Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

New Jersey Supreme Court Reaffirms *Accutane* as the Controlling Standard for the Admissibility of Expert Testimony

The New Jersey Supreme Court has reaffirmed that courts must apply the rigorous expert-reliability gatekeeping framework established in *In re Accutane Litigation*, 234 N.J. 340, 380-400 (2018), making clear that this analysis remains the controlling standard for the admissibility of expert testimony under New Jersey Rules of Evidence (N.J.R.E.) 702 and 703. The decision in *Beavan v. Allergan U.S.A., Inc.*, No. 090150, 2026 WL 1475427 (N.J. May 27, 2026), reinforces that trial judges must scrutinize both the methodology used by experts and the underlying data relied upon, and may apply the *Daubert* factors where relevant. The Court also emphasized, without mandating, that Rule 104 hearings are an important tool for resolving complex causation disputes and should be strongly considered whenever expert methodology or underlying data is contested.

In Re Accutane Background

In *Accutane*, the New Jersey Supreme Court stopped short of declaring New Jersey a "*Daubert* jurisdiction," but it reinforced the rigorous gatekeeping role that trial courts are required to perform when assessing the reliability and admissibility of scientific causation evidence under N.J.R.E 702 and 703.

The *Accutane* decision provided New Jersey courts with clearer guidance on how the gatekeeping function was to be carried out and, for the first time, formally adopted the four key factors recognized in *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), as "perhaps pertinent for consideration, but not dispositive or exhaustive" guideposts for evaluating the reliability of scientific evidence: (1) whether the scientific theory can be, or has been, tested; (2) whether the theory has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether standards exist for maintaining or controlling the technique's operation; and (4) whether there is general acceptance in the relevant scientific community.

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The *Accutane* Court also prescribed the following standard: the proponent of expert testimony must demonstrate that the expert applies "scientifically recognized methodology in the way that others in the field practice the methodology," and when the proponent fails to 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."

The *Beavan v. Allergan* Decision

Factual Background

In *Beavan*, the plaintiff, who had a longstanding history of ophthalmic conditions, alleged severe left-eye injuries following a November 6, 2018 Ozurdex injection. After receiving the injection, the plaintiff developed retinal detachment, anterior migration of the Ozurdex implant into the anterior chamber, corneal edema, and progressive left-eye vision loss culminating in the complete loss of light perception.

The Ozurdex unit administered to the plaintiff came from one of twenty-two lots later identified by the defendant as potentially containing silicone particulates. The defendant's testing showed that 2.2 percent of sampled units from that lot contained a silicone particulate. Between July and December 2018, the defendant reported the particulate issue to the FDA, identified a manufacturing-process defect in the silicone sleeve used in Ozurdex assembly, notified the FDA that certain lots were affected, and issued an Urgent Drug Recall on December 18, 2018. Notably, the FDA recommended that the defendant "address the problem for the sake of product quality" but stated that it did not consider the problem "to be a safety concern," and the FDA never approved a proposed Dear Health Care Provider letter that the defendant attempted more than twenty times to send.

Procedural Background

The plaintiff asserted product liability manufacturing defect and failure-to-warn claims under the New Jersey Product Liability Act. In support of her claims, the plaintiff relied on two purported experts: (1) Dr. Maziar Lalezary, a retained board-certified ophthalmologist, who provided a written report finding causation via differential diagnosis; and (2) her treating ophthalmologist, Dr. William Phillips, who was designated to provide expert causation testimony but did not provide a written report, despite being asked to do so.

Dr. Lalezary opined that the November 6, 2018 injection caused a silicone particulate to be unintentionally dispensed into the plaintiff's eye, resulting in retinal detachment and subsequent vision loss. He acknowledged, however, that no physician was able to identify or document a silicone particulate in the plaintiff's eye, but maintained that this did not mean it was not in the eye. Dr. Phillips offered a similar opinion at his deposition, testifying that a silicone particulate caused the plaintiff's injuries. He explained that "the

only thing we were going by" was that "it was a recalled lot" and that the particulate was "the only thing that was different." Dr. Phillips likewise conceded that neither he nor any other treating physician observed a silicone particle in the plaintiff's eye, but stated that he would not have been able to see it even if it were present.

The defendant moved to bar the opinions of both experts as insufficiently reliable under N.J.R.E. 702 and 703, and as net opinions. The trial court denied the defendant's motion without conducting the gatekeeping analysis outlined in *Accutane* and then relied on those experts' opinions to deny the defendant's motion for summary judgment. The Appellate Division reversed, deeming the experts' opinions net opinions, finding an "utter lack of evidence of both general and specific causation," and directing summary judgment in the defendant's favor.

The Supreme Court concluded that neither the trial court nor the Appellate Division performed the *Accutane* reliability analysis. The trial court had accepted the experts' opinions without probing their methodological soundness, while the Appellate Division effectively conducted its own reliability review despite lacking a factual record developed in accordance with *Accutane* or trial court findings as to the relevant factors. The Court held that both approaches were improper.

Critically, because the trial court failed to apply the proper legal standard, the Court reviewed the evidentiary ruling *de novo* rather than under the typical abuse of discretion standard.

Differential Diagnosis Is Not Exempt From *Accutane*

On appeal, the plaintiff argued that the *Daubert* factors incorporated into *Accutane* should not apply to differential diagnosis opinions and urged reliance on *Creanga v. Jardal*, 185 N.J. 345, 357-61 (2005), where the Court recognized that differential diagnosis, involving standard diagnostic techniques such as physical exams, taking medical history, and ruling out alternative causes, provided a valid scientific foundation for expert causation opinions under N.J.R.E. 702.

The Court rejected this position, holding that *Accutane* "did not carve out an exception for expert opinions based on a differential diagnosis methodology." Differential diagnosis remains a permissible methodology, but it is not exempt from reliability review. Courts must rigorously examine both steps of the differential diagnosis: the "rule in" of all plausible causes and the "rule out" or elimination of alternatives.

In the first step, the "rule in," the trial court should assess the methodology used by the expert to determine 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. Expert testimony that rules in a potential cause that is not capable of causing the patient's symptoms is unreliable, as is testimony that neglects to consider a hypothesis that might explain the clinical findings under consideration.

In the second step, the "rule out," the expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures, and the elimination must be founded on more than subjective beliefs or unsupported speculation. As the Court summarized: "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*."

Net Opinion/Written Report Analysis

The Court separately addressed the net opinion doctrine, a corollary to New Jersey's Evidence Rules, which precludes the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data and requires experts to set forth the why and wherefore supporting their opinions.

The Court held that Dr. Lalezary's report was not a net opinion because he explained the factual basis and reasoning underlying his conclusions. Although the defendant disputed Dr. Lalezary's assumptions and methodology, those criticisms went to reliability and weight under *Accutane*, not whether the opinion was merely conclusory.

The Court reached a different conclusion regarding Dr. Phillips. Although Dr. Phillips was a treating physician, New Jersey Rules of Court still require a written expert report if he is to provide expert causation testimony. A report was requested by the defendants in discovery, but the plaintiff never served one. Because there was no report, the Court could not determine whether Dr. Phillips's opinion constituted a net opinion.

Remand

The Court reversed the Appellate Division and remanded for a proper *Accutane* analysis, strongly encouraging the trial court to conduct a hearing under N.J.R.E. 104. The Court took no position on whether the disputed opinions should be admitted or excluded, leaving that determination to the trial court based on an appropriate record.

On remand, the trial court was also directed to determine whether the plaintiff should be permitted to serve a late expert report from Dr. Phillips. If a late report is permitted, the trial court should then conduct the appropriate *Accutane* and net opinion analysis.

Practical Implications for Litigants

Beavan confirms that *Accutane's* rigorous gatekeeping standard governs any dispute about the reliability of expert testimony where the parties contest admissibility under N.J.R.E. 702 and 703. Experts relying on differential diagnosis cannot invoke *Creanga* to bypass *Accutane* review. Both the "rule in" and "rule out" steps must be grounded in scientifically sound methodology, and trial courts must probe each component of the analysis. Litigants challenging such experts should press for scrutiny of each step independently.

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Although not mandatory, the Court strongly encouraged trial courts to conduct Rule 104 hearings when expert reliability is in dispute, especially in cases involving complex causation issues. Parties should anticipate hearings to build a proper record.

Net opinion challenges remain distinct from *Accutane* reliability challenges. An expert may clear the net opinion bar yet still be excluded if the methodology or data application is unreliable under *Accutane*. Litigants should preserve both lines of attack.

The Court reaffirmed that when a trial court faces an evidence determination precedent to a summary judgment motion, it must address the evidentiary question first. A failure to conduct the required gatekeeping before ruling on summary judgment is error.

The *Beavan* decision serves as a reminder that treating physicians designated to provide expert causation testimony must serve written expert reports in accordance with the New Jersey Rules of Court. Failure to do so can jeopardize the admissibility of their testimony and the viability of claims dependent on it.

Finally, if a trial court fails to apply the *Accutane* framework, the appellate court reviews the evidentiary ruling *de novo* rather than under the deferential abuse of discretion standard. This underscores the importance for trial courts to conduct and document a thorough *Accutane* analysis on the record.

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