 702.**

A trial court faces significant challenges in evaluating scientific testimony, particularly when a judge is asked to determine the sufficiency and reliability of an expert's conclusions on scientific causation. "Experts may rely upon different types of evidence to prove or disprove general causation, including as bases for an inference of general causation, including epidemiological studies, toxicological studies (dose-response relationship), and physiological-mechanism evidence."[79] "[T]hese types of evidence are

not all afforded the same weight"[80] and require the judge to act as gatekeeper. But these challenges underscore the need for the court to faithfully apply DRE 702 so that the jury does not receive unreliable evidence.

The trial court undertook substantial effort to resolve the numerous motions in this case, which incorporated a significant factual and scientific record. Nevertheless, we conclude that the court erred in interpreting DRE 702 and the Plaintiffs' burden by: (1) stating that DRE 702 should be applied with a "liberal thrust" favoring admission; (2) concluding that Delaware's standard for admissibility is different from the analogous federal standard; and (3) dismissing any argument regarding the experts' application of methodology as going to weight rather than admissibility. Correctly understood, DRE 702 and its interpretive precedent required exclusion of the challenged expert opinions.

### 1. The Superior Court's "liberal thrust" standard

The Superior Court, before engaging in its *Daubert* analysis, noted that courts are directed to "conduct their *Daubert* analyses 'with a liberal thrust favoring admission.' "[81] The phrase "liberal thrust" is taken from *Daubert* itself, but the Superior Court adopted the phrase in a manner that divorced it from its context.[82]

***11** In *Daubert*, the United States Supreme Court explained that the *Frye* test that previously governed expert testimony had imposed a "rigid 'general acceptance' requirement" on admissibility that was not consistent with the "liberal thrust" of the federal rules of evidence.[83] The Supreme Court concluded that the "permissive backdrop" of the federal rules was inconsistent with the use of the *Frye* test as the exclusive test for admitting expert scientific testimony.[84]

The *Daubert* Court did not, however, adopt a "liberal thrust" or presumption favoring admissibility. Although *Daubert* recognized the limitations inherent in *Frye's* general acceptance test, Rule 702 and *Daubert* establish the sufficiency and reliability elements and the threshold that a proponent of expert testimony must meet to establish admissibility. Unless that threshold is met, expert testimony is not admissible, and trial courts should not approach a challenge to expert testimony with any presumption toward admissibility.

"[W]hen it comes to making preliminary determinations about admissibility, the judge *is* and *always has been* a factfinder."[85] Under Delaware's rules of evidence, the court must resolve any preliminary questions of admissibility, and the proponent of an expert opinion must prove its admissibility by a preponderance of the evidence.[86] The Superior Court's holding to the contrary, applying a "liberal thrust" that favors admissibility in the manner it did here, failed to hold Plaintiffs to their burden of proof.

### 2. Delaware follows the federal

**standard**

"The Delaware Rules of Evidence are modeled after, and in many instances, track the Federal Rules of Evidence."[87] DRE 702's comment explicitly notes that it "was amended in 2001 to track [FRE] 702" as well as "amended in 2017 in response to the 2011 restyling of the Federal Rules of Evidence."[88]

Nevertheless, the Superior Court concluded that there were differences between Delaware law and federal law that required the court to apply standards distinct from those used by the MDL court. The Superior Court drew several broad conclusions as to why Delaware law required the court to part ways with the MDL court's decision and federal law. For instance, the Superior Court held that "Delaware law holds that statistical significance is 'not necessary to prove causality,' "[89] citing *Barrera v. Monsanto Company*[90] and *In re Zoloft*.[91] But although statistical significance may not be a prerequisite in every case, it remains an important consideration, and its absence should, at a minimum, require the expert to explain why it is not necessary under the particular facts of the case. Although the United States Court of Appeals for the Third Circuit in *In re Zoloft* cautioned that "[a] court should not ... usurp the role of the fact-finder," the court reiterated that "plaintiffs ultimately must prove a causal connection between [the product] and [the injury]."[92]

***12** Similarly, the Superior Court held that "Delaware does not recognize a 'threshold dose' requirement as part of the general causation analysis,"[93] again citing its decision in *Barrera v. Monsanto Company*.[94] *Barrera* involved whether the herbicide product known as "Roundup" caused the plaintiffs' cancer.[95] Unlike the Superior Court's holding here, *Barrera* did not hold that there is no "threshold dose" requirement in Delaware law. Instead, the court in *Barrera* made findings about the admissibility of epidemiological studies and noted that there is no "bright-line rule requiring statistical significance to prove causality."[96] Although we do not reach the "threshold dose" question in this appeal, we note that *Barrera* does not address threshold dose, and there is no consensus in Delaware law as to "threshold dose."

We do not suggest that the Superior Court should have simply adopted the MDL court's conclusions. The trial court correctly undertook an independent analysis of the admissibility of Plaintiffs' experts' opinions. But the Superior Court's dismissal of the significant methodological flaws identified by the MDL court—flaws that also appeared in the expert reports in Delaware—on the basis that Delaware has a different standard, was error.[97] The Superior Court was free to reach a different conclusion from the MDL court concerning whether to admit evidence under Rule 702, but it was required to faithfully apply the sufficiency and reliability standards set forth in Delaware and pertinent federal law.

**3. The court's "weight, not admissibility" conclusions**

As a result of its belief that Delaware applies a "liberal thrust" favoring admissibility that

  

is distinct from the federal rule, the trial court applied the wrong standard to its gatekeeping function. In denying Defendants' motions to exclude Plaintiffs' general causation experts, the Superior Court abdicated its gatekeeping role by passing crucial questions of sufficiency and reliability to the jury.[98] The Superior Court repeatedly dismissed Defendants' arguments regarding the admissibility of Plaintiffs' experts' opinions by finding that the arguments went to "weight, not admissibility."[99] As explained above, this is inconsistent with a trial court's gatekeeping function, DRE 702 and its federal analogue, and Delaware caselaw.

***13** This Court has made clear that, under DRE 702, an expert's opinion must be " 'the product of reliable principles and methods' reliably applied to the facts of each case."[100] For instance, in *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, the plaintiffs' expert applied an established model (the "Potts-Guy model") for estimating the amount of a substance that human skin will absorb, and the plaintiffs argued that the expert's opinion was admissible because that model was a "widely accepted methodology."[101] This Court noted that the issue was "not whether the Potts-Guy model is ever a reliable tool," but rather, whether it was applied reliably in the present case by the expert being challenged.[102] We held that the expert's decision to "rely exclusively upon the Potts-Guy model and to ignore or discard 'more favorable' methodologies" "directly undermine[d] the reliability of his methodology."[103] Analogously, in this case, Defendants repeatedly challenged Plaintiffs' experts for "cherry-picking" favorable data regarding NDMA while ignoring studies focusing directly on ranitidine.[104] Rather than addressing Defendants' arguments and determining whether the challenged experts reliably applied appropriate methodologies, the court dismissed these objections and labeled them as questions for the jury.

The Superior Court appeared to view its role as not extending to evaluating the strength of an expert's science. But the proponent of expert evidence is charged with establishing its sufficiency and reliability, and a trial court must determine whether that burden is met.[105] Although that may present a substantial challenge, as few judges are steeped in scientific knowledge, the trial judge may receive and evaluate testimony and ask questions of the experts and the parties' lawyers until the court feels comfortable drawing conclusions on sufficiency and reliability. An expert who cannot explain to the court's satisfaction why her method is reliably applied should not be permitted to opine for a jury.

The Superior Court did not require Plaintiffs' experts to meet that burden. More particularly, the court did not require the challenged experts to explain their rejection of epidemiological, peer-reviewed studies. For example, Defendants challenged Dr. Neugut's analysis and reliance on non-statistically significant results to support his opinion, even though in his professional work he requires that findings be statistically significant to find an association between an exposure and an outcome. In denying the motion, the Superior Court surmised that all of Defendants' challenges were reserved for the jury.[106] Similarly, Dr. Rustgi declined to provide an explanation of how he weighed the diverse set of studies he considered.[107]

  

Rather than assessing whether Dr. Rustgi's opinion was based on a reliable methodology and application, the court held that

> This Court will not inject itself into a dispute over which party has the better science. Defendants' quarrel with Dr. Rustgi's reading of the Wang study is also unavailing, as the balance of Defendants' challenges to admissibility sound in areas reserved in the first instance to the expert witness's discretion and, ultimately, the jury's wisdom (i.e., cherry picking evidence, improper rejection of relevant data, vagueness in describing methodology, inconsistent testimony, etc.)[.] These issues present a classic battle of the experts. Resolution of those disputes lies with the jury.[108]

***14** In a similar way, Dr. Miller reached his conclusions by prioritizing studies that compared cancer rates in ranitidine users to the general population, despite acknowledging that studies comparing ranitidine users to users of other heartburn medications better controlled for confounders and therefore delivered stronger, more reliable results. Notwithstanding this objection and others, the Superior Court found that "Defendants may have succeeded at times in making this a close call. But close calls go to the jury."[109] This is not the correct standard under Delaware law.

As another example, Dr. Trock admitted that the exact probability that NDMA is responsible for the outcomes observed in the occupational studies is "really speculation" that he "can't put a number on."[110] The Superior Court dismissed this issue with the occupational studies and others raised by Defendants by repeating its view that "Defendants can take up these challenges before the jury."[111] By failing to require Plaintiffs' experts to explain their reliance on these studies and their rejection of epidemiological, peer-reviewed studies of the product, the Superior Court did not fulfill its role as gatekeeper.

In sum, we conclude that the trial court misinterpreted DRE 702 and the Plaintiffs' burden in three ways. First, the trial court stated that DRE 702 should be applied with a "liberal thrust" favoring admission, contrary to the preponderance-of-the-evidence standard and *Daubert*. Second, the court misconstrued Delaware's admissibility standard as being different from, and impliedly more permissive than, the analogous federal standard. Third, the court dismissed any argument regarding the experts' application of methodology as going to weight rather than admissibility, relinquishing the court's role as a gatekeeper. These collective errors resulted in the court finding that Plaintiffs' experts' opinions were admissible even though their sufficiency and reliability was not established by a preponderance of the evidence.

  

**B. The trial court erred in defining the general causation question as focusing on the allegedly toxic agent rather than the product at issue in the case.**

In addition to its error in framing the legal standard governing admissibility of expert opinions, the trial court also erred in defining the general causation question presented by Plaintiffs' claims. General causation in toxic tort cases addresses whether a substance is capable of causing a particular injury or condition in the general population, while specific causation addresses whether a substance caused a particular plaintiff's injury.[112] On appeal, Appellants argue that the Superior Court erred in focusing the general causation analysis on NDMA, rather than ranitidine.[113] NDMA is a ubiquitous substance found in many common materials and even in air and water.[114] Appellants assert that Plaintiffs bear the burden of showing that use of the Defendants' *product* may cause the alleged cancers and not that NDMA alone causes cancer.[115] Further, Appellants argue that "[t]he Court gave no tenable justification for [its] holding, which takes an approach contrary to that of every independent scientist who has investigated whether there is a relationship between ranitidine and cancer."[116]

***15** In framing the general causation question in this case, the Superior Court held that "the discrete issue before the Court at this stage is whether NDMA can cause cancer ... [but] [b]oth sides disagree as to how to frame the general causation question."[117] In resolving this question, the Superior Court acknowledged that "[t]his fundamental dispute of whether the science should focus on ranitidine versus NDMA lies at the heart of every challenge mounted in the Motions."[118] The Superior Court stated that although Defendants' desire to have the inquiry focus on ranitidine, not NDMA, is "understandable," "the Court cannot turn a blind eye to the focus on NDMA."[119] The court then listed facts from the record that could be viewed as exhibiting Defendants' knowledge and recognition—by voluntarily participating in the recall—that ranitidine may contain NDMA.[120]

The experts' reliance on, and the Superior Court's acceptance of, studies regarding NDMA, without connecting the NDMA exposure in those studies to the exposure caused by ranitidine—the product at issue—was inconsistent with DRE 702 and Delaware law. A general causation expert's opinion must focus on the product at issue and must show that exposures examined in non-product studies on which the expert relied are reliably linked to the exposures caused by the product at issue.[121]

The Superior Court viewed the issue as similar to one resolved in a series of opinions in *In re Asbestos Litigation*, in which the Superior Court and this Court considered whether the plaintiffs' experts could rely on data regarding the disease-producing effects of chrysotile to establish that the defendants' brake pads, which contained chrysotile, were capable of causing mesothelioma.[122] We agree that the decisions in *In re Asbestos Litigation* directly address the general causation question that Defendants raised in the

*Daubert* motions in this case. But we disagree with the trial court that those precedents support the admissibility of the opinions proffered by Plaintiffs' general causation experts.

In *In re Asbestos Litigation*, the Superior Court declined to adopt the syllogism "that the Court need not evaluate the *Daubert* evidence that has been presented because we already know that friction products contain chrysotile, chrysotile causes disease and, therefore, friction products cause disease."[123] The court rejected the plaintiffs' position that "Chrysler's admission that its products contain a known carcinogen ends the inquiry," and instead explained that

> [P]laintiffs must establish that their experts can reliably conclude that exposure to friction products increases the risk of contracting an asbestos-related disease. This does not, however, preclude the plaintiffs from attempting to carry this burden by presenting competent evidence that friction products, in certain circumstances, release respirable chrysotile fibers [that can cause disease].[124]

The court found that to satisfy the reliability component of DRE 702 and *Daubert*, the plaintiffs bore the burden of establishing a link between the product and the carcinogen or disease-causing agent in order to establish the general causation link between the product and the disease.

The *Asbestos* court explained that the plaintiffs' general causation experts could rely on studies of the disease-causing agent, as opposed to the product, but only if they reliably linked those studies to the product at issue.[125] That is, to rely on evidence or data concerning other asbestos-containing products, the plaintiffs' experts had to show that the exposures from other products were "indistinguishable" or identical to exposures from the defendants' products.

***16** In *General Motors Corp. v. Grenier* ("*Grenier I*")[126] this Court agreed with that standard. But the *Grenier I* court found that the Superior Court made certain factual findings at the *Daubert* hearing that were not supported by the record and therefore remanded the case for reconsideration of whether the challenged experts' opinions created a "bridge, grounded in reliable science, between the scientific data regarding the association between unrefined chrysotile and asbestos-related diseases and the association between friction products and asbestos-related diseases."[127] The trial court then clarified its decision, and this Court affirmed, holding that the experts had "provide[d] the necessary scientific basis" to conclude that "the two forms of chrysotile [ ] [were] equally carcinogenic" by submitting research that compared "the morphology, size and shape of respirable chrysotile fibers," which are the "primary factors that explain the carcinogenicity of asbestos."[128]

These cases encapsulate the general causation question that Plaintiffs were facing with respect to ranitidine. It was not enough for Plaintiffs' experts to opine that

  

NDMA—a pervasive substance found in air and water—causes cancer, ranitidine contains or degrades into NDMA, and therefore ranitidine causes cancer. As the decisions in *In re Asbestos Litigation* make clear, a general causation expert's conclusion must reliably bridge the gap by scientifically linking the disease-causing agent to the product at issue. The Superior Court's holding regarding the general causation question was inconsistent with this precedent.[129]

Although it is true that "NDMA's dangers, the science, the studies, and the opinions therein must be given due consideration,"[130] ultimately an expert offering an opinion regarding general causation for a product must opine as to the product itself. The general causation standard explained in *In re Asbestos Litigation* requires a trial judge to closely examine what a proffered expert is—and is not—saying. An expert may rely on studies of the allegedly toxic or carcinogenic agent within the product, but they also must reliably link the toxic agent (here, NDMA) and the product at issue in order to opine that the product is capable of causing the harm alleged. Appellants aptly point out that "Plaintiffs' general-causation experts did not undertake the sort of painstaking, peer-reviewed analysis that this Court found sufficient in *Grenier II*."[131]

The MDL court explained the problem with the MDL experts' reliance on NDMA studies that were based on dietary and occupational data:

> [R]eliance on studies of NDMA-rich foods and NDMA-rich air, [ ] focused on the consumption of processed meats and the inhalation of fumes in rubber factories. Processed meats contain other carcinogens besides NDMA, and people struggle to accurately remember what they have eaten the prior day, let alone what they have eaten throughout the entire course of their lifetime. And the inhalation of rubber factory fumes (which also contain many carcinogens in addition to NDMA) is too far removed from the ingestion of ranitidine to be reliably applied.[132]

Similar infirmities arise in the challenged reports in this case: Plaintiffs' experts do not reliably opine as to general causation with respect to ranitidine. Plaintiffs' experts rely on data regarding NDMA exposure in food and rubber fumes to draw conclusions about alleged harms caused by NDMA exposures from ranitidine. Plaintiffs' experts do not account for the fact that food and rubber fumes contain other chemicals, including other established carcinogens. None of Plaintiffs' experts accounted for those other exposures or concluded that the levels of NDMA in ranitidine were comparable to the levels of NDMA that the subjects in the dietary and occupational studies ingested or inhaled. In other words, Plaintiffs' experts did not reliably link the NDMA studies to the product at issue.

  

***17** Dr. Sawyer was the only expert Plaintiffs offered to opine as to the conversion between "the inhalation doses of NDMA ... into an equivalent oral dose."[133] But Dr. Sawyer's opinion faced numerous challenges that the court failed to resolve. The court admitted that "his science may be a bridge too far," but dismissed these challenges as questions for the jury.[134]

Properly applied, Rule 702 and Delaware precedent required the trial judge, not the jury, to resolve the challenges to Dr. Sawyer's report. Dr. Sawyer relied on a single occupational study of rubber factory workers in the United Kingdom from the 1960s, the "Hidajat study." The Superior Court quoted the MDL court multiple times to describe the Hidajat study, but ignored that court's conclusion that "an expert opinion that relies upon the dietary or occupational studies [ ] to conclude that ranitidine can cause cancer utilizes an unreliable methodology for [ ] [many] reasons."[135]

The Superior Court gave no explanation for its conclusion that Dr. Sawyer's methodology and wholesale dependence on the Hidajat study was reliable, and did not distinguish the MDL court's opposite conclusion. Instead, the court noted that Dr. Sawyer's opinion was limited to "conversion of inhalation dose to oral dose."[136] But, although limited, Dr, Sawyer's opinion was essential to Plaintiff's general causation burden because Plaintiffs' other experts did not opine as to whether the levels of NDMA in these studies were comparable to levels of NDMA in ranitidine. Without Dr. Sawyer's opinion, which was not based on a reliable methodology, Plaintiffs lost the link between the general NDMA studies and ranitidine.

The problems with Plaintiffs' experts' analysis and conclusions are not limited to Dr. Sawyer. Dr. Miller, whom Plaintiffs relied on to provide opinions regarding NDMA exposure and pancreatic cancer, acknowledged that he did not "attempt[ ] to correlate the doses observed" in the non-ranitidine studies "to the doses in ranitidine."[137] Dr. Hatzaras, who was testifying as to "whether NDMA exposure from ranitidine can cause esophageal, stomach and colorectal cancer," conducted a literature review[138] that relied on dietary and occupational NDMA studies, including the Hidajat rubber worker study.[139] Another of Plaintiffs' experts, Dr. Margulis, admitted that "none of those rubber worker studies reported an increased risk of kidney cancer,"[140] but he nevertheless relied on the occupational studies in reaching his opinion on "whether it is likely that the NDMA in ranitidine can cause cancer."[141]

***18** The Superior Court did not address these gaps nor discuss why it was appropriate for the experts to opine that ranitidine causes cancer when the research on which these experts relied did not examine NDMA exposure from ranitidine or establish that the exposure to NDMA in the occupational and dietary studies could be scientifically linked to the exposure to NDMA caused by ingesting ranitidine. Further, none of the experts explained their reliance on non-ranitidine studies rather than the ranitidine studies, which showed no increased cancer risk.

* * *

Because the Superior Court erred in defining Rule 702 and the general causation question, we reverse. Plaintiffs did not carry their burden to establish the admissibility of their general causation experts' opinions by a preponderance of the evidence. Having reached that conclusion, we do not need to address Defendants' argument that the Superior Court erred in holding that Plaintiffs' experts did not need to identify a threshold dose required to cause the cancers at issue, and we offer no conclusion regarding the Superior Court's holdings on that issue.

## IV. CONCLUSION

For the foregoing reasons, we **REVERSE** the Superior Court's decision denying Defendants' motions to exclude Plaintiffs' expert opinions and remand this case to the Superior Court for further proceedings consistent with this decision. Jurisdiction is not retained.

### All Citations

--- A.3d ----, 2025 WL 1903760

## Footnotes

1 Unless otherwise stated, the facts are adopted from the *In re Zantac (Ranitidine) Litig.*, 2024 WL 2812168 (Del. Super. May 31, 2024) (footnotes and record citations omitted) [hereinafter the "Order at __"].

2 Ranitidine has not been sold in the United States since the U.S. Food and Drug Administration issued a voluntary recall of the product in the spring of 2020. All manufacturers complied with the voluntary recall. Ranitidine was sold under the brand name Zantac during the pendency of the events of the litigation, and we therefore use ranitidine and Zantac interchangeably in this opinion, as do the parties to this litigation.

3 *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F.Supp.3d 1075, 1094-95 (S.D. Fla. 2022) [hereinafter the "MDL Order" at ___].

4 Patheon was a contract manufacturing organization ("CMO") for Zantac.

  

[5] Order at *2.

[6] MDL Order at 1095.

[7] *Id.* at 1106.

[8] *Id.* at 1095.

[9] *See id.* at 1092 ("To achieve a test result of 3,000,000 ng, however, Valisure had to heat the ranitidine to a temperature well above the 98 degrees Fahrenheit found in the human body; Valisure used a temperature of 266 degrees Fahrenheit. When Valisure tested ranitidine with a temperature of 98 degrees Fahrenheit, Valisure detected no NDMA. Valisure's testing, however, extended beyond just temperature-based tests. Using the human body's base temperature, Valisure tested ranitidine's reaction with salt in an artificial stomach. Once ranitidine was mixed with salt, Valisure detected NDMA in excess of 300,000 ng. The amount of salt Valisure used, however, is worth noting. According to a Plaintiffs' expert in this MDL, the amount of salt Valisure used to generate 300,000 ng of NDMA was so great that it was close to the level where, upon consumption, the salt intake would cause death. When Valisure tested ranitidine with salt concentrations more closely approximating what a human could safely ingest, Valisure detected no NDMA.").

[10] *See id.* ("The FDA did not immediately act on Valisure's information, however, for at least two reasons. First, the FDA concluded that the laboratory equipment that Valisure used to test for NDMA actually created NDMA. In other words, Valisure's laboratory equipment created the very substance for which it was testing. Second, the FDA wanted to conduct its own tests using laboratory equipment that did not create NDMA. Using its own laboratory equipment, the FDA tested ranitidine pills from several different manufacturers. Some of the ranitidine pills tested showed no NDMA or almost no NDMA. Others showed NDMA, but the NDMA was below the FDA's limit of 96 ng.").

[11] *Id.*

  

[12] *See id.* ("Why then did the FDA initiate a voluntary recall of ranitidine? Although the FDA's tests revealed NDMA levels far below Valisure's, and although many of the FDA's tests showed NDMA levels that were acceptable, the fact remained that some of the FDA's tests showed ranitidine samples that eclipsed the 96 ng daily limit. Based upon the potential of some ranitidine pills to eclipse the 96 ng limit, the FDA initiated its voluntary recall of ranitidine.").

[13] The MDL court noted that the plaintiffs in the MDL intended to "prove that ranitidine causes bladder, esophageal, gastric, liver, and pancreatic cancers (the 'Designated Cancers'), as opposed to other cancers ('Non-Designated Cancers.')." *Id.* at 1098.

[14] *See id.* at 1093–94.

[15] *See id.* at 1109.

[16] *See id.*

[17] *See id.*

[18] *See id.* at 1104–06.

[19] *See id.* at 1106.

[20] *See id.* at 1218.

[21] *See id.*

  

[22] *See id.* at 1167.

[23] *See id.* at 1191–92.

[24] *See id.* at 1188, 1191–92 ("Because ranitidine, an immensely successful and popular drug, has been consumed by the public for almost forty years, and because ranitidine has been sold for much of that time as an over-the-counter drug, the public health consequences, if ranitidine causes cancer, would be significant. Given that risk to the public health, it is unsurprising that the FDA's initiation of a voluntary recall of ranitidine in the spring of 2020 resulted in 10 epidemiological studies that investigated the link between ranitidine and cancer.").

[25] *See id.* at 1191–92.

[26] Appellants' Opening Br. at 11.

[27] 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

[28] Order at *14–15.

[29] The Hidajat study was "a study of 36,441 men who worked in a rubber factory in the United Kingdom in 1967." Appendix to Appellants' Opening Br. at A148 [hereinafter A__].

[30] Order at *17–18.

[31] *Id.* at *18–20.

  

[32] *Id.* at *20–21.

[33] *Id.* at *21–22.

[34] *Id.* at *22–23.

[35] *Id.* at *23–25.

[36] *Id.* at *26–27.

[37] *Id.* at *27–29.

[38] *Id.* at *29–30.

[39] *Id.* at *31.

[40] *Id.* at *7.

[41] *See id.* at *8–10.

[42] *Id.* at *7.

[43] *Id.* at *5.

  

44 *In re Zantac (Ranitidine) Litig.*, 2024 WL 3271976 (Del. Super. July 1, 2024); D.I. 17 at 5 (Order Accepting Interlocutory Appeal).

45 D.I. 17 at 5 (Order Accepting Interlocutory Appeal).

46 *Id.*

47 Appellants' Opening Br. at 18–27.

48 Appellees' Answering Br. at 17–33.

49 *Id.* at 23–27.

50 *Id.* at 27–33.

51 Appellants' Opening Br. at 28.

52 *Id.*

53 Appellees' Answering Br. at 34.

54 *Id.* at 12.

55 Order at *8.

  

[56] Appellants' Opening Br. at 38.

[57] *Id.* at 38–47.

[58] Appellees' Answering Br. at 42.

[59] *Id.* at 45.

[60] *Clark v. Clark*, 47 A.3d 513, 517 (Del. 2012); *Kahn v. Kolberg Kravis Roberts & Co., L.P.*, 23 A.3d 831, 836 (Del. 2011)*; see also State v. Kelly*, 947 A.2d 1123 (Del. 2008) ("We review interpretations of court rules and statutes *de novo*."); *Hopkins v. State*, 893 A.2d 922, 927 (Del. 2006) ("[W]e review a trial judge's interpretation of the Superior Court Rules relating to discovery *de novo*.").

[61] *Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264, 1268 (Del. 2013); *Gen. Motors Corp. v. Grenier*, 981 A.2d 531, 536 (Del. 2009) ("*Grenier II*"); *M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 522 (Del. 1999), *as modified on denial of reargument* (May 27, 1999).

[62] *Spencer v. Wal-Mart Stores E., LP*, 930 A.2d 881, 887 (Del. 2007) (citing *Chavin v. Cope*, 243 A.2d 694, 695 (Del. 1968)).

[63] *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 139, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

[64] D.R.E. 702.

  

[65] *Tumlinson*, 81 A.3d at 1269 (citing and quoting *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923); *M.G. Bancorporation*, 737 A.2d at 513).

[66] *Tumlinson v. Advanced Micro Devices, Inc.*, 106 A.3d 983, 990 (Del. 2013) (citing *Daubert*, 509 U.S. at 597, 113 S.Ct. 2786).

[67] *Daubert*, 509 U.S. at 580, 593–94, 113 S.Ct. 2786.

[68] *Id.* at 594, 113 S.Ct. 2786.

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

[70] *Scottoline v. Women First, LLC*, ––– A.3d ––––, 2025 WL 1707364, at *4 (Del. June 18, 2025); *Tumlinson*, 106 A.3d at 989–90 ("In *M.G. Bancorporation, Inc. v. Le Beau*, we adopted the United States Supreme Court's holdings in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* and *Kumho Tire Co. v. Carmichael* as 'the correct interpretation of Delaware Rule of Evidence 702.' "); *M.G. Bancorporation*, 737 A.2d at 523 ("Delaware Rule of Evidence 702, like its federal counterpart, 'establishes a standard of evidentiary reliability.' "); *see also* Del. Unif. R. Evid. 702 cmt. (stating D.R.E. 702 was amended in 2001 and 2017 to track F.R.E. 702); *Ricketts v. State*, 488 A.2d 856, 857 n.2 (Del. 1985) ("The Delaware Study Committee, which drafted the D.R.E., has stated that the historical materials surrounding the promulgation of the Federal Rules and the F.R.E. official notes and comments, 'should be considered as being part of the comments prepared by the Delaware Study Committee and a court should refer to these materials in construing these rules.' ") (quoting D.R.E., Delaware Study Committee Prefatory Note); *see also*, *e.g.*, *Manna v. State*, 945 A.2d 1149, 1154 (Del. 2008) (looking to the F.R.E. to help interpret the D.R.E.).

[71] *Ricketts*, 488 A.2d at 857 n.2.

[72] Fed. R. Evid. 702 Advisory Committee's note to the 2023 amendments ("Rule 702(d) has

  

also been amended to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology. Judicial gatekeeping is essential because just as jurors may be unable, due to lack of specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support.").

[73] COMM. ON RULES OF PRAC. & PROC. OF THE JUD. CONF. OF THE U.S., REPORT OF THE ADVISORY COMMITTEE ON EVIDENCE RULES at 6 (May 15, 2022), https://perma.cc/PK3B-Q8G5.

[74] Fed. R. Evid. 702 Advisory Committee's note to the 2023 amendments.

[75] COMM. ON RULES OF PRAC. & PROC. OF THE JUD. CONF. OF THE U.S., REPORT OF THE ADVISORY COMMITTEE ON EVIDENCE RULES at 6, https://perma.cc/PK3B-Q8G5.

[76] Fed. R. Evid. 702 Advisory Committee's note to the 2023 amendments.

[77] *Id.*

[78] Delaware is not the only state to grapple with these issues or to consider its state rule in light of the clarification to FRE 702. For example, the Maryland Supreme Court recently observed that the post-FRE 702 amendment "confirms our understanding of meaningful gatekeeping" and broadly affirmed the trial court's exclusion of expert testimony. *Katz, Abosch, Windesheim, Gershman & Freedman, P.A. v. Parkway Neuroscience & Spine Inst., LLC*, 485 Md. 335, 301 A.3d 42, 68 (Md. 2023). The Maryland Supreme Court reversed the intermediate appellate court's decision to admit unreliable expert testimony, finding that the intermediate court recited the erroneous "weight and not admissibility" aphorism in making its decision. *Id.*

  

79 MDL Order at 1104 (citing *In re Denture Cream Prods. Liab. Litig.*, 795 F.Supp.2d 1345, 1351 (S.F. Fla. 2011)).

80 *Id.*

81 Order at *5 (quoting citing *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014)).

82 *See Messick*, 747 F.3d at 1196 ("Although Rule 702 should be applied with a 'liberal thrust' favoring admission ... it requires that '[e]xpert testimony ... be both relevant and reliable ....' ") (quoting *Daubert*, 509 U.S. at 588, 113 S.Ct. 2786).

83 *Daubert*, 509 U.S. at 588, 113 S.Ct. 2786.

84 *Id*. at 588–89, 113 S.Ct. 2786.

85 COMM. ON RULES OF PRAC. & PROC. OF THE JUD. CONF. OF THE U.S., REPORT OF THE ADVISORY COMMITTEE ON EVIDENCE RULES 6, https://perma.cc/PK3B-Q8G5.

86 D.R.E. 104(a) ("The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible."); *Bowen*, 906 A.2d at 795 ("The party seeking to introduce the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence."); *Minner v. Am. Mortgage & Guar. Co.,* 791 A.2d 826, 843 (Del. Super. 2000) (citing *Nat'l Bank of Com. v. Dow Chem. Co.,* 965 F.Supp. 1490, 1497 (D. Ark. 1996), *aff'd* 133 F.3d 1132 (8th Cir. 1998)); *see also Daubert*, 509 U.S. at 592 n.10, 113 S.Ct. 2786 (citing F.R.E. 104(a)); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000) ("The proponent must satisfy this burden 'by a preponderance of proof.' ").

87 *Nelson v. State*, 628 A.2d 69, 74 n.7 (Del. 1993); *Atkins v. State,* 523 A.2d 539, 542 (Del.

1987); *Ricketts*, 488 A.2d at 857 n.2.

88 D.R.E. 702, cmt.

89 Order at *6.

90 *Barrera v. Monsanto Co.*, 2019 WL 2331090, at *5 (Del. Super. May 31, 2019).

91 *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 793 (3d Cir. 2017).

92 *Id.*

93 Order at *6–7.

94 *Barrera*, 2019 WL 2331090, at *5.

95 *Id.* at *1.

96 *Id.* at *5.

97 Order at *7.

98 *See id.* at *16–17 ("Defendants' challenges to the reliability of Dr. Jameson's methodology are as follows: he cherry picked his evidence; did not rank or weigh his studies; the tests do not imitate conditions in humans; his reliance on non-peer reviewed studies; reliance on bad science and improperly rejecting or favoring unreliable studies; and, generally, relying on unreliable exogenous studies. These challenges are for the

jury."); *id.* at *18 ("Defendants reject his science. Perhaps, as presented during oral arguments, his science may be a bridge too far. But at this juncture, the criticisms go to weight and do not preclude admission."); *id.* at *20 ("Every case is different. In this early phase of the litigation, the Court is more compelled to its conclusion by the legal concepts that animate *Daubert* proceedings, especially as they recognize and uphold the distinct roles of the Court as gatekeeper and that of the jury as the ultimate fact finder, and by the encouragement of *In re Asbestos Litig*. and *Long* to allow the jury to consider debatable scientific approaches. Defendants can take up their challenges before the jury on cross examination."); *id.* at *21 ("This Court will not inject itself into a dispute over which party has the better science. Defendants' quarrel with Dr. Rustgi's reading of the Wang study is also unavailing, as the balance of Defendants' challenges to admissibility sound in areas reserved in the first instance to the expert witness's discretion and, ultimately, the jury's wisdom (i.e., cherry picking evidence, improper rejection of relevant data, vagueness in describing methodology, inconsistent testimony, etc.) These issues present a classic battle of the experts. Resolution of those disputes lies with the jury."); *id.* at *22 ("Defendants' arguments may undermine Dr. Hatzaras' opinion and be fodder for cross examination, but they cannot exclude that opinion. These expert battles are to be fought before the factfinders."); *id.* at *23 ("These decisions, made within the framework constructed by *Daubert* and progeny, are reserved to the jury."); *id.* at *25 ("Delaware law does not impose a bright line threshold dose requirement, as discussed above. Moreover, none of these challenges rises above the credibility-oriented questions that *Daubert* and progeny for years have reserved to the jury."); *id.* at *27 ("These challenges, along with claims of cherry-picking and flawed reliance on certain NDMA studies, fall victim to the wisdom of *Daubert*: they belong to the jury."); *id.* at *29 ("At this stage, it cannot be said that the scope of his review and the science used to formulate his opinions do not support admissibility. Defendants may have succeeded at times in making this a close call. But close calls go to the jury.").

99 *Id.* at *28 ("Likewise, the arguments that Dr. Miller made a 'faulty assumption' and improperly 'flipped the burden' of proof, or turned 'limitations in the 'negative' studies into strengths in the studies he preferred,' go to weight, not admissibility."); *id.* at *35 ("As the several cases repeatedly cited above make clear, such criticism goes to weight, not admissibility."); *id.* at *37 (discussing Defendants' challenges to Emery's Simulated Gastric Fluid Test as going to "weight, not admissibility").

100 *Bowen*, 906 A.2d at 797 (quoting D.R.E. 702).

  

101 *Id.*

102 *Id.*

103 *Id.*

104 *See* Order at *17 (discussing Dr. Sawyer's opinion, which relied on the Hidajat occupational, rubber worker, study); *id.* at *28 (discussing Dr. Miller's opinion, which relied on dietary and occupational studies); *id.* at *26–27 (discussing Dr. Margulis' opinion, which relied on studies in animals and non-living organisms in addition to his principal reliance on NDMA dietary and worker studies).

105 *See Zayas v. State*, 273 A.3d 776, 788 (Del. 2022) (reversing admission of opinion based on "an incomplete factual predicate"); *Scaife v. AstraZeneca LP*, 2009 WL 1610575, at *18 (Del. Super. June 9, 2009) (excluding an expert opinion because "the expert cannot accept some but reject other data from the medical literature without explaining the bases for her acceptance or rejection").

106 A9046–48 (Deposition of Alfred Neugut); Order at *20.

107 A10044 (Deposition of Dr. Rustgi, where he states: "I think they're all important. I can't say that I emphasize one over the other.").

108 Order at *21 (footnotes omitted).

109 *Id.* at *28.

110 A011012–13.

  

111 Order at *30. Defendants raised other concerns with Dr. Trock's opinion, including the reliability of his analysis and his failure to address epidemiological evidence that was inconsistent with his opinion. *See id.* at *29.

112 *See, e.g. Richards v. Copes-Vulcan, Inc.*, 213 A.3d 1196, 1197–98 (Del. 2019) (addressing Ohio law); *Sheehan v. Oblates of St. Francis de Sales*, 15 A.3d 1247, 1254–55 (Del. 2011) (explaining that, in a sexual abuse case, general causation related to the type of injuries that survivors of childhood sexual abuse suffer, while specific causation related to the actual cause of the plaintiff's injuries); *Tumlinson v. Advanced Micro Devices, Inc.*, 2013 WL 7084888, at *1 (Del. Super. Oct 15, 2013), *aff'd* 81 A.3d 1264 (Del. 2013).

113 Appellants' Opening Br. at 28.

114 MDL Order at 1106.

115 Appellants' Opening Br. at 28.

116 *Id.*

117 Order at *8.

118 *Id.* at *10.

119 *Id.* at *9.

120 *Id.*

121 *See In re Asbestos Litig.*, 911 A.2d 1176, 1202 (Del. Super. 2006); *Grenier II*, 981 A.2d at

  

531.

122 Order at *10.

123 *In re Asbestos Litig.*, 911 A.2d at 1201.

124 *Id.* at 1202.

125 *Id.*

126 981 A.2d 524 (Del. 2009) ("*Grenier I*").

127 *Id.* at 530.

128 *Grenier II*, 981 A.2d at 536–37.

129 *See In re Asbestos Litig.*, 911 A.2d at 1202.

130 Order at *10.

131 Appellants' Opening Br. at 34.

132 MDL Order at 1094.

133 Order at *17.

  

134 *Id.* ("Dr. Sawyer's opinion is limited, plainly so. He is not testifying on causation, but instead on his conversion of inhalation dose to oral dose. Defendants reject his science. Perhaps, as presented during oral arguments, his science may be a bridge too far. But at this juncture, the criticisms go to weight and do not preclude admission.").

135 MDL Order at 1214–15.

136 Order at *17.

137 A7814–16 (Deposition of Dr. Miller).

138 Of the nine peer-reviewed studies that Dr. Hatzaras examined that considered whether there is an association between ranitidine use and colorectal cancer, none reported a statistically significant increased risk of colorectal cancer and two reported statistically significant decreased risks. A188. Dr. Hatzaras reviewed seven peer-reviewed studies to examine an association between ranitidine and esophageal cancer; only one of these studies actually examined ranitidine use and gastric/esophageal cancer and none of these study authors concluded that ranitidine was causally associated with an increased risk of esophageal cancer. A189. Similarly, for gastric cancer, eleven peer-reviewed studies examined whether there is an association between ranitidine use and gastric cancer, and none of these study authors concluded there was a casual association between ranitidine and gastric cancer. A190–91. Despite these findings by his peers, Dr. Hatzaras interpreted "all non-statistically significant risk estimates above 1.0 as an increased risk" and did not apply his disregard of statistical significance consistently. A194.

139 Order at *21–22.

140 A7499–500 (Deposition of Dr. Margulis).

  

141 Order at *26.

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2006 WL 6872309
Only the Westlaw citation is currently available.
United States District Court, D. New Jersey.

Nova MOODY, et al., Plaintiffs,
v.
GENERAL MILLS, INC., et al., Defendants.

Civil Action No. 04–1942(KSH).
|
Feb. 9, 2006.

Named Expert: Dr. David F. Porter.

**Attorneys and Law Firms**

Charles P. Ingenito, Festa & Ingenito, Hawthorne, NJ, for Plaintiffs.

**ORDER ON INFORMAL APPLICATION**

PATTY SHWARTZ, United States Magistrate Judge.

***1** This matter having come before the Court by way of motion of the defendant to exclude the testimony and report of David Porter, D.O. on *Daubert* grounds;

and the Hon. Faith S. Hochberg having referred this nondispositive motion to the Undersigned for disposition;

and the Court having reviewed the submission in support of the motion and the record of proceedings;

and the Court having entered an Order dated November 18, 2005, which set December 20, 2005 as the deadline for any response to the motion;

and the plaintiffs having submitted no written response to the motion;

and the Court having reviewed the Final Pretrial Order;

and there being no opposition to the motion embodied therein;

and given the absence of opposition, the Court treats the motion as undisputed and it shall be granted, *see Alexander v. Cit Technology Financing Services, Inc.,* 217 F.Supp.2d 867, 882 (N.D.Ill.2002);

and the Court having further reviewed the motion, supporting papers, Final Pretrial Order, and governing law;

and it appearing that the parties have stipulated in the Final Pretrial Order that Dr. Porter: (1) did not ask the plaintiffs about their food history on the days before the onset of the symptoms; (2) did not account for the timing of the onset and resolution of the symptons; (3) did not ask about other common sources of disease transmission; (4)

 

could not identify any known bacteria or toxin that could have caused the symptoms in light of their onset, duration and type; and (5) testified that neither plaintiff experienced a life threatening event, exposure to which is a criteria for diagnosing post-traumatic stress disorder, Final Pretrial Order at 4–5;

and Dr. Porter's deposition reflecting that he based his conclusion solely on the temporal relationship between the plaintiffs' description of what they ingested and their symptoms, and that he was unable to identify the causative organism or toxin, Deposition of David Porter, dated September 14, 2005, at 102–103;

and various courts having noted that reliance on a temporal relationship in the absence of scientific studies, authoritative research or peer review is insufficient to constitute a reliable opinion, *see Wynacht v. Beckman Instruments, Inc.,* 113 F.Supp.2d 1205, 1209 (E.D.Tenn.2000) (excluding expert opinion regarding causation in the absence of any scientific studies to support the same); *Cuevas v. DuPont,* 956 F.Supp. 1306, 1311–12 (S.D.Miss.1997); *Schmaltz v. Norfolk & Western Railway Co.,* 878 F.Supp. 1119, 1122 (N.D.Ill.1995) (excluding expert causation opinion because it was not derived from the scientific method); *cf. Heller v. Shaw Industries, Inc.,* 167 F.3d 146, 157 (3d Cir.1999) (barring an expert where the chronology of events, the continuation of symptoms after the offending substance was removed, and the absence of discussion of scientific studies concerning the amount of the offending substance that could cause illness);

***2** and the Court further noting that Dr. Porter is unqualified to render the opinion regarding post-traumatic stress disorder where he has no special training in the area of psychiatric disorders, is an osteopath who describes himself as having "extensive experience with musculoskeletal disorders, particularly related to the spine," *see* Curriculum Vitae of Dr. Porter, and is unfamiliar with the DSM–IV criteria for the diagnosis of post-traumatic stress disorder, Deposition of Dr. Porter at 154;

and for good cause shown,

IT IS ON THIS 8th day of February, 2006

ORDERED that the motion to exclude the testimony and report of Dr. Porter is granted.

**All Citations**

Not Reported in F.Supp.2d, 2006 WL 6872309

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713 Fed.Appx. 11



United States Court of Appeals, Second Circuit.

IN RE: MIRENA IUD PRODUCTS LIABILITY LITIGATION
Mirena MDL Plaintiffs,
Plaintiffs-Appellants,
v.
Bayer HealthCare Pharmaceuticals Inc., Defendant-Appellee.

16-2890-cv(L), 16-3012-cv(CON)
|
October 24, 2017

**Synopsis**

**Background:** Patients who had experienced uterine perforation following insertion of intrauterine devices (IUD) filed suit against the device's manufacturers, alleging negligence, strict liability, manufacturing defect, design defect, failure to warn, breach of warranty, negligent misrepresentation, fraud, and various state-specific statutory violations. Following consolidation as part of multi-district litigation (MDL), the United States District Court for the Southern District of New York, Cathy Seibel, J., 202 F.Supp.3d 304, granted manufacturers summary judgment. Patients appealed.

**Holdings:** United States Court of Appeals for the Second Circuit held that:

patients' proffered expert witnesses' opinion as to general causation were not reliable, and

even if admissions could substitute for expert testimony in products liability case to allow jury to find causation, manufacturers' alleged admissions were insufficient to substitute for such testimony.

Affirmed.

**Procedural Posture(s):** On Appeal; Motion for Summary Judgment.

***12** Appeal from a judgment of the United States District Court for the Southern District of New York (Cathy Seibel, *Judge*).

**UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** that the July 29, 2016 judgment of the District Court be and hereby is **AFFIRMED**.

  

**Attorneys and Law Firms**

FOR PLAINTIFFS-APPELLANTS: Jay L.T. Breakstone (Melanie H. Muhlstock & Jessica L. Richman, on the brief), Parker Waichman LLP, Port Washington, NY.

FOR DEFENDANT-APPELLEE: Lisa S. Blatt (Sarah M. Harris & Said O. Saba, Jr., on the brief), Arnold & Porter Kaye Scholer LLP, Washington, DC., Shayna S. Cook & Brian P. O'Donoghue, Goldman Ismail Tomaselli Brennan & Baum LLP, Chicago, IL. Michael X. Imbroscio, Paul W. Schmidt, & Phyllis A. Jones, Covington & Burling LLP, Washington, DC., William P. Harrington, Bleakley Platt & Schmidt, LLP, White Plains, NY., E. James Shepherd, Shook Hardy & Bacon LLP, Houston, TX.

FOR AMICI CURIAE IN SUPPORT OF DEFENDANT-APPELLEE: Brian D. Boone (David Venderbush, New York, NY, on the brief), Alston & Bird LLP, Charlotte, NC, for the Chamber of Commerce of the United States of America and Pharmaceutical Research and Manufacturers of America.

PRESENT: John M. Walker, Jr., José A. Cabranes, Reena Raggi, Circuit Judges.

***13 SUMMARY ORDER**

Plaintiffs-appellants, women who were injured when the intrauterine device ("IUD") Mirena injured their uteruses ("Plaintiffs"), appeal the July 29, 2016 judgment of the District Court. On appeal, Plaintiffs argue that the District Court improperly excluded their expert witnesses on general causation in a March 8, 2016 Opinion and Order, and improperly granted summary judgment for defendant-appellee Bayer Pharmaceuticals Inc. ("Bayer") in a July 28, 2016 Opinion and Order, thereby terminating the multi-district litigation ("MDL"). We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal.

Mirena is a plastic, T-shaped, 1.26 by 1.26 inch IUD that delivers the hormone levonorgestrel ("LNG") into the uterus to prevent pregnancy. Plaintiffs are women from across the country who were injured when Mirena perforated, became embedded in, and/or migrated from their uteruses. Plaintiffs sued the manufacturer of Mirena, Bayer, alleging negligence, strict liability, manufacturing defect, design defect, failure to warn, breach of warranty (implied and express), negligent misrepresentation, fraud, and various state-specific statutory violations. In 2013, the nearly 1,300 cases were certified as part of this MDL. Several were chosen to be part of an Initial Disposition Pool and went through full discovery.

At bottom, the MDL is about *when* Mirena perforated Plaintiffs' uteruses. Both parties agree—and Bayer has always warned—that Mirena can injure a woman's uterus *during insertion* and afterward migrate outside the uterus (what is called "primary perforation"). But the parties disagree about

  

whether, in the absence of an injury at the time of insertion, Mirena can *later* perforate and migrate from a uterus (what is called "secondary perforation"). Bayer did not warn about the possibility of post-insertion, secondary perforation, and thus is exposed to liability if secondary perforation in fact occurred.

The instant appeal concerns the evidence Plaintiffs proffered to establish general causation of secondary perforation by Mirena. General causation concerns whether the type of injury at issue can be caused by the product. Plaintiffs principally proffered three categories of evidence for general causation of secondary perforation: 1) statements from Bayer employees, including short excerpts from a handful of Bayer employee emails, a PowerPoint presentation slide, and a sentence in a deposition all appearing to say that secondary perforation can occur; 2) the 2014 change Bayer made to the Minera warning label; and 3) expert witnesses.

On March 8, 2016, the District Court issued an Opinion and Order excluding all of Plaintiffs' experts on general causation because, it found, their testimony was not reliable and thus not helpful to the trier of fact. The District Court emphasized that the expert opinions all assumed the existence of the very fact in dispute—the possibility of secondary perforation—and then "worked backwards to hypothesize a mechanism by which it might occur." Joint App'x at 349. The District Court also applied the *Daubert* factors to each witness, finding that none of their tests had known error rates, none was subject to peer review, none was generally accepted in the scientific community, all had been developed ***14** for the purpose of litigation, and most used tests that are not easily replicable.

Bayer then filed an omnibus motion for summary judgment in the MDL docket, arguing that expert witnesses were necessary to prove general causation and thus Plaintiffs, lacking any such witnesses, could not prove general causation. Plaintiffs responded that summary judgment was inappropriate because a reasonable jury could find general causation on the basis of the admissible evidence, in particular the employee statements and the 2014 label change.

On July 28, 2016, the District Court granted summary judgment to Bayer and terminated the entire MDL. The District Court found, first, that in all fifty states expert witness testimony is typically required to prove causation in complex medical device cases. Second, assuming *arguendo* that Federal Rule of Evidence 801(d)(2) admissions could substitute for expert testimony in some jurisdictions, the District Court found that the "admissions" here were too ambiguous to do so.

Judgment was entered on July 29, 2016. This appeal followed.

## STANDARD OF REVIEW

This Court "review[s] the district court's decision to admit or exclude expert testimony under a highly deferential abuse of discretion standard." *Zuchowicz v. United*

*States*, 140 F.3d 381, 386 (2d Cir. 1998). Accordingly, a district court Rule 702 ruling "will be reversed only for manifest error." *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004). "That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

This Court reviews a district court's award of summary judgment *de novo*, "constru[ing] the evidence in the light most favorable to the [losing party]" and "drawing all reasonable inferences and resolving all ambiguities in [its] favor." *Darnell v. Pineiro*, 849 F.3d 17, 22 (2d Cir. 2017) (internal quotation marks omitted). This Court "will affirm only when 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.' " *In re 650 Fifth Ave. & Related Props.*, 830 F.3d 66, 86 (2d Cir. 2016) (quoting Fed. R. Civ. P. 56(a)).

## DISCUSSION

### I. The District Court Properly Excluded Plaintiffs' Expert Witnesses on General Causation under *Daubert*

We first consider whether, in its March 8, 2016 Opinion and Order, the District Court properly excluded three of Plaintiffs' expert witnesses on general causation: Dr. Young, Dr. Jarrell, and Dr. Wray. Upon review, we conclude that it did.

In *Daubert*, the Supreme Court provided a non-exhaustive list of factors for a district court to consider when determining whether an expert's specialized knowledge will assist the trier of fact. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). The *Daubert* factors include: "[1] the theory's testability, [2] the extent to which it has been subjected to peer review and publication, [3] the extent to which a technique is subject to standards controlling the technique's operation, [4] the known or potential rate of error, and [5] the degree of acceptance within the relevant scientific community." *United States v. Romano*, 794 F.3d 317, 330 (2d Cir. 2015) (internal quotation marks omitted). "These factors do not constitute ... a definitive checklist or test," and the inquiry "will necessarily vary from case to case." ***15** *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (internal quotation marks omitted).

In its careful and well-reasoned Opinion and Order, the District Court identified numerous problems with the Plaintiffs' experts, but three are particularly noteworthy.

First, the theories proffered by Plaintiffs' experts are not accepted in the wider obstetrics and gynecological scientific community. *See Romano*, 794 F.3d at 330. Not only do the experts fail to identify any authorities that directly support the existence of secondary perforation, but what scientific authority there is casts doubt on the phenomenon's existence.

Second, the experts lacked pre-litigation

expertise in the phenomenon of secondary perforation and developed their theories for the purposes of this litigation. *See Washburn v. Merck & Co.*, 213 F.3d 627 (2d Cir. 2000) (summary order). For instance, Dr. Young had no specialized expertise in Mirena or uterine perforation before this litigation. Dr. Jarrell had no previous experience with IUDs or hormonal contraception. And Dr. Wray had not even heard of secondary perforation before consulting in the litigation.

Third, finding no direct support in the literature for secondary perforation and having conducted no prior research on the subject, the experts all assumed the existence of the very phenomenon in dispute and then hypothesized how it could occur. Plaintiffs argue that this is no different than "the engineering expert in *Kumho* [*Tire Co. v. Carmichael*, 526 U.S. 137 [119 S.Ct. 1167, 143 L.Ed.2d 238] (1999) being] asked to determine the mechanism that caused the tire to blow." Plaintiffs' Opening Br. at 34 n.11. But in *Kumho* there was no dispute about *whether* the tire had blown, only how it happened. *See Kumho*, 526 U.S. at 142, 119 S.Ct. 1167 ("On July 6, 1993, the right rear tire of a minivan driven by Patrick Carmichael blew out."). Here, by contrast, the parties dispute whether secondary perforation has ever occurred. The experts thus begged the very question they were trying to answer.

In short, we conclude that the District Court properly excluded Plaintiffs' expert testimony for substantially the reasons provided in its March 8, 2016 Opinion and Order.

## II. The District Court Properly Granted Summary Judgment to Defendant Bayer

Having concluded that the District Court properly excluded Plaintiffs' witnesses on general causation, we next turn to whether the District Court correctly granted summary judgment in favor of Defendant Bayer. We conclude that it did.

As a preliminary matter, state law controls on the question of what evidence is necessary to prove an element of a state law claim, such as general causation. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002); *see also* 29 Charles Alan Wright & Victor James Gold, Federal Practice & Procedure: Evidence § 6263 (2d ed.) ("[S]tate law controls where it makes a precondition to recovery in a medical-malpractice action the proffer of expert testimony to prove an element of the substantive-law claim, such as standard of care or causation.").

The District Court determined that all fifty states typically require expert testimony to prove causation where the causal relationship is outside the common knowledge of lay jurors. *See In re Lipitor Mktg., Sales Practices & Prod. Liab. Litig.*, 227 F.Supp.3d 452, 469–77 (D.S.C. 2017) (surveying all States and U.S. territories); *see also Barnes v. Anderson*, 202 F.3d 150, 159 (2d Cir. 1999) ("Expert medical opinion ***16** evidence is usually required to show the cause of an injury or disease because the medical effect on the human system of the infliction of injuries is generally not within

the sphere of the common knowledge of the lay person." (internal alterations and quotation marks omitted)). And Plaintiffs have not identified any state that does not require expert testimony in the circumstances at issue here. Nevertheless, Plaintiffs identify dicta from several cases suggesting that party admissions can sometimes substitute for expert testimony on general causation. *See* Plaintiffs' Opening Br. at 48–51.

We need not reach the question of whether party admissions could ever substitute for expert testimony. Assuming *arguendo* that they could, the putative admissions proffered by Plaintiffs are simply not enough to establish general causation. As the District Court correctly found, no reasonable juror could find general causation more likely than not based on the Plaintiffs' admissible evidence.

**Employee emails.** The Plaintiffs first proffer three short excerpts from emails authored by Bayer employees that purportedly "admit" that secondary perforation can occur. Plaintiffs' Opening Br. at 7–9. But as Bayer notes and Plaintiffs do not contest, these excerpts were from emails in which the employees reported, without necessarily endorsing, adverse event reports. Bayer Br. at 55. Moreover, adverse event reports are anecdotal, and thus of very limited probative value. *See Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989–90 (8th Cir. 2001); *In re Fosamax Prod. Liab. Litig.*, 645 F.Supp.2d 164, 184 (S.D.N.Y. 2009). The District Court therefore properly concluded that a reasonable jury could not rely upon the email excerpts to find general causation.

**PowerPoint Presentation.** Plaintiffs also argue that one sentence from a 2008 Bayer lunchtime PowerPoint presentation slide proved general causation of secondary perforation. That sentence read: "Migration into the abdomen (spontaneous perforation unrelated to insertion) can occur." Plaintiffs' Opening Br. at 9. We do not know the context in which this slide was presented, let alone what was said at the meeting. Nor does the sentence supply the jury with knowledge of the causes of secondary perforation. As such, the District Court correctly found that it cannot be a substitute for expert testimony.

**Costales Testimony.** Plaintiffs further note that in 2013, Dr. Costales, Bayer's Global Medical Expert, Women's Healthcare, testified that "a perforation happening unrelated to insertion, rare as it may be, ... could happen." Plaintiffs' Opening Br. at 9. However, acknowledgement of the possibility of causation does not establish that causation is more likely than not, as the District Court correctly found.

**2014 Label Change.** Finally, Plaintiffs contend that the 2014 changes Bayer made to the Mirena label constitute proof of general causation. In 2014, Bayer changed the Mirena label to read: "Perforation (total or partial, including penetration/embedment of Mirena in the uterine wall or cervix) may occur most often during insertion, although the perforation may not be detected until sometime later." As the District Court incisively observed, the grammatical structure of this label is cryptic at best, and at most suggests the hypothetical possibility of secondary performation. It therefore

cannot substitute for expert testimony.

In sum, we conclude that the District Court properly granted Defendant's motion for summary judgment for substantially the reasons provided in its July 28, 2016 Opinion and Order.

## *17 CONCLUSION

We have reviewed all of the arguments raised by Plaintiffs on appeal and find them to be without merit. For the foregoing reasons, we **AFFIRM** the July 29, 2016 judgment of the District Court.

### All Citations

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