Beavan v. Allergan U.S. Inc.

Supreme Court of New Jersey

January 22, 2026, Argued; May 27, 2026, Decided

A-53 September Term 2024, 090150

Reporter
2026 N.J. LEXIS 461 *; 2026 LX 285572

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.

Prior History: **[*1]** On certification to the Superior Court, Appellate Division.

Headnotes/Summary

Headnotes

This syllabus is not part of the Court's opinion. It has been prepared by the Office of the Clerk for the convenience of the reader. It has been neither reviewed nor approved by the Court and may not summarize all portions of the opinion.

Alison Beavan v. Allergan U.S.A., Inc. **(A-53-24) (090150)**

Argued January 22, 2026 -- Decided May 27, 2026

JUSTICE PATTERSON, writing for a unanimous Court.

This appeal concerns expert testimony presented by plaintiff Alison Beavan in a product liability action against defendant Allergan U.S.A., Inc. Determination of the admissibility of that evidence must be governed by the "rigorous" gatekeeping analysis prescribed in *In re Accutane Litigation*, 234 N.J. 340, 380-400, 191 A.3d 560 (2018).

Plaintiff alleges that she sustained serious eye injuries as a result of a defect in a product manufactured and sold by defendant. She served a report by a retained expert (Dr. Lalezary), who relied on a differential diagnosis methodology on the issue of causation. Plaintiff also designated her treating physician (Dr. Phillips) to provide expert testimony on causation but did not serve a report setting forth his opinion. Defendant moved to bar the opinions as insufficiently reliable **[*2]** to satisfy N.J.R.E. 702 or 703, and as net opinions. Defendant also sought summary judgment. Without conducting the gatekeeping inquiry that *Accutane* requires, the trial court denied the motion to bar the testimony and, relying in part on plaintiff's experts' opinions, also denied summary judgment. The Appellate Division deemed the experts' opinions to constitute net opinions and reversed both denials. The Court granted certification. 260 N.J. 351 (2025).

HELD: *Accutane* mandates that any dispute about the reliability of expert testimony in a civil case be resolved by the trial court, acting as gatekeeper and applying the factors set forth in *Accutane* if it deems those factors relevant. The current record does not provide an adequate basis to determine whether the proposed testimony is sufficiently reliable under *Accutane*. A remand is necessary for the proceeding that the Court envisioned in *Accutane*. The report by plaintiff's retained expert adequately explains the basis for his proposed testimony, and the Court therefore reverses the Appellate Division's determination that he rendered a net opinion. Because there is no report by plaintiff's treating physician in the record, the Court cannot determine whether the physician's **[*3]** testimony should be excluded on net opinion grounds. The Court leaves to the trial court on remand the question whether

plaintiff should be permitted to serve a written report at this stage of the litigation, and, if so, whether the proposed testimony is admissible. Because the Appellate Division's reversal of the denial of summary judgment was premised on the exclusion of the expert testimony, the Court reverses that determination, without prejudice to the parties' right to seek summary judgment following the trial court's expert admissibility determinations on remand.

1. The admissibility of expert testimony is governed by N.J.R.E. 702 and N.J.R.E. 703. New Jersey courts were among the foremost to shift from exclusive reliance on a "general acceptance" standard for testing the reliability of scientific evidence to a methodology-based approach. In *Accutane*, 234 N.J. at 385, the Court noted the federal standard for expert reliability determinations in the wake of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). It reviewed New Jersey decisions identifying the trial court's function in expert witness evidentiary disputes "as that of a gatekeeper" and reiterated "the rigor expected of the trial court in that role under our existing case law." 234 N.J. at 388-89. The Court also made clear that in **[*4]** challenges to the reliability of expert testimony in civil cases, trial courts must "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. (pp. 25-28)

2. As a framework for the trial court's gatekeeping function, the *Accutane* Court identified four factors that the Supreme Court relied on in *Daubert* as "perhaps pertinent for consideration, but not dispositive or exhaustive," *id.* at 398, and it prescribed a procedure for the trial court's reliability determination under N.J.R.E. 702 and N.J.R.E. 703, *id.* at 399-400. *Accutane* does not mandate a hearing under N.J.R.E. 104 in every setting in which parties dispute the admissibility of expert testimony; in other New Jersey decisions, however, the courts have recognized the importance of a pretrial Rule 104 hearing in adjudicating disputes over the reliability of expert testimony. The procedural framework adopted in *Accutane* is not limited to the specific setting in which that case arose; it applies to all civil cases in which the parties dispute the reliability of expert testimony under N.J.R.E. 702 and 703. *See id.* at 347-48, 390, 396-400. (pp. 28-31)

3. The net opinion rule forbids the admission into evidence of an expert's conclusions that are not supported by factual **[*5]** evidence or other data. Under that rule, experts must set forth the "why and wherefore" that supports the opinion, rather than a mere conclusion. They must also be able to identify the factual bases for their conclusions and explain their methodology. (p. 31)

4. New Jersey's court rules make clear that Dr. Phillips's status as a treating physician does not obviate the need for a written report setting forth his opinions. On remand, the trial court should determine whether plaintiff should be permitted to serve an expert report by Dr. Phillips at this stage of the litigation. The Court takes no position as to that question and provides guidance about the remand. (pp. 32-33)

5. For both her manufacturing defect and inadequate warning claims, plaintiff must prove causation. To meet that burden, plaintiff relies on a theory of differential diagnosis based on *Creanga v. Jardal*, 185 N.J. 345, 886 A.2d 633 (2005), which identified the required steps for an expert to conduct a differential diagnosis to prove causation in a legal proceeding: first, the expert must rule in all plausible causes for the patient's condition; second, the expert must rule out, through a process of elimination, the causes that did not produce the patient's condition. **[*6]** The Court rejects plaintiff's argument that, by virtue of *Creanga*, her expert witness testimony is admissible, and neither *Accutane* nor the *Daubert* factors are relevant. *Accutane* did not carve out an exception for expert opinions based on a differential diagnosis methodology. To the contrary, in a dispute over the differential diagnosis opinion in this appeal -- as in any other civil case in which a party contests the admissibility of expert testimony -- the trial court must conduct the gatekeeping inquiry mandated by *Accutane*. And when the expert relies on a differential diagnosis methodology, the inquiry prescribed in *Accutane* must be conducted with respect to both steps of the differential diagnosis. Here, the trial court did not conduct any inquiry as to whether the methodology used by plaintiff's experts met the requirements of *Accutane*. The Court thus reverses the Appellate Division's ruling, which was based on an inadequate record, and remands the matter for the "rigorous" gatekeeping procedure mandated by *Accutane* with respect to Dr. Lalezary and -- if plaintiff is permitted to serve a written report by Dr. Phillips -- with respect to Dr.

Phillips. The Court strongly encourages **[*7]** the trial court to conduct a hearing under N.J.R.E. 104 on remand. (p. 34-43)

6. The Court next applies the net opinion standard. Dr. Lalezary adequately explained the "why and wherefore" of his opinion. He did not offer a circular, unsupported, or conclusory opinion that would constitute a net opinion under case law. The Court does not address whether Dr. Phillips's proposed expert opinion is a net opinion. If, on remand, the trial court permits plaintiff to serve a written expert report by Dr. Phillips, it should make that determination. (p. 43)

7. As to summary judgment, the Court agrees with the Appellate Division that if plaintiff's experts' reports are excluded, defendant is entitled to summary judgment. That determination, however, must await the proceedings on remand to determine the admissibility of the experts' opinions. Following the trial court's decision on the admissibility question on remand, the parties may file motions for summary judgment based on the record as supplemented on remand. (pp. 44-45)

REVERSED and REMANDED to the trial court.

Counsel: Dennis M. Donnelly argued the cause for appellant (The Donnelly Law Firm, attorneys; Dennis M. Donnelly, and David R. Shoop and Thomas S. Alch (Shoop) **[*8]** members of the California bar, admitted pro hac vice, and Brian Panish and Adam Shea (Panish, Shea, & Ravipudi) members of the California bar, admitted pro hac vice, on the briefs).

Daniel B. Rogers, a member of the Florida bar, admitted pro hac vice, argued the cause for respondent (Shook, Hardy & Bacon, and Schenck Price Smith & King, attorneys; Timothy I. Duffy, and Jonathan F. Donath, on the briefs).

Christina Vassiliou Harvey argued the cause for amicus curiae New Jersey Association for Justice (Lomurro Munson, attorneys; Jonathan H. Lomurro, of counsel, Christina Vassiliou Harvey, of counsel and on the brief, and Andrew Broome, on the brief).

Varu Chilakamarri a member of the District of Columbia bar, admitted pro hac vice, argued the cause for amici curiae Chamber of Commerce of the United States of America and New Jersey Civil Justice Institute (K&L Gates, attorneys; Erin C. Cassidy, Varu Chilakamarri, and David R. Fine, a member of the Pennsylvania bar, admitted pro hac vice, on the brief).

Michael C. Zogby submitted a brief on behalf of amicus curiae The Product Liability Advisory Council, Inc. (Barnes & Thornburg, attorneys; Michael C. Zogby, Kaitlyn Stone, and Marquis Whitney, **[*9]** on the brief).

Natalie H. Mantell submitted a brief on behalf of amici curiae Healthcare Institute of New Jersey and New Jersey Business & Industry Association (McCarter & English, attorneys; Natalie H. Mantell, on the brief).

Judges: JUSTICE PATTERSON delivered the opinion of the Court. JUSTICES PIERRE-LOUIS, WAINER APTER, FASCIALE, NORIEGA, and HOFFMAN join in JUSTICE PATTERSON's opinion. CHIEF JUSTICE RABNER did not participate.

Opinion by: PATTERSON

Opinion

JUSTICE PATTERSON delivered the opinion of the Court.

When a party in a civil action challenges the reliability of an opposing party's expert witness testimony pursuant to New Jersey Rules of Evidence 702 and 703, this Court's decision in *In re Accutane Litigation*, 234 N.J. 340, 380-

400, 191 A.3d 560 (2018), governs the trial court's determination. In accordance with *Accutane*, the trial court must conduct a "rigorous" gatekeeping analysis to ensure that any expert evidence presented to a jury is supported by reliable methodology. *Id.* at 389-90, 396-400. In that inquiry, a trial court may apply factors derived from the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-95, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), as well as other considerations relevant to the inquiry. *Accutane*, 234 N.J. at 396-400 (citing *Daubert*, 509 U.S. at 591-95).

This appeal arises from a product liability action in which plaintiff Alison Beavan alleges that she sustained serious eye injuries as a result of a defect **[*10]** in a pharmaceutical product manufactured and sold by defendant Allergan U.S.A., Inc. Plaintiff designated a retained expert on the question of causation and served a report by that expert, in which the expert relied on a differential diagnosis methodology on the issue of causation. Plaintiff also designated her treating physician to provide expert testimony on the question of causation but did not serve a report setting forth the treating physician's opinion.

Defendant moved to bar the experts' opinions on the grounds that they were insufficiently reliable to satisfy N.J.R.E. 702 or 703 and that they constituted inadmissible net opinions. Defendant also sought summary judgment dismissing plaintiff's claims.

The trial court denied defendant's motion to bar the testimony of plaintiff's experts. Without conducting the gatekeeping inquiry that *Accutane* requires, the trial court held that the experts' opinions were admissible. The court also concluded that the experts' opinions did not constitute net opinions. Relying in part on those expert opinions, the trial court ruled that plaintiff had demonstrated genuine issues of material fact as to product defect and causation and denied defendant's motion for **[*11]** summary judgment.

The Appellate Division affirmed in part and reversed in part the trial court's judgment. Finding no support in the evidence for plaintiff's differential diagnosis methodology under the factors identified in *Accutane* and deeming the experts' opinions to constitute net opinions, the appellate court reversed the trial court's decision denying defendant's motion to bar plaintiff's expert testimony and its motion for summary judgment.

We granted plaintiff's petition for certification, in which she challenged the Appellate Division's determinations regarding expert admissibility and summary judgment. With respect to the central question in this appeal -- the reliability of the experts' methodology under N.J.R.E. 702 and 703 -- we view *Accutane* to mandate that any dispute about the reliability of expert testimony in a civil case be resolved by the trial court, acting as gatekeeper and applying the factors set forth in that decision if it deems those factors relevant. *Accutane*, 234 N.J. at 347-48, 390-91. Consequently, we do not view the current record to provide an adequate basis for a determination whether the proposed expert testimony is sufficiently reliable under *Accutane* to be admitted at trial, and we conclude that a **[*12]** remand is necessary for the proceeding that this Court envisioned in *Accutane*.

We view the report of plaintiff's retained expert witness to adequately explain the basis for his proposed testimony and therefore reverse the Appellate Division's determination that the expert witness rendered a net opinion. Because there is no report by plaintiff's treating physician in the record, we cannot determine whether the physician's testimony should be excluded on net opinion grounds. We leave to the trial court on remand the question whether plaintiff should be permitted to serve a written report by the treating physician at this stage of the litigation, and, if so, whether the physician's proposed expert testimony is admissible.

Because the Appellate Division's reversal of the trial court's denial of summary judgment was premised on its holding that the experts' testimony should be excluded, we reverse that determination, without prejudice to the parties' right to seek summary judgment following the trial court's evidentiary determinations on remand.

I.

A.

The pharmaceutical product at the center of this case is Ozurdex, approved by the Food and Drug Administration (FDA) to treat certain ophthalmic **[*13]** conditions. It is a steroid pellet that is injected into a patient's eye, distributed in a single-use applicator with a needle stored in a silicone sleeve. During the relevant period, defendant assembled Ozurdex at a facility in Ireland, using certain component parts supplied by other manufacturers.[1]

On July 23, 2018, defendant advised the FDA that a routine inspection of Ozurdex units during assembly had revealed that in specific units, there was a potential for a silicone particulate, "rubberoid in nature and of approximately 300 [microns] size at its widest diameter," to detach and to be ejected with the pellet. Defendant stated that its representative had visited the manufacturer of the silicone sleeve and had identified "a potential root cause linked to" the manufacturing process, which "may extend to previously manufactured sleeve lots" used in the final assembly of needle batches for certain Ozurdex units.

On September 5, 2018, defendant notified the FDA in a Field Alert that "batch E83364, of which 38 units were distributed to the US market, is within the apparent impacted boundary identified during investigation. Five health care providers received these units." It stated that **[*14]** it that it had quarantined the remaining units in that batch, and those units were not distributed.

On October 3, 2018, defendant sent a draft "Dear Health Care Provider" letter to the FDA for its review. The draft letter stated that silicone particles had been observed in certain Ozurdex implants, and advised that clinicians and patients exercise extra vigilance. As possible clinical implications, the letter listed "[o]bscuration of vision by particle," "[i]ntraocular inflammation," and "[c]orneal adverse reaction." It described the possible "corneal adverse reaction" as the possibility that "[i]n patients that have an opening between the anterior and the posterior segment of the eye (e.g., following capsulotomy or iridectomy) the particle could potentially migrate to the anterior chamber."

According to defendant's expert, defendant attempted more than twenty times to secure the FDA's authorization to send the letter to healthcare providers. Based on the record of the appeal, it appears that the FDA never approved the letter and that the letter was not sent.

On October 17, 2018, the FDA recommended that defendant "address the problem for the sake of product quality" but stated that it **[*15]** did not consider the problem "to be a safety concern."

On October 25, 2018, defendant issued a Field Alert identifying twenty-two Ozurdex lots that its sample testing indicated had been impacted by the silicone particle issue. One lot identified in the Field Alert was lot E82852; based on testing conducted by defendant, the Field Alert stated that in lot E82852, two of ninety units -- representing 2.2 percent of those units -- contained a silicone particulate.

On December 18, 2018, defendant issued an "Urgent Drug Recall" to health care providers who received units from the twenty-two lots identified in the Field Alert. The Field Alert stated in part that "[m]ild transient visual disturbance or intraocular inflammatory reaction in sensitive patients" were "potential safety risks" and that there was "a remote possibility of corneal reaction if the particulate migrates to the anterior chamber." It asked that any inventory of the recalled product lots be quarantined and instructed recipients to "cease supplying the recalled product lots to your customers."

B.

Plaintiff, a resident of Maryland, was treated for ophthalmic conditions including uveitis and cystoid macular edema in her left eye **[*16]** beginning in 2007. In 2009, plaintiff underwent a surgical implant procedure using Retisert, a corticosteroid intravitreal implant. Between 2012 and 2015, she received two Ozurdex injections in her left eye, one in her right eye, and other ophthalmic treatments.

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[1] In addition to naming defendant Allergan U.S.A., plaintiff named Allergan Inc., Allergan PLC, and Abbvie Inc. as defendants in her complaint. The record indicates that Allergan U.S.A. is now the only defendant in this matter.

On July 27, 2015, plaintiff became a patient of William B. Phillips, M.D., a Maryland ophthalmologist specializing in the treatment of retinal conditions. Dr. Phillips noted plaintiff's eight-year history of uveitis in each eye, as well as prior glaucoma and macular surgery on her left eye. Medical records indicate that prior to plaintiff's November 6, 2018 Ozurdex injection, Dr. Phillips administered Ozurdex injections to plaintiff's left eye six times and to her right eye three times, and that he conducted other procedures to treat her conditions.

On November 6, 2018, Dr. Phillips injected plaintiff's left eye with Ozurdex. It is undisputed that the Ozurdex unit that Dr. Phillips used in his treatment of plaintiff on that date was a unit from lot E82852.

Asked at his deposition whether, as of November 6, 2018, he had "not heard" that "during the administration of certain Ozurdex lots," there was a risk that a silicone particulate **[*17]** could be injected into a patient's eye, Dr. Phillips affirmed that he had not.

On November 13, 2018, plaintiff returned to Dr. Phillips, complaining of blurred and decreased vision and a blind spot in her left eye. Dr. Phillips diagnosed a total retinal detachment. The next day, he conducted a vitrectomy to repair the retinal detachment, observing the Retisert implant "floating over the macula." Plaintiff again consulted Dr. Phillips on November 26, 2018, complaining of blurry vision. Dr. Phillips determined that the Ozurdex implant had migrated to the anterior chamber of plaintiff's left eye; he also noted the presence of corneal edema.

During visits to Dr. Phillips in December 2018, January 2019, and February 2019, plaintiff reported deteriorating vision, pain, and tearing in her left eye. Dr. Phillips referred plaintiff to Dr. Jonathan Solomon, a specialist in the treatment of corneal conditions. Dr. Solomon recommended a partial corneal transplant.

When plaintiff consulted Dr. Phillips between July 2019 and May 2021 for treatment of cystoid macular edema in her right eye, the vision in her left eye was reported to have worsened from "light perception" to "no light perception." In **[*18]** May 2021, plaintiff sustained a total retinal detachment in her left eye and was diagnosed with recurrent uveitis in both eyes.

Plaintiff asserts that she is "now completely blind in her left eye without any ability to even detect light."

II.

A.

1.

Plaintiff filed this action, asserting claims for strict liability under the New Jersey Product Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, negligence, and breach of an implied warranty. She asserted PLA claims for design defect, manufacturing defect, and failure to warn, contending that the Ozurdex unit administered to plaintiff was defective when it "left the possession" of defendant, and that it "did, in fact, cause personal injuries" while being used in a reasonably foreseeable manner, "thereby rendering [it] defective, unsafe, and dangerous for [its] intended use." Plaintiff sought compensatory damages, punitive damages, and costs.

Defendant denied plaintiff's allegations and asserted, among other affirmative defenses, that plaintiff's claims are preempted by the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301.

During discovery, plaintiff designated as a "retained expert" Dr. Maziar Lalezary, a board-certified ophthalmologist who completed a vitreoretinal surgical fellowship. Plaintiff's counsel served a report by Dr. Lalezary dated June 28, 2022. **[*19]** [2] Relying on plaintiff's deposition testimony, the medical records and deposition testimony of Dr. Phillips and Dr. Solomon, the deposition testimony of a former employee of defendant, and documents produced by defendant, Dr. Lalezary opined within a reasonable degree of medical certainty that:

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[2] Although plaintiff's counsel referred to two other expert physicians in proceedings before the trial court, it is undisputed that Dr. Lalezary and Dr. Phillips are plaintiff's only proposed expert witnesses.

1. The November 6, 2018 Ozurdex injection resulted in a silicone particulate being unintentionally dispensed from the defective actuator.

2. The silicone particulate likely migrated to the anterior chamber along with the Ozurdex steroid pellet.

3. The defective Ozurdex with silicone particulate being injected into Ms. Beavan's left eye likely incited retinal detachment which occurred within a week of treatment. Following retinal detachment surgery, the anterior chamber migration of the silicone particulate was a substantial factor in causing significant vision loss and the need for multiple subsequent surgeries in the left eye. The silicone particulate caused excessive ocular inflammation in Ms. Beavan's left eye and corneal edema, both of which were adverse effects identified in Allergan's Ozurdex recall. Despite corneal surgery, compounded damage from retinal detachment likely limited potential **[*20]** recovery resulting in Ms. Beavan's loss of vision.

4. Dr. Phillips complied with the requisite standard of care at all times with regard to his treatment of Ms. Beavan. He was not informed appropriately in a timely manner of the defective Ozurdex until early January, 2019.

5. Dr. Solomon complied with the requisite standard of care at all times with respect to his treatment of Ms. Beavan.

In his deposition, Dr. Lalezary confirmed that his written report contained all of his opinions in this case.

Asked at his deposition to state his opinion as to what caused the injury of plaintiff's left eye, Dr. Lalezary testified that a silicone particulate in Ozurdex "caused inflammation and traction in [plaintiff's] peripheral retina" that "induced a retinal break and led to her retinal detachment." He further opined that plaintiff "had detachment repair that led to the anterior migration of the Ozurdex pellet. That compromised her vision because a patient with uveitis that develops a retinal detachment has a poor prognosis for recovery and vision." Dr. Lalezary conceded that retinal detachment is "a possible risk" following any intraocular procedure and that plaintiff's prior history of eye surgeries **[*21]** "poses a risk of retinal detachment." He viewed "the temporal relationship" between the Ozurdex injection and plaintiff's symptoms to mean that the injection posed the more relevant significant risk compared to her prior surgeries and her Retisert implant.

Asked what evidence he could cite "that shows a silicone particulate was generated from [plaintiff's] November 6, 2018 Ozurdex injection," Dr. Lalezary stated that, although "nobody was able to identify or document" such a particulate, "that doesn't mean it wasn't in the eye," and he "wouldn't expect to see it anyway." According to Dr. Lalezary, he concluded that plaintiff had a silicone particle in her left eye "[b]ecause she developed an adverse event after the defective Ozurdex was administered." He testified that he determined that the Ozurdex administered on November 6, 2018 was defective because "[i]t was part of the lot that was recalled" and because plaintiff "had injections before and never developed a problem until she received a defective implant. It would be more than coincidental."

In discovery, plaintiff designated Dr. Phillips as a "non-retained expert," characterizing him as a "treating physician to testify regarding **[*22]** causation" and referring defendant to Dr. Phillips's deposition testimony for his opinion. Although defendant requested a written report by Dr. Phillips in interrogatories, plaintiff's counsel did not serve a report by Dr. Phillips on defense counsel.

Asked at his deposition whether he had formed an opinion as plaintiff's treating physician that the November 6, 2018 Ozurdex injection "contained a silicone particulate that ultimately caused her to lose her vision," Dr. Phillips answered in the affirmative. He testified that neither he nor another treating physician saw a silicone particulate but stated that he would not be able to see the particulate if it were present "since it was 300 microns." Dr. Phillips said that "the only thing we were going by" was that "it was a recalled lot." Dr. Phillips detailed plaintiff's many prior Ozurdex injections and eye procedures, and stated he believed that the "silicone oil particulate" could have caused the inflammatory response because "it's the only thing that was different." He noted, however, that plaintiff had an "unusual" inflammatory response that "persisted long after the Ozurdex implant itself was gone."

Defendant served the expert report **[*23]** of Dr. Dean Elliott, a board-certified ophthalmologist who completed a fellowship in vitreoretinal surgery. Dr. Elliott stated, among other opinions, that there is no evidence that the Ozurdex unit administered to plaintiff on November 6, 2018 generated a silicone particulate. He identified other risk factors in plaintiff's history and opined that plaintiff's retinal detachment in November 2018 and a recurrent retinal detachment with severe proliferative vitreoretinopathy, not the Ozurdex unit, caused her injuries.

Defendant moved to bar plaintiff's expert testimony under N.J.R.E. 702 and N.J.R.E. 703, arguing that the opinions of Dr. Lalezary and Dr. Phillips did not meet the standard of reliability and that they constituted net opinions. Defendant relied on the experts' concession that no direct evidence showed the release of a silicone particulate during plaintiff's November 6, 2018 Ozurdex injection. It contended that no evidence supported the experts' opinions that such a particulate -- as distinct from plaintiff's prior procedures or other factors -- caused her injuries.

Plaintiff countered that her experts met the standard of N.J.R.E. 702 and 703. She argued that her experts relied upon defendant's corporate representative's **[*24]** admission in deposition testimony that an Ozurdex applicator that dispenses a silicone particulate would be defective. Plaintiff also stated that her experts' causation opinions were based on a differential diagnosis methodology. As plaintiff's counsel explained to the trial court, given that prior eye treatments did not produce the injury that plaintiff experienced after her November 6, 2018 Ozurdex injection, the experts had a basis to opine that a defect in the Ozurdex unit used on that specific occasion caused her injury.

The trial court did not assess plaintiff's expert opinions pursuant to *Accutane*, 234 N.J. at 380-400, or apply the *Daubert* factors addressed in that decision to plaintiff's differential diagnosis theory of causation. Instead, the court quoted Dr. Lalezary's opinion that a silicone particulate caused plaintiff's retinal detachment and summarized Dr. Phillips's deposition testimony to assert that an "alleged silicone particulate created persistent inflammation in [p]laintiff's eye that proximately caused her injuries," finding both to be "sufficiently based in fact and data to be admissible under N.J.R.E. 703." The court observed that the experts' opinions were based in part on plaintiff's history of multiple **[*25]** prior Ozurdex applications with no complications, so "the only variable and most likely explanation for the complications arising after the November 6, 2018 procedure is that the Ozurdex applicator was from a defective lot."

The trial court ruled that the experts' opinions met the requirements of N.J.R.E. 702 and 703, and denied defendant's motion to bar the experts' testimony.

Defendant also moved for summary judgment dismissing plaintiff's PLA claims. It argued that there was no evidence that the specific Ozurdex unit used in plaintiff's November 6, 2018 injection was defective or that a silicone particulate was injected into plaintiff's left eye. Defendant also asserted that plaintiff's failure to warn claim was not viable under the PLA and was preempted by federal law.

The trial court denied defendant's motion, holding that there was a dispute of material fact as to whether plaintiff's injuries were caused by a defect under the PLA.

With respect to the existence of a manufacturing defect, the trial court stated that plaintiff "presented sufficient evidence that the Ozurdex applicator was defective to survive a motion for summary judgment." The court cited the testimony of defendant's corporate representative **[*26]** that if the Ozurdex unit were to dispense a silicone particulate, it would deviate from defendant's performance standards, and that the Ozurdex applicator was not designed to dispense such a particulate. The court did not address the question whether plaintiff had presented prima facie evidence that the specific Ozurdex unit used in her November 6, 2018 injection had dispensed a silicone particulate and was therefore defective.

With respect to the causation issue, the trial court relied on the opinions of plaintiff's expert witnesses that a product defect proximately caused plaintiff's injuries, finding that the expert testimony was sufficient to "create a dispute of material fact as to whether the alleged defect (i.e., the silicone particulate) proximately caused" plaintiff's injuries.

Defendant moved for reconsideration. It contended, among other arguments, that the trial court's reasoning contravened this Court's opinion in *Accutane*. The trial court denied reconsideration, reiterating that the experts' opinions were "sufficiently based in fact and data to be admissible under N.J.R.E. 703." It also rejected defendant's argument that plaintiff's PLA failure to warn claim was preempted by the FDCA, **[*27]** a contention it had not addressed in its original decision.

B.

The Appellate Division granted defendant's motion for leave to appeal. The appellate court granted amicus curiae status to the Healthcare Institute of New Jersey (HINJ) and the New Jersey Business and Industry Association (NJBIA) (jointly represented) and to the Product Liability Advisory Council, Inc. (PLAC) and the Chamber of Commerce of the United States of America (Chamber of Commerce) (jointly represented).

The Appellate Division affirmed in part and reversed in part the trial court's determination. It affirmed the trial court's decision that plaintiff's PLA failure to warn claim was not preempted by the FDCA, holding that plaintiff asserted a "viable PLA claim based on defendant's failure to warn patients of the product defect."[3]

The Appellate Division next addressed the trial court's decision denying defendant's motion for summary judgment dismissing plaintiff's manufacturing defect claim. Noting that expert testimony is indisputably necessary to "identify the manufacturing defect alleged by plaintiff," the appellate court held that the evidence of a manufacturing defect presented by plaintiff gave rise to a jury question **[*28]** with respect to one element of the claim: the existence of a defect. The Appellate Division noted, however, that a plaintiff must also present sufficient evidence that the alleged product defect proximately caused her injuries, rather than leave the jury to speculate as to that issue. It therefore turned to the question whether the trial court had abused its discretion when it denied defendant's motion to bar plaintiff's expert testimony on the question of causation.

Citing case law regarding the net opinion rule, the Appellate Division stated that its "difficulty" was "not with the theory of causation espoused by each expert or that causation could be established through a differential diagnosis," which "is certainly permitted." The Appellate Division found, however, that in this case there was an "utter lack of evidence of both general and specific causation." The appellate court viewed plaintiff's experts' theory of causation to be "based on evidence that does not exist," and opined that the theory would "leave a jury to speculate whether there was ever a particulate in the applicator or particulate injected into plaintiff's eye." The court identified potential alternative causes **[*29]** for plaintiff's injuries, including plaintiff's Retisert silicone insert, her chronic eye inflammation, inflammation from cigarette smoking, and plaintiff's "history of ophthalmic procedures and intravitreal injections." It found that the experts' differential diagnosis was "unavailing."

The Appellate Division acknowledged this Court's adoption of the *Daubert* factors in *Accutane* but did not remand the case for a determination pursuant to that decision. Instead, it found "no evidence presented by plaintiff's experts to convince us their theory of causation would pass muster under *Daubert*." The Appellate Division held that the trial court abused its discretion when it declined to bar the testimony of plaintiff's experts and that the trial court should have granted defendant's motion for summary judgment due to the lack of proof of causation. It did not reach defendant's argument that the trial court improperly denied its motion for reconsideration.

C.

We granted plaintiff's petition for certification. 260 N.J. 351 (2025). We maintained the amicus curiae status of the organizations that participated in this appeal before the Appellate Division. HINJ and NJBIA continued to participate jointly; PLAC participated **[*30]** on its own behalf before us; and the Chamber of Commerce participated jointly with the New Jersey Civil Justice Institute (NJCJI), to which we granted leave to appear. We also granted amicus curiae status to the New Jersey Association for Justice (NJAJ).

III.

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[3] The federal preemption issue is not before the Court in this appeal.

Plaintiff argues that this Court should not apply the *Daubert* factors addressed in *Accutane* to her experts' opinions and that we should instead find those opinions reliable on the basis of *Creanga v. Jardal*, 185 N.J. 345, 357-61, 886 A.2d 633 (2005). She argues that her experts' opinions were not net opinions and should have been held admissible. Plaintiff asserts that she presented sufficient evidence of general causation and specific causation to defeat defendant's motion for summary judgment on both her manufacturing defect claim and her failure to warn claim.

Defendant counters that the Appellate Division properly reversed the trial court's denial of its motion to bar plaintiff's experts and its motion for summary judgment. It argues that plaintiff failed to meet her burden under *Accutane* to demonstrate the reliability of those opinions. Defendant asserts that plaintiff's experts' reports are inadmissible net opinions because they consist of unsupported conclusory statements.

NJAJ urges **[*31]** the Court to reverse the Appellate Division's decision, contending that the *Daubert* factors do not govern expert determinations in civil cases and that plaintiff's experts satisfied the applicable test. The Chamber of Commerce and NJCJI assert that the trial court failed to conduct the gatekeeping function that *Accutane* mandates, and that the court did not rigorously review the experts' application of a differential diagnosis methodology to establish causation. PLAC argues that differential diagnosis is not a methodology capable of demonstrating general causation, and it describes that methodology's limited role in establishing the cause of an individual plaintiff's condition. HINJ and NJBIA contend that the trial court failed to determine whether plaintiff's experts applied differential diagnosis concepts in a reliable manner that satisfies *Accutane*.

IV.

A.

As a general rule, "the abuse of discretion standard applies in the appellate review of a trial court's determination to admit or deny scientific expert testimony on the basis of unreliability in civil matters." *Accutane*, 234 N.J. at 392; *see also id.* at 391 ("A reviewing court must apply an abuse of discretion standard to a trial court's determination, after a full **[*32]** Rule 104 hearing, to exclude expert testimony on unreliability grounds." (citing *Hisenaj v. Kuehner*, 194 N.J. 6, 12, 16, 942 A.2d 769 (2008)). When that deferential standard applies, 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, 203 A.3d 114 (2019) (quoting *Griffin v. City of East Orange*, 225 N.J. 400, 413, 139 A.3d 16 (2016)).

"[W]here the trial court fails to apply the proper legal standard in evaluating the admissibility of evidence, we review the evidentiary ruling de novo." *State v. Trinidad*, 241 N.J. 425, 448, 228 A.3d 1243 (2020); *accord Hassan v. Williams*, 467 N.J. Super. 190, 214, 251 A.3d 370 (App. Div. 2021) (conducting a de novo review of a trial court's evidentiary determination after determining that the trial court did not apply the proper legal standard).

We review de novo a trial court's ruling denying summary judgment, applying the legal standard that governs the trial court's determination. *In re Est. of Jones*, 259 N.J. 584, 594, 328 A.3d 923 (2025). Summary judgment should be granted "if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." *R.* 4:46-2(c).

Where, as here, "a trial court is 'confronted with an evidence determination precedent to ruling on a summary judgment motion,' it 'squarely must address the evidence decision **[*33]** first.'" *Townsend v. Pierre*, 221 N.J. 36, 53, 110 A.3d 52 (2015) (quoting *Est. of Hanges v. Metro. Prop. & Cas. Ins. Co.*, 202 N.J. 369, 384-85, 997 A.2d 954 (2010)). "Appellate review of the trial court's decisions proceeds in the same sequence, with the evidentiary issue resolved first, followed by the summary judgment determination of the trial court." *Ibid.* (citing *Est. of Hanges*, 202 N.J. at 385).

B.

1.

The admissibility of expert testimony is governed by N.J.R.E. 702 and N.J.R.E. 703. Under N.J.R.E. 702, "[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." N.J.R.E. 703 provides that "[t]he facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the proceeding" and that if those facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence."

Thus, "'while [N.J.R.E.] 702 permits a qualified expert witness to testify 'in the form of an opinion or otherwise,' N.J.R.E. 703 'addresses the bases of opinion testimony by experts.'" *Polzo v. County of Essex*, 196 N.J. 569, 582, 960 A.2d 375 (2008) (emphasis omitted) (quoting *State v. Townsend*, 186 N.J. 473, 494, 897 A.2d 316 (2006)).

Defendant's **[*34]** motion to bar the testimony of plaintiff's expert witnesses was based on two distinct grounds: (1) the requirement that expert testimony be premised on a reliable methodology, *see Accutane*, 234 N.J. at 380-400; and (2) the requirement that an expert report set forth the basis for the expert's opinion, commonly referred to as the "net opinion" rule, *see Townsend*, 221 N.J. at 55-59; *Polzo*, 196 N.J. at 583. We address the law governing each of those arguments.

2.

This Court has long grappled with the standard governing the determination whether an expert's testimony is sufficiently reliable under N.J.R.E. 702 and N.J.R.E. 703 to be admitted into evidence. New Jersey courts were "among the foremost to shift from exclusive reliance on a 'general acceptance' standard for testing the reliability of scientific evidence to a methodology-based approach." *Accutane*, 234 N.J. at 347 (footnote omitted) (citing *Landrigan v. Celotex Corp.*, 127 N.J. 404, 414, 605 A.2d 1079 (1992); *Rubanick v. Witco Chem. Corp.*, 125 N.J. 421, 447, 593 A.2d 733 (1991)).

Accutane represents a significant step in the evolution of our law governing the admissibility of expert testimony. This Court's decision arose from a dispute over the reliability of the plaintiffs' expert testimony in pharmaceutical product liability litigation. *Id.* at 350-51. Plaintiffs in that litigation alleged that Accutane, an FDA-approved drug prescribed to treat severe acne, caused Crohn's disease in certain patients. **[*35]** *Ibid.*

Addressing the defendants' challenge to the plaintiffs' expert witnesses, the trial court held an evidentiary hearing under N.J.R.E. 104 in accordance with this Court's decision in *Kemp ex rel. Wright v. State*, 174 N.J. 412, 427-28, 809 A.2d 77 (2002), and excluded the expert testimony. *Id.* at 371. The Appellate Division reversed, holding that the experts' methodology was sufficiently reliable to be admissible at trial. *In re Accutane Litig.*, 451 N.J. Super. 153, 163-64, 165 A.3d 832 (App. Div. 2017). This Court granted the defendants' petition for certification.

The Court noted the federal standard for expert reliability determinations under Fed. R. Evid. 702 in the wake of the United States Supreme Court's decision in *Daubert*, 509 U.S. at 592-93, and two subsequent Supreme Court decisions clarifying the *Daubert* standard, *General Electric Co. v. Joiner*, 522 U.S. 136, 138-47, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-48, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999). *Accutane*, 234 N.J. at 385. It reviewed prior New Jersey decisions identifying the trial court's function in an expert witness evidentiary dispute "as that of a gatekeeper -- deciding what is reliable enough to be admitted and what is to be excluded" -- and reiterated "the rigor expected of the trial court in that role under our existing case law." *Id.* at 388-89.

In *Accutane*, the Court made clear that in challenges to the reliability of expert testimony in civil cases, trial courts must "assess both the methodology used by the expert to arrive at an opinion and the underlying data used in the formation **[*36]** of the opinion." *Id.* at 396-97. As a framework for the trial court's gatekeeping function, this Court identified four factors that the Supreme Court relied on in *Daubert* as "perhaps pertinent for consideration, but not dispositive or exhaustive":

(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.

[*Id.* at 398 (citing *Daubert*, 509 U.S. at 593-95).]

This Court observed that the fourth factor, general acceptance in the scientific community, "continues to have a bearing because, minimally, it permits the identification of a relevant scientific community and facilitates an express determination of a particular degree of acceptance within that community, or contrarily permits a technique with minimal support to be viewed with skepticism." *Ibid.* (citing *Daubert*, 509 U.S. at 594). The Court did not declare New Jersey a "*Daubert* ***[*37]*** jurisdiction," noting its hesitation to "embrace the full body of *Daubert* case law as applied by state and federal courts" given the lack of a "monolithic body of case law uniformly or even consistently applying *Daubert*." *Id.* at 399. The Court therefore declined to "adopt a 'standard' that we cannot fully discern in its application at this time." *Ibid.*

Instead, in *Accutane*, this Court prescribed a procedure for the trial court's reliability determination under N.J.R.E. 702 and N.J.R.E. 703:

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 . . . 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.

[234 N.J. at 399-400.]

Addressing the expert admissibility dispute before it, the Court found that the trial court had conducted the "rigorous gatekeeping" required, and found no **[*38]** abuse of discretion in that court's exclusion of the experts' testimony. *Id.* at 400. It therefore reversed the Appellate Division's judgment. *Ibid.*

This Court did not rule in *Accutane* that a hearing under N.J.R.E. 104 is mandatory in every setting in which parties dispute the admissibility of expert testimony. *See id.* at 391-400. It noted, however, that in *Kemp*, it had "solidified the requirement of a pretrial Rule 104 hearing for assessing an expert's testimony" and that, under prior case law, "a *Kemp* hearing is a common pretrial occurrence for resolving the reliability of expert scientific testimony." *Id.* at 350 (citing *Kemp*, 174 N.J. at 430). In other New Jersey decisions, the courts have recognized the importance of a pretrial Rule 104 hearing in adjudicating disputes over the reliability of expert testimony. *See, e.g., Lanzo v. Cyprus Amax Mins. Co.*, 467 N.J. Super. 476, 507, 254 A.3d 691 (App. Div. 2021) (noting that "[t]he trial court did not conduct a Rule 104 hearing to perform the analysis required by *Accutane* and the prior decisions upon which it is based," and "did not assess the methodology, or the underlying data used by the two experts to form their opinions"); *Carl v. Johnson & Johnson*, 464 N.J. Super. 446, 506, 237 A.3d 308 (App. Div. 2020) (holding that a trial court's role at a Rule 104 hearing under *Accutane* is to "assess the soundness of the methodology of plaintiff's experts and the soundness of the 'underlying data and information'" **[*39]** (quoting *Accutane*, 234 N.J. at 390)).

The procedural framework adopted in *Accutane* is not limited to the specific setting in which that case arose; it applies to all civil cases in which the parties dispute the reliability of expert testimony under N.J.R.E. 702 and 703. *See Accutane*, 234 N.J. at 347-48, 390, 396-400.

3.

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*, 221 N.J. at 53-54 (alterations in original) (citing *Polzo*, 196 N.J. at 583). It "is a 'prohibition against speculative testimony.'" *Ehrlich v. Sorokin*, 451 N.J. Super. 119, 134, 165 A.3d 812 (App. Div. 2017) (quoting *Harte v. Hand*, 433 N.J. Super. 457, 465, 81 A.3d 667 (App. Div. 2013)).

Under the net opinion rule, experts must set forth '"the why and wherefore' that supports the opinion, 'rather than a mere conclusion.'" *Townsend*, 221 N.J. at 54 (quoting *Borough of Saddle River v. 66 E. Allendale, LLC*, 216 N.J. 115, 144, 77 A.3d 1161 (2013)). They must also "be able to identify the factual bases for their conclusions" and "explain their methodology." *Id.* at 55 (quoting *Landrigan*, 127 N.J. at 417). An opinion that is "circular" or contains "bare conclusions, unsupported by factual evidence, is inadmissible." *Buckelew v. Grossbard*, 87 N.J. 512, 524, 435 A.2d 1150 (1981).

C.

Against that backdrop, we address the trial court's denial of defendant's motion to bar the testimony of Dr. Lalezary and Dr. Phillips.

1.

We briefly note a procedural issue that is not before the Court but should be resolved on remand. The issue concerns the expert opinion of Dr. Phillips.

Our **[*40]** court rules make clear that Dr. Phillips's status as a treating physician designated to provide expert testimony on causation -- as distinct from an expert witness retained by a party solely for litigation -- does not obviate the need for a written report setting forth his opinions. To the contrary, a party is obligated to furnish a copy of the report of a treating physician whom that party expects to call to provide expert testimony if the adversary serves an interrogatory requesting the report.[4] Here, defendant requested a copy of Dr. Phillips's report in an interrogatory served on plaintiff's counsel, but plaintiff provided no report and referred defense counsel to the physician's "deposition testimony" for his opinion. Defendant informed the trial court that plaintiff had not provided a report. It is unclear, however, whether defendant moved before the trial court for an order compelling the service of a written report by Dr. Phillips. No such order is in the record.

The trial court and Appellate Division determined the admissibility of Dr. Phillips's expert opinion on the question of causation notwithstanding the absence of a written report by the treating physician setting forth **[*41]** his opinion. We caution courts and counsel that written reports of treating physicians providing expert testimony -- like written reports of expert witnesses retained for litigation -- must be served in accordance with the court rules. A court assessing the admissibility of expert opinion must consider the written report by the expert in order to make that determination.

On remand, the court should resolve the question whether plaintiff should be permitted to serve an expert report by Dr. Phillips at this stage of the litigation. We take no position as to that question. If the trial court allows plaintiff to serve a report by Dr. Phillips, it should allow defendant to respond to that report before determining whether to admit Dr. Phillips's testimony.

2.

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[4] Under *Rule* 4:10-2(d), "[a] party may through interrogatories require any other party to disclose the names and addresses of each person whom the other party expects to call at trial as an expert witness, including a treating physician who is expected to testify," and such "interrogatories may also require, as provided by *R.* 4:17-4(a), the furnishing of a copy of that person's report." *Rule* 4:17-4(a), in turn, states that if an interrogatory "requests the name of an expert or treating physician of the answering party or a copy of the expert's or treating physician's report, the party shall comply with the requirements of paragraph (e) of this rule." Pursuant to *Rule* 4:17-4(e), the report must contain, among other information, "a complete statement of that person's opinions and the basis therefor."

We next address the application of *Accutane* to the setting of this appeal.

Plaintiff offered the testimony of Dr. Lalezary and Dr. Phillips to prove the element of causation for her product liability claims under the PLA. That statute provides that

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not **[*42]** reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
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> [N.J.S.A. 2A:58C-2].

Here, plaintiff asserts two PLA claims: a claim that the "product causing the harm" was defective because of a manufacturing defect, *id.* at -2(a), and a claim that the "product causing the harm" was defective because of an inadequate warning, *id.* at -2(b), -4.[5] To prevail on either claim, plaintiff must prove that the alleged defect in the product caused her harm. N.J.S.A. 2A:58C-2.

When a plaintiff premises a PLA claim on an alleged manufacturing defect, the "deviation 'from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae'" "occurs when the product comes off the production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing **[*43]** specifications." *Myrlak v. Port Auth. of N.Y. & N.J.*, 157 N.J. 84, 97-98 (1999) (quoting N.J.S.A. 2A:58C-2(a)); *accord, Navarro v. George Koch & Sons, Inc.*, 211 N.J. Super. 558, 576, 512 A.2d 507 (App. Div. 1986).

In a PLA failure to warn claim, the plaintiff must prove that "the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it . . . failed to contain adequate warnings or instructions." *In re Reglan Litig.*, 226 N.J. 315, 334, 142 A.3d 725 (2016) (omission in original) (quoting N.J.S.A. 2A:58C-2). A manufacturer or seller "shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction." N.J.S.A. 2A:58C-4.[6]

Thus, for each of the PLA claims asserted here, **[*44]** plaintiff must prove, among other elements, the element of causation. *See* N.J.S.A. 2A:58C-2, -4. To meet her burden to prove causation, plaintiff relies on a theory of differential diagnosis based on this Court's opinion in *Creanga*, 185 N.J. at 357-61. In *Creanga*, the plaintiff claimed that a motor vehicle collision was "the proximate cause of her premature labor and the resultant death of one of her

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[5] The record makes clear that plaintiff no longer asserts the PLA claim for design defect that she pled in her complaint.

[6] The PLA defines an "adequate product warning or instruction" as

> one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [N.J.S.A. 2A:58C-4.]

See also Perez v. Wyeth Labys., Inc., 161 N.J. 1, 20-21, 734 A.2d 1245 (1999) (holding that the "learned intermediary rule" set forth in N.J.S.A. 2A:58C-4 "does not apply to the direct marketing of drugs to consumers"). If the warning at issue has been approved by the FDA under the FDCA, "a rebuttable presumption shall arise that the warning or instruction is adequate." N.J.S.A. 2A:58C-4.

twins" two days later. *Id.* at 349-50. The plaintiff's treating physician opined that the accident was the cause of the plaintiff's harm. *Ibid.* He stated that he "tried to rule out the other causes of premature labor like preeclampsia, high blood pressure, any trauma or accident, [or] any infective cause to cause infection and premature labor." *Id.* at 351 (alteration in original). The physician testified with a reasonable degree of medical certainty that the trauma of the collision was "probably the cause of [the plaintiff's] premature labor." *Id.* at 351-52.

The trial court concluded that the physician's opinion was a net opinion and dismissed the plaintiff's claims; the Appellate Division affirmed. *Id.* at 354.

This Court held that the physician's opinion was not a net opinion, but rather was "based on a properly conducted differential diagnosis," and deemed it sufficiently reliable **[*45]** under N.J.R.E. 702. *Id.* at 349-50, 354-62. It defined the term "differential diagnosis," as used in the medical community, to denote a "medical construct for determining 'which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their symptoms.'" *Id.* at 355 (quoting *Dorland's Illustrated Medical Dictionary* 377 (23d ed. 1957)). The Court noted that in judicial settings, the term "differential diagnosis" has been used "'in a more general sense to describe the process by which *causes* of the patient's *condition* are identified." *Id.* at 355-56 (quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 n.4 (9th Cir. 2003)).

The Court identified the steps required for an expert to conduct a differential diagnosis to prove causation in a legal proceeding. *Id.* at 356. In the first step, the expert must "'rule[] in' all plausible causes for the patient's condition by compiling 'a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. *Ibid.* At that initial stage, "the issue 'is which of the competing causes are *generally* capable of causing the patient's symptoms or mortality.'" *Ibid.* (quoting *Clausen*, 339 F.3d at 1057-58).

In the second step, the expert "must rule out those causes that did not produce the patient's condition [through] 'a process **[*46]** of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case.'" *Ibid.* (quoting *Clausen*, 339 F.3d at 1058). The Court stated that "[a]n expert 'need not conduct every possible test to rule out all possible causes of a patient's [injury], so long as [the expert] employed sufficient diagnostic techniques to have good grounds for [the] conclusion'" reached. *Ibid.* (first alteration in original) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999)). Nonetheless, a court evaluating an expert's conduct of the second step is "justified in excluding evidence if an expert 'utterly fails . . . to offer an explanation for why the proffered alternative cause' was ruled out." *Id.* at 358 (quoting *Clausen*, 339 F.3d at 1058).

This Court stated in *Creanga* that to properly rule out an alternative cause, "the expert must use 'scientific methods and procedures' and justify an elimination on more than 'subjective beliefs or unsupported speculation.'" *Ibid.* (quoting *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994)). As the Court noted, "conclusions based on discredited or improperly performed diagnostic tools are suspect." *Ibid.* (quoting *Carlson v. Okerstrom*, 267 Neb. 397, 675 N.W.2d 89, 106 (Neb. 2004)).

Applying that standard to the expert opinion before it, the Court held that the treating **[*47]** physician properly conducted his differential diagnosis as to the cause of the plaintiff's harm and reversed the Appellate Division's judgment. *Id.* at 358-60.

In this appeal, plaintiff contends that by virtue of *Creanga*, her expert witness testimony is admissible, and that neither *Accutane* nor the *Daubert* factors are relevant to the analysis.

We disagree. In *Accutane*, this Court did not carve out an exception for expert opinions based on a differential diagnosis methodology. *See* 234 N.J. at 380-400. To the contrary, in a dispute over the differential diagnosis opinion in this appeal -- as in any other civil case in which a party contests the admissibility of expert testimony -- the trial court must conduct the gatekeeping inquiry mandated by *Accutane. Id.* at 347-48, 390-91.

When the expert relies on a differential diagnosis methodology, the inquiry prescribed in *Accutane* must be conducted with respect to both steps of the differential diagnosis: the "rule in" of "all plausible causes," and the

"process of elimination" to "rule out" plausible causes and identify "the most likely cause of the findings in that particular case" -- a step in which "the expert must use 'scientific methods and procedures'" to justify the elimination of an alternative **[*48]** cause. *See Creanga*, 185 N.J. at 356, 358.

In the first stage of the analysis -- the "rule in" step -- the trial court should assess the methodology used for each determination by the expert that a particular cause is a plausible cause of the plaintiff's harm, applying the *Daubert* factors identified in *Accutane* to the extent the court deems them relevant, as well as other factors pertinent to the specific case. As the Circuit Court of Appeals for the Ninth Circuit has observed,

> [t]he first step in the diagnostic process is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. The issue at this point in the process is which of the competing causes are *generally* capable of causing the patient's symptoms or mortality. Expert testimony that rules in a potential cause that is *not* so capable is unreliable. . . . Similarly, expert testimony that neglects to consider a hypothesis that might explain the clinical findings under consideration may also be unreliable.
>
> [*Clausen*, 339 F.3d at 1057-58 (citations omitted).]

In the second step of the inquiry -- the "rule out" stage -- the trial court should scrutinize the methodology used by the expert to eliminate causes previously ruled in, **[*49]** and the methodology used in the expert's determination not to rule out a given cause. *Creanga*, 185 N.J. at 356. As the Ninth Circuit explained, "[a]fter the expert rules in all of the potential hypotheses that might explain a patient's symptoms," that expert "must then engage in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case." *Clausen*, 339 F.3d at 1058. "The expert must provide reasons for rejecting alternative hypotheses 'using scientific methods and procedures' and the elimination of those hypotheses must be founded on more than 'subjective beliefs or unsupported speculation.'" *Ibid.* (quoting *Claar*, 29 F.3d at 502).

In short, the trial court must scrutinize each component of the expert's opinion to determine whether it is grounded in a methodology that satisfies *Accutane*.

Here, the trial court did not conduct any inquiry as to whether the methodology used by plaintiff's experts met the requirements of *Accutane*. Consequently, there was neither a factual record developed in accordance with *Accutane* nor trial court findings as to the relevant factors. Although the Appellate Division acknowledged this **[*50]** Court's decision in *Accutane* and noted the absence of evidence of "testing, error rates, peer reviews, publications, or general acceptance in the scientific community to support the method of causation in this case," it had no record of a gatekeeping proceeding under *Accutane* to review. Instead of remanding with instructions to the trial court to conduct an *Accutane* analysis, the Appellate Division based its ruling on an inadequate record.

Accordingly, we reverse the Appellate Division's determination and remand this matter to the trial court for the "rigorous" gatekeeping procedure mandated by *Accutane* with respect to Dr. Lalezary and -- if plaintiff is permitted to serve a written report by Dr. Phillips at this stage -- with respect to Dr. Phillips. Given the complexity of the causation issue raised in this matter, we strongly encourage the trial court to conduct a hearing under N.J.R.E. 104 on remand. *See Accutane*, 234 N.J. at 391-92. We take no position as to whether the disputed opinions should be admitted or excluded under that standard. That determination is for the trial court to make on remand based on an appropriate record, subject to appellate review.

3.

We apply the net opinion standard set forth in *Polzo*, 196 N.J. at 583, and *Townsend*, 221 N.J. at 55-59, to the **[*51]** record of this case.

We do not view the opinion of Dr. Lalezary to constitute a net opinion. Dr. Lalezary adequately explained the "why and wherefore" of his opinion. He made clear his reliance on the fact that plaintiff's November 6, 2018 injection involved an Ozurdex unit from a recalled lot in which 2.2 percent of tested units contained a silicone particulate, and

on the events that followed her November 6, 2018 Ozurdex injection. He did not offer a circular, unsupported, or conclusory opinion that would constitute a net opinion under our case law. *See Townsend*, 221 N.J. at 53-54; *Polzo*, 196 N.J. at 583.

We do not address the question whether Dr. Phillips's proposed expert opinion is a net opinion. If, on remand, the trial court permits plaintiff to serve a written expert report by Dr. Phillips, it should determine whether that report constitutes a net opinion.

D.

Finally, we briefly address the Appellate Division's decision reversing the trial court's denial of summary judgment.[7]

When it denied defendant's motion for summary judgment, the trial court relied on the opinions of Dr. Lalezary and Dr. Phillips, holding that those opinions were sufficient to create a genuine issue of material fact under *Rule* 4:46-2(c). In the wake of its determination **[*52]** that the experts' opinions should be barred, the Appellate Division held that "[d]efendant should have been granted summary judgment due to the lack of proof of causation."

We agree with the Appellate Division that if plaintiff's experts' reports are excluded, defendant is entitled to summary judgment. That determination, however, must await the proceedings on remand to determine the admissibility of the experts' opinions. Following the trial court's decision on the admissibility question on remand, the parties may file motions for summary judgment based on the record as supplemented on remand.

V.

The judgment of the Appellate Division is reversed, and the matter is remanded to the trial court for proceedings consistent with this opinion.

JUSTICES PIERRE-LOUIS, WAINER APTER, FASCIALE, NORIEGA, and HOFFMAN join in JUSTICE PATTERSON's opinion. CHIEF JUSTICE RABNER did not participate.

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[7] Plaintiff argues that the Appellate Division should have applied a proximate cause standard to her failure to warn claim based on the heeding presumption, citing *Coffman v. Keene Corp.*, 133 N.J. 581, 594, 628 A.2d 710 (1993), and other cases, and that the appellate court should have concluded there was prima facie evidence of proximate cause for the warning claim because 2.2 percent of Ozurdex units in the affected lots were found to include a silicone particulate. In its opinion denying summary judgment, the trial court noted that plaintiff's causation argument for her failure to warn claim was made for the first time in a sur-reply that defendant contended was filed without leave of court in violation of *Rule* 1:6-3(a). The trial court did not address that argument in its decision. Plaintiff did not raise that argument before the Appellate Division, and the Appellate Division did not address it. Accordingly, the argument is not properly presented to this Court. *See State v. Robinson*, 200 N.J. 1, 19-20, 974 A.2d 1057 (2009) (noting the "'well-settled principle that our appellate courts will decline to consider questions or issues not properly presented to the trial court when an opportunity for such a presentation is available unless the questions so raised on appeal go to the jurisdiction of the trial court or concern matters of great public interest'" (quoting *Nieder v. Royal Indem. Ins. Co.*, 62 N.J. 229, 234, 300 A.2d 142 (1973))).