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Client Alert Product Liability Law

In re Accutane Litigation II: The New Jersey Appellate Division Follows the New Jersey Supreme Court's Lead in Holding Scientific Experts to the *Daubert* Standard

On August 1, 2018, the New Jersey Supreme Court published *In re Accutane Litig.*, 234 N.J. 340 (2018) ("*Accutane I*"), a landmark decision in which the New Jersey Supreme Court adopted the use of the factors set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) in assessing the reliability of scientific expert testimony. Although *Accutane I* fell short of making New Jersey a *Daubert* state, it directed trial courts to employ a more exacting standard in assessing the scientific validity of expert testimony in performing their gatekeeping role.[1] On January 17, 2020, the New Jersey Appellate Division published *In re Accutane Litig.*, Docket No. A-4952-16T1, 202 N.J. Super. Unpub. LEXIS 123 (App. Div. Jan. 17, 2020) ("*Accutane II*"), embracing the standards pronounced by *Accutane I* and affirming the trial judge's preclusion of expert testimony because it failed to satisfy the *Daubert* factors.

Case Discussion

In re Accutane II arose out of the Accutane multicounty litigation (the "Accutane MCL"), in which Plaintiffs allege that they developed inflammatory bowel disease, either in the form of ulcerative colitis or Crohn's disease, as a result of taking Accutane, a prescription drug that treats a severe form of acne called recalcitrant nodular acne. In early 2017, the trial judge conducted a ten-day *Kemp*[2] hearing, and granted a defense motion to bar Plaintiffs' experts, Dr. David Sachar, a gastroenterologist, and Dr. April Zambelli-Weiner, an epidemiologist, from testifying that Accutane can cause ulcerative colitis. Plaintiffs filed an appeal, which the Appellate Division stayed while awaiting the New Jersey

[1] In *Accutane I*, The Supreme 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: (i) whether the scientific theory can be, or at any time has been tested; (ii) whether the scientific theory has been subjected to peer review and publication, noting that publication is only one form of peer review; (iii) 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 (iv) whether there does exist a general acceptance in the scientific community about the scientific theory. *Id.* at 398.

[2] *Kemp ex. rel. Wright v. State*, 174 N.J. 412 (2002).

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Supreme Court's decision in *Accutane I*.[3] After the New Jersey Supreme Court rendered its decision, the Appellate Division examined the record and applied the standards set forth in *Accutane I*, noting its applicability despite being decided after the trial judge's ruling.[4] The Appellate Division concluded that although Drs. Sachar and Zambelli-Weiner were qualified, the trial judge did not abuse his discretion in excluding their testimony because their opinions incorporated the same "methodological defects" identified by the Court in *Accutane I*, including disregarding the same epidemiological studies in favor of animal studies and case reports.[5]

The Trial Court's Ruling

In ascertaining whether to preclude the expert testimony, the trial court applied the methodology-based standard for assessing the admissibility of scientific expert testimony first enunciated in *Rubanick v. Witco*, 125 N.J. 421 (1992). The trial judge concluded that the methodology employed by both experts was unsound, and precluded them from testifying.

The trial judge found that Dr. Zambelli-Weiner, who had very limited exposure to issues related to pharmaco-epidemiology, disregarded the medical-evidence hierarchy by relying on scientific evidence at the very bottom, such as a widely criticized non-peer reviewed abstract and anecdotal case reports, while disregarding evidence at the very top, such as valid epidemiological studies. The trial judge also noted that Dr. Zambelli-Weiner placed "unswerving reliance" on only one epidemiological study, which had never been replicated, and did not submit her findings to peer review.

Similarly, the trial judge found that Dr. Sachar disregarded the medical-evidence hierarchy by elevating case reports and animal studies over epidemiological studies. The trial judge further admonished Dr. Sachar for his lack of restraint in advocating for plaintiffs, noting that Dr. Sachar's use of disparaging language toward the peer-reviewed treatises of other scientists was indicative of a "hired gun mentality." The trial judge also noted

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[3] In *Accutane I*, which also arose out of the Accutane MCL, the trial judge granted a defense motion to exclude two plaintiffs' experts, Dr. Arthur Kornbluth, a gastroenterologist, and Dr. David Madigan, a statistician, from testifying that Accutane can cause Crohn's disease. The Appellate Division reversed that determination, *In re Accutane Litigation*, 451 N.J. Super. 153 (App. Div. 2017), and the Supreme Court subsequently reversed the Appellate Division.

[4] The Appellate Division applied *Accutane I* retroactively because, the Court concluded, the Supreme Court's decision neither overruled past precedent nor decided an issue of first impression—it merely reconciled the standards under *N.J.R.E.* 702 and 703, with the federal *Daubert* standard to incorporate its factors for civil cases. *N.J.R.E.* 702 is entitled "**Testimony by Experts**" and provides: "If 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 is entitled "**Bases of Opinion Testimony by Experts**" and provides: "The 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 hearing. If 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."

[5] The Court noted that while some of the epidemiological studies were "slightly more supportive of an association between Accutane and ulcerative colitis," there was not enough evidence of a difference between ulcerative colitis and Crohn's disease to warrant excluding plaintiffs' experts' testimony on Crohn's disease in *Accutane I*, while allowing similar expert testimony as to ulcerative colitis here.

that Dr. Sachar had "ample time to organize his thoughts and present them for scrutiny by the scientific community," but never published a peer-reviewed article supporting his opinions, and did not propose a hypothesis on the causal association between Accutane and IBD.

In precluding both experts, the trial judge quoted the following language from the National Research Council's *Reference Manual on Scientific Evidence* (Nat'l Acad. Press 3d ed. 2011): "If something is not published in a peer reviewed journal, it scarcely counts" and "[t]he scientific community has little regard for opinions confined to the courtroom." *Id.* at 768. The trial judge concluded that while some of the epidemiological studies cited by the experts showed a positive association between Accutane and ulcerative colitis, the experts were unable to point to any consistent showing across the studies, and were motivated by preconceived conclusions rather than scientific evidence.

The Appellate Division's Ruling

The Appellate Division affirmed the trial judge's exclusion of Drs. Zambelli-Weiner and Sachar for the "same essential reasons" that the Supreme Court excluded Drs. Kornbluth and Madigan in *Accutane I*.

As in *Accutane I*, the record below focused on the experts' reliance upon an unreliable methodology, which involved rejecting eight of nine epidemiological studies while relying on scientifically inferior case reports and animal studies to support their opinions. In affirming the trial judge's ruling, the Appellate Division identified the following flaws in Dr. Sachar's methodology:[6]

- The failure to follow accepted scientific methodology by elevating lower forms of scientific evidence (*e.g.*, case reports) over higher forms of scientific evidence (*e.g.*, epidemiological studies);
- Placing exclusive reliance on one portion of an epidemiological study, which found a strong statistically significant association between Accutane and ulcerative colitis, while disagreeing with the authors' conclusion in the same study that there was no link between Accutane and Crohn's disease;
- Relying on a single study that had never been replicated, while dismissing other published studies and, instead, relying on case reports and studies of animals that cannot develop ulcerative colitis or other forms of IBD;
- Dismissing epidemiological studies because they did not report on ulcerative colitis, while relying on animal studies, causality assessments, internal Roche documents, and published scientific literature that was not specific to ulcerative colitis; and

[6] The Appellate Division focused its discussion on Dr. Sachar, perhaps because of Dr. Zambelli-Weiner's limited exposure to pharmaco-epidemiology.

- Organizing his testimony to support his personal views that a causal association existed between Accutane and ulcerative colitis through the improper use of the Bradford Hill guidelines because the epidemiological studies do not support an association between exposure to Accutane and ulcerative colitis.[7]

In sum, the Appellate Division concluded "there is little to distinguish between" the Supreme Court's ruling in *Accutane I* and the ruling here. The Appellate Division found that while the epidemiological data was only slightly more favorable in the case of ulcerative colitis, it does not support a finding that there is an association, much less a causal association, between Accutane and ulcerative colitis.

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* state in *Accutane I*, 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. The Appellate Division's embrace of this approach in *Accutane II* is further indication that New Jersey courts will hold scientific experts to a stricter standard than in the past, and therefore will be less likely to tolerate an expert's result-driven advocacy without sound scientific support. From both decisions, we expect that there will be greater consistency in subsequent New Jersey caselaw pertaining to admissibility of expert testimony, an increase in the preclusion of scientific experts by New Jersey trial judges, and, for that reason, a reduction in the number of toxic tort lawsuits in New Jersey as forum-shopping plaintiffs look to more favorable jurisdictions.

[7] The Bradford Hill Guidelines should be invoked only after scientific evidence has established an association between an agent and a specific disease. Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 *Proc. Of the Royal Soc'y of Med.* 295 (1965). The Appellate Division concluded that because the epidemiological studies do not support an association between exposure to Accutane and ulcerative colitis, Dr. Sachar improperly used the Bradford Hill guidelines to create an association that the studies had not detected.

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