FILED, Clerk of the Supreme Court, 04 Sep 2025, **090150**, **AMENDED**

SUPREME COURT OF NEW JERSEY
DOCKET NO. 090150

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

AMICI CURIAE BRIEF 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*)
K&L GATES LLP
1601 K Street NW
Washington, DC 20006
Telephone: (202) 778-9165
Facsimile: (202) 778-9100
varu.chilakamarri@klgates.com

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

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

David R. Fine (*Pro Hac Vice*)
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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

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

---

[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.

> (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*)
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*)
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*