

[Products Liability Law Daily Wrap Up, EXPERT EVIDENCE—DRUGS—N.J. Sup. Ct.: N.J. high court clarifies evaluation of expert testimony; upholds trial court's exclusion of experts in Accutane® MCL, \(Aug. 2, 2018\)](#)

Products Liability Law Daily Wrap Up

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By Leah S. Poniatowski, J.D.

The Supreme Court of New Jersey clarified how state courts should evaluate the methodology used by scientific experts testifying in civil cases by allowing use of the *Daubert* factors when determining admissibility. The state high court also reaffirmed that appellate courts should review admissibility of expert scientific testimony under an abuse of discretion standard. Consequently, the court determined that the reasoning of the trial court in the multi-county products liability lawsuit against Hoffmann-La Roche Inc. and Roche Laboratories for their Accutane® product was correct, reversing the appellate court (*In re Accutane Litigation*, August 1, 2018, LaVecchia, J.).

Hoffmann-La Roche Inc. and Roche Laboratories manufacture Accutane®, which is a prescription drug used to treat recalcitrant nodular acne and is known chemically as isotretinoin. Before the drug was approved by the Food and Drug Administration (FDA), approximately one-fifth of patients in clinical studies experienced gastrointestinal side effects, which also was reported from users after approval. A series of lawsuits were filed in New Jersey, and one set of cases involving more than 2000 individuals who allegedly developed Crohn's disease from the drug were designated as a mass tort multi-county litigation (MCL). At present, there is no known exact cause of Crohn's disease and all of the epidemiological studies published on whether there was a causal relationship between the drug and the disease concluded that there was no such causation.

Prior rulings. Following a Kemp hearing, the trial court granted an omnibus motion by the defense barring plaintiffs' experts—a gastroenterologist whose testimony was proffered on the issue of general causation, and a statistician who was to assess existing studies examining the association between isotretinoin and Crohn's disease—from testifying that the epidemiology studies relied upon by the defense were flawed and unreliable, and that Accutane can cause Crohn's disease. In the absence of the experts' testimony, the trial court dismissed all 2076 MCL claims with prejudice.

The state appellate court opined that based on the record, the plaintiffs' experts provided well-explained scientific reasons for analyzing the available evidence differently from the defense experts' analysis and for relying more heavily on different evidence than that relied upon by the defense experts. The appellate court reversed the trial court, allowing the testimony to be presented to the jury in order to weigh the witnesses' credibility and determine the veracity of the information provided [see Product Liability Law Daily's July 31, 2017 [analysis](#)].

Whether the appellate court employed the correct standard in reviewing and overturning that decision, and whether the standard for assessing the reliability of expert witnesses was in need of clarification were questions presented to the Supreme Court of New Jersey; the state high court granted certification.

Daubert factors. The state high court agreed that the existing framework for courts to make admissibility determinations on scientific expert testimony in civil cases required clarification. Like New Jersey, the U.S. Supreme Court amended the "general acceptance" standard established in the 1920s by adopting a more relaxed approach for causation expert testimony, noting in its opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) that the trial court must focus on the expert's principles and methodology—not on the conclusions they generate. The New Jersey high court explained that it was persuaded that the factors identified originally in *Daubert* should be incorporated for use by New Jersey courts because the factors "dovetail with the overall goals of our evidential standard and would provide a helpful—but not necessary or definitive—guide for our courts to consider when performing their gatekeeper role concerning the admission of

expert testimony." However, the state supreme court emphasized that it was not coloring the state as a "Daubert jurisdiction" in light of the lack of harmony within Daubert case law with respect to the gatekeeping function. Accordingly, if a proponent's approach to reasoning and use of data are not demonstrably sound as viewed by others in the relevant scientific community, testimony on that basis should be excluded as unreliable, the court held.

Exclusion of testimony. In light of the weight of the evidence presented to the trial court, the state high court agreed that exclusion of the testimony by the plaintiffs' experts on causation was correct because the underlying methodology was not sound. Specifically, the plaintiffs' experts disregarded eight of nine applicable epidemiological studies with thousands of subjects—the top of the evidentiary hierarchy—and relied on case reports and animal studies. The one study upon which they relied was unpublished and examined only 509 total subjects. Additionally, the expert testifying as to causation relied on his personal view, which had not been peer reviewed or published. Because these opinions reflected inconsistencies, were premised on cherry-picked evidence in deviation from the accepted hierarchy of the scientific community, the trial court's finding that the methodology was unsound was well supported, the supreme court found.

Abuse of discretion. The New Jersey Supreme Court also affirmed that state courts reviewing whether a trial court correctly admitted or excluded expert testimony must apply an abuse of discretion standard. The supreme court observed that the Appellate Division panel remarked that a reviewing court owes "somewhat less deference to a trial court's determination" regarding expert testimony. However, the supreme court found that the appellate court improperly relied on a decision in a criminal case applying the "general acceptance" test. This was not appropriate, the state high court stated, in the context of a civil mass tort case in which the trial court had been entrusted with methodology-based review as the gatekeeper of expert testimony.

In the case at bar, state high court found that the trial court had explained its reasons for concluding that the plaintiffs' experts deviated from core scientific principles and strayed from their own claimed methodology in order to reach their conclusions. Ample evidence supported the trial court's finding that the testimony of the plaintiffs' experts was unreliable. Applying the abuse of discretion standard and the principles of prior New Jersey Supreme Court decisions, the supreme court concluded that the trial court's did not abuse its discretion when it excluded the plaintiffs' experts' testimonies. Therefore, the Appellate Division's judgment, reversing the trial court's exclusion of the expert testimony, was reversed by the state high court.

The case is No. [A-25-17](#).

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Companies: Hoffmann-La Roche Inc.; Roche Laboratories Inc.

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