Sills Cummis & Gross P.C.

# Client Alert Product Liability Law

## *In re: Accutane Litigation*: Is New Jersey a *Daubert* Jurisdiction? The New Jersey Supreme Court Adopts *Daubert* Factors But Stops Short of Declaring New Jersey a *Daubert* Jurisdiction

Even before *Daubert v. Merrell Dow Pharmaceuticals*, Inc., 509 U.S. 579 (1993), New Jersey courts recognized the limitations of *Frye's* general acceptance standard for assessing the reliability of scientific expert testimony and adopted a methodology-based approach.[1] New Jersey courts, however, have never accepted the rigorous standard set forth in *Daubert*. *In re: Accutane Litig.*, No. A-25-17, 2018 N.J. LEXIS 988 (Aug. 1, 2018) is a landmark decision emphasizing the trial court's role as the gatekeeper of scientific expert testimony in civil cases and clarifying the standard to be applied in administering that function. *In re Accutane* adopts the use of the *Daubert* factors and directs trial courts to employ a more exacting standard in assessing the scientific validity of expert testimony in performing their gatekeeping role, while stopping short of declaring New Jersey a *Daubert* jurisdiction.

### Case Discussion

*In re Accutane* involved 2,076 cases coordinated in a multi-county litigation before Judge Nelson Johnson in Atlantic County. Plaintiffs allege that they developed Crohn's disease, a form of inflammatory bowel disease ("IBD"), as a result of taking Accutane, a drug that treats a severe form of acne called recalcitrant nodular acne.[2] In late 2014,

1. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (expert opinion based on a scientific technique is admissible only where it is generally accepted as reliable in the relevant scientific community).
2. *In re Accutane* is one of many coordinated litigations spanning over a decade related to Accutane and the development of various digestive diseases including Crohn's disease and ulcerative colitis, two forms of IBD.

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defendants filed a motion seeking a *Kemp* hearing[3] to preclude plaintiffs' experts from presenting testimony regarding a causal link between Accutane and Crohn's disease and rejecting the evidence and conclusions of a number of recent epidemiological studies which found no evidence of an association between Accutane and Crohn's disease. Plaintiffs' experts argued that the epidemiological studies were unreliable because: (1) some of them analyzed data for IBD generally and not for Crohn's disease; (2) most of them did not account for the period of time between ingestion and the onset of symptoms (the prodrome); (3) some were underpowered because they did not have enough patients; and (4) some did not adjust for certain confounders such as family history and smoking, and for various other reasons. Instead, the experts relied on case reports, animal studies, the unadjusted results of one of the epidemiological studies which they asserted showed a statistically significant increased risk of Crohn's disease for people taking Accutane, and an untested theory that Accutane can cause Crohn's disease.[4]

Defendants' experts argued that epidemiological studies are currently the best available data on the issue of Accutane and Crohn's disease, that the available epidemiological studies on this issue (including a meta-analysis of the pooled data of the studies) are as strongly negative as epidemiological evidence can be, and that epidemiological studies are always preferred to case reports and animal studies in the hierarchy of scientific evidence. Defendants' experts also noted that plaintiffs' expert's hypothesis was not submitted for peer review, that the scientific evidence shows that the epidemiological studies accounted for the prodrome, and that the animal studies relied on by plaintiffs' experts related to dogs, which cannot get IBD.

The trial court granted defendants' motion, precluding plaintiffs' experts from testifying on causation, and entered an order dismissing the 2,076 cases with prejudice. Applying the standard set forth in *Rubanick v. Witco Chemical Corp.*, 125 N.J. 421 (1991), the trial court found plaintiffs' expert testimony was a conclusion-driven attempt to pick evidence supportive of their opinions while dismissing better forms of evidence that refuted their opinions.[5]

The Appellate Division reversed, 451 N.J. Super. 153 (App. Div. 2017) (Reisner, Koblitz

3. A *Kemp* hearing is a pretrial hearing where the trial court assesses the reliability of expert scientific testimony. *See Kemp ex rel. Wright v. State*, 174 N.J. 412 (2002)

4. One of Plaintiffs' experts hypothesized that retonic acid, a breakdown product of Accutane, marks inflammatory cells known as "T-cells" with a compound known as "alpha 4 beta 7." The expert concluded that this binding process allows the inflammatory T-cells to travel through the digestive tract and bind to another receptor known as "MadCAM," which causes the inflammation that results in Crohn's disease.

5. *Rubanick* requires that expert opinion be based on a "sound, adequately-founded scientific methodology involving data of the type reasonably relied on by experts in the scientific field." *Rubanick*, 125 N.J. at 449.

and Sumners), concluding that plaintiffs' experts "relied on methodologies and data of the type reasonably relied upon by comparable experts." The panel explained that the experts merely "interpret[ed] the epidemiological studies differently" and that a difference of opinion did not mean that plaintiffs' experts failed to rely upon a sound methodology. The panel further noted that although the trial court's decision to admit or exclude evidence is subject to an abuse of discretion standard, less deference is owed to a trial court's determination regarding expert testimony.

The Supreme Court granted certification and reversed the Appellate Division. Numerous parties were granted amicus status, including various industry, academic, medical, defense bar and plaintiffs' bar associations.

## The New Jersey Supreme Court's Ruling

In its decision, the New Jersey Supreme Court explained the methodology-based standard for assessing reliability with respect to emerging scientific theory on causation in toxic tort litigation first articulated in *Rubanick v.* Witco, 125 N.J. 421 and *Landrigan v. Celotex Corp.*, 127 N.J. 404 (1992). The proper inquiry is not general acceptance, but rather, whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field.

The Court observed that when it abandoned the general acceptance standard in favor of a more relaxed approach, it envisioned the trial court's role as that of a gatekeeper, which involved making legal determinations about the reliability of an expert's methodology. The Court recognized the need for more clear direction on how the gatekeeping function is properly performed.

In reversing, the Supreme Court criticized the Appellate Division's decision to veer off the abuse of discretion standard in its review of the trial court's decision, and concluded that while appropriate in criminal cases (where the general acceptance standard is still employed), applying a less deferential standard of review is not appropriate in the context of civil cases where the trial court is the gatekeeper of expert testimony.

The Court then assessed the trial court's ruling. The Supreme Court agreed with the trial court's conclusion that plaintiffs' experts deviated from core scientific principals in developing their methodology, which was not based on science, but was merely a means to support their case. The Supreme Court admonished Plaintiffs' experts for employing a methodology that disregarded the epidemiological studies while relying on case reports and animal studies to support their opinions, noting that case

reports are at the lower tier of the evidence hierarchy and are generally not considered reliable evidence of scientific causation, and that animal studies are far less probative in the face of substantial epidemiologic evidence. The Court also noted internal inconsistencies in the experts' methodology, including their refusal to consider two epidemiological studies for failure to report specific data for Crohn's disease, while at the same time relying on case reports that were not specific to Crohn's disease and relying on animal studies performed on animals incapable of having IBD. Applying the abuse of discretion standard, the Court concluded that the trial court's determination was unassailable and reversed the Appellate Division's judgment.

## Acceptance of the *Daubert* Factors

Noting the divergent outcomes reached by the Appellate Division and the trial court in this case, the Court next considered the request by defendants and many of the amici to adopt the *Daubert* standard to bring greater consistency to the trial court's gatekeeping function. Observing that New Jersey law and *Daubert* are aligned in their general approach to a methodology-based test for reliability, the Court concluded that the following non-exhaustive list of factors identified in *Daubert* should be considered by trial courts exercising their role as gatekeepers of scientific expert testimony:

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 only one form of peer review;
3. Whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the operation of the scientific technique; and
4. Whether there does exist a general acceptance in the scientific community about the scientific theory.

The Court, however, stopped short of declaring New Jersey a *Daubert* jurisdiction, declining to adopt the full body of *Daubert* case law because: (1) New Jersey has retained the general acceptance test for reliability in criminal matters; and (2) inconsistency in the *Daubert* caselaw.

## What Does This Ruling Mean?

New Jersey's standard for admissibility of scientific expert testimony has traditionally been more relaxed than most other states, many of which have adopted the *Daubert*

standard. Although the New Jersey Supreme Court declined to declare New Jersey a *Daubert* jurisdiction, its adoption of the *Daubert* factors signals the beginning of a more rigorous standard for evaluation of proposed expert testimony, particularly in toxic tort cases involving novel theories of causation. By providing clear guidance to trial courts, we anticipate that this decision will result in greater consistency in the law pertaining to admissibility of expert testimony. Moreover, because of its implementation of a more rigorous standard, *In re: Accutane* may make New Jersey a less attractive venue for plaintiffs in toxic tort cases and should reduce forum shopping.

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