

NEW JERSEY

Nathan A. Schachtman
nschachtman@mccarter.com
McCARTER & ENGLISH, LLP
Woodcrest Pavillion
10 Melrose Avenue, Suite 350
Cherry Hill, NJ 08003

David J. Cooner
dcooner@mccarter.com
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4096

<http://www.mccarter.com>

A. Does Daubert apply in our state courts?

The Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993) and its progeny are persuasive authority in the New Jersey courts. In 1993, the year that Daubert was decided, our state courts adopted most of the Federal Rules of Evidence, including Rule 702, which was at issue in Daubert. Even before Daubert and New Jersey's adoption of Rule 702, the New Jersey courts were embracing a reliability standard rather than "general acceptance" as the admissibility test for expert witness opinion in "toxic tort" cases.¹

The 1991 Supreme Court Committee Comment to N.J. Rule 702 discusses the intent to incorporate the criteria set forth in set out in State v. Kelly, 97 N.J. 178, 208 (1984) for admissibility of expert opinion. In Kelly, the criminal defendant raised a defense of battered-woman syndrome through a proffer of testimony from an expert witness. Reversing the trial court's exclusion of the testimony, the Court held that the syndrome was the appropriate subject of expert testimony. Id. at 187. In passing on the admissibility of such testimony, the New Jersey Supreme Court instructed trial courts to assess whether the scientific field is "at a state of art such that an expert's testimony could be sufficiently reliable." Id. at 209. Almost a decade before Daubert, the Kelly Court noted that "expert opinion that is not reliable is of no assistance to anyone." Id.

In the context of novel scientific fields of research or of novel devices, New Jersey's courts continue to look to "general acceptance" as the test for sufficient reliability. In the realm of so-called toxic torts, New Jersey courts have abandoned general acceptance as the measure for whether a proffered theory of causation is sufficiently reliable. Perhaps the high-water mark of xenobiotic-phobia came in

¹ There is appellate authority in New Jersey that the Frye general acceptance standard applies in non "toxic tort" cases. See In re Commitment of R.S., 339 N.J.Super. 507, 534 (App. Div. 2001) ("Although Frye has been replaced in the federal court system in favor of the more lenient standards of Federal Rule of Evidence 702 as set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), in New Jersey, with the exception of toxic tort litigation, Frye remains the standard.") Since most of the challenges to experts in medical device and pharmaceutical products liability litigation will raise issues analogous to those in the "toxic tort" arena, we focus, of necessity, on the cases applying Daubert principles in New Jersey. In so doing, however, we also address a number of Frye issues, which, in New Jersey, emanate from our supreme court's decisions in Kelly and Windmere, which are referenced in Section B, infra.

Rubanick v. Witco Chemical Corp., 125 N.J. 421 (1991), in which the plaintiffs claimed that PCB caused colon cancer. In Rubanick, the New Jersey Supreme Court appeared to be more impressed with “the extraordinary and unique burdens facing plaintiffs who seek to prove causation in toxic-tort litigation,” id. at 433, than the lack of sufficiently reliable evidence and methodology supporting the plaintiff’s claim. Citing what the Court perceived as “the extremely high level of proof before scientists will accept a new theory,” and “the current inability of science to fully comprehend carcinogenesis,” the Rubanick Court rejected a requirement of general acceptance for a theory of scientific causation in toxic-tort litigation. Id. at 433, 449. The Rubanick Court held that the offered scientific theory must have a sound, adequate foundation in scientific methodology, employing data of the type reasonably relied upon by experts in the relevant field.

The New Jersey Supreme Court confirmed its move from the general acceptance test to a reliability-based standard in Landrigan v. Celotex Corp., 127 N.J. 404 (1992). The plaintiff in Landrigan claimed that her husband’s colon cancer was caused by asbestos. In ruling on defendant’s objection to plaintiff’s expert witnesses, Landrigan held that the admissibility of expert testimony in a toxic tort case “depends on the expert’s ability to explain pertinent scientific principles and to apply those principles to the formulation of his or her opinion.” Id. at 414. The “key” to the admission of an expert’s opinion “is the validity of the expert’s reasoning and methodology.” Id. Landrigan made clear that the trial court must evaluate that validity, and “distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs.” Id.

Whether Daubert applies in New Jersey is further answered in large measure by observing the common heritage of both Daubert and Rubanick. By the time Rubanick rejected general acceptance in favor of sound methodology, the reliability-based approach had already gained approval in the Third Circuit’s landmark decision of United State v. Downing, 753 F.2d 1224 (3d Cir. 1985). In Downing, the court held that, in determining whether a scientific theory is admissible, a judge must conduct a preliminary inquiry focusing on, inter alia, the soundness and reliability of the process or technique used in generating the evidence. Id. at 1237.

In 1991, Rubanick found the approach taken in Downing to be “compatible with our own rules of evidence.” Rubanick, 125 N.J. at 447. In 1993, Daubert interpreted Federal Rule of Evidence 702 as rejecting a general acceptance test. Citing Downing, Daubert interpreted Rule 702’s requirement of assisting the trier of fact as requiring expert witnesses to demonstrate the use of sound and reliable method or technique in arriving at their opinions. Daubert, 509 U.S. at 594.

Since Daubert was decided in 1993, both the federal courts and the New Jersey courts have continued to develop a jurisprudence that demands judicial scrutiny of scientific evidence. Federal and New Jersey evidence law have developed and grown intertwined, inasmuch as both rely on Rules 702 and 703 as the basis for imposing reliability and relevance standards on scientific evidence.

In Bahrle v. Exxon Corp., 279 N.J. Super. 5 (App. Div. 1995), aff'd, 145 N.J. 144 (1996), the Appellate Division continued its reliance on the reliability-based standard applied in Rubanick and Landrigan, and acknowledged the influence of Daubert. In Bahrle, a groundwater contamination case in which plaintiffs alleged that gasoline from a nearby station had seeped into their wells, the appellate court upheld the trial court's exclusion of the testimony of plaintiff's chemistry expert. The expert had conducted self-designed tests to determine whether deteriorating gasoline diluted in water would increase the wear on plumbing seals, such as those found in plaintiffs' wells. The court held that "[t]he expert must identify the factual bases for his or her conclusions, explain methodology, and demonstrate that both the factual bases and the methodology are reliable." Id. at 33 (citing New Jersey cases and Daubert, 509 U.S. at 592-93).²

B. If not Daubert, what is the standard or criteria governing expert testimony?

In those litigation contexts that still require a showing of general acceptance, proponents of expert testimony are required to show that the field of science is "at a state of the art that such an expert's testimony could be sufficiently reliable." State v. Kelly, 97 N.J. 178, 187 (1984). The reliability of a new field of research can be shown to be reliable by proof of the general acceptance of the expert's opinion or theory within the relevant scientific community. Id. at 210. Such proofs may include:

- (1) the testimony of knowledgeable experts;
- (2) authoritative scientific literature; or
- (3) persuasive judicial decisions which acknowledge such general acceptance of expert testimony.

Windmere v. International Insurance Co., 105 N.J. 373, 379 (1987) (rejecting voiceprints as not generally accepted).

C. What criteria are applied in our state courts to determine reliability, relevance, fit, and methodology of expert testimony relating to scientific or technical issues?

Some observers regarded the 1991 Rubanick decision as having "pulled out all the stops on admission of expert testimony." See e.g., New Jersey Law Journal, Sept. 7,

² Even prior to Rubanick and Daubert, the New Jersey courts afforded redress to litigants confronted by a self-validating expert, holding that an expert who would otherwise be qualified to offer opinion testimony would not be allowed to give a "net opinion" to the jury. (A "net opinion" is an opinion based on "an expert's bare conclusions, unsupported by factual evidence." Buckelew v. Grossbard, 87 N.J. 512, 524 (1981).) In short, such "expert" opinions would be inadmissible. See e.g., Lanzet v. Greenberg, 126 N.J. 168, 186 (1991); Buckelew, 87 N.J. at 524; Molino v. B.F. Goodrich Co., 261 N.J. Super. 85, 98 (App. Div. 1992), certif. denied, 134 N.J. 482 (1993); Vuocolo v. Diamond Shamrock Chem. Co., 240 N.J. Super. 289, 299 (App. Div.), certif. denied, 122 N.J. 333 (1990).

1992, Supplement at 3. Those observers incorrectly interpreted the abandonment of “general acceptance” as heralding open season for shabby, unreliable opinions. In the decade since Rubanick, the New Jersey courts have demonstrated their vigilance as gatekeepers of expert testimony. In the New Jersey courts, as in the federal courts, there is no right, constitutional or otherwise, to present unreliable expert opinion testimony. The criteria employed in the New Jersey gatekeeping process are similar to those articulated in Daubert itself, and ultimately derive from the scientific method’s indicia of reliability.

The New Jersey courts have shown that expert witnesses’ conclusory opinions or ipse dixit will not pass through the judicial gate. The appellate court in Bloedorn v. Linoleum Factory Outlet, No. A-2278-95T5, Slip Op. at 4 (App. Div. June 16, 1999) affirmed the trial court’s exclusion of the plaintiffs’ expert, who opined that plaintiffs’ respiratory symptoms were caused by their exposure to volatile organic chemicals emanating from newly installed carpet. Plaintiffs’ expert had not relied on a recognized scientific methodology; but rather, the expert reached his conclusions after examining the plaintiffs and questioning them about the timing and intensity of their symptoms vis-à-vis the installation of the carpet. The trial judge noted, “what I observe is occurring is an acceptance of the history provided to the physician by the patient . . . who takes that history, takes the symptoms presented, and then begins to address treatment.” Id. at 10-11. The problem, the judge said, “is that others in the field do not necessarily accept the soundness of that methodology . . . and don’t similarly rely on the information that it produces.” Id. at 11. Instead, other experts “say that you need to look further. For example, air samples, other environmental factors, medical tests, things of that nature.” Id. In particular, the judge noted, experts in the field “speak of the need to do further chemical analysis and to consider the length and extent of the exposure.” Id.

The appellate court affirmed the trial court’s grant of summary judgment, holding that “[p]laintiffs’ conclusory statement that [their expert’s] ‘methodology was sound and is [of] the type reasonably relied upon by other physicians’” was insufficient to defeat the defendant’s motion. Id. at 13.

In Reiter v. 3M Company, No. UNN-L-8504-92 (Slip Op., April 30, 1998), the trial court issued a comprehensive opinion that relied on state and federal court precedent to exclude the testimony of plaintiff’s expert witness regarding plaintiff’s alleged “Multiple Chemical Sensitivities (MCS).” Citing its “gate-keeping function” pursuant to Daubert and General Electric v. Joiner, the trial court undertook an analysis of plaintiff’s evidence to determine whether it was “based ‘on sound, adequately founded scientific methodology involving data and information of the type reasonably relied upon by experts in the scientific field’ . . . upon which conclusions of medical causation can reasonably and reliably be based for someone circumstanced such as [plaintiff].” Slip Op. at 10, (quoting Rubanick, 125 N.J. at 449).

The plaintiff in Reiter alleged that because of her repeated occupational exposure to the chemical 1,1,1-Trichloroethane (“1,1,1-Tri”), she developed MCS. The evidence in the case demonstrated that 1,1,1-Tri is a known health hazard, and that it can affect

one's health if exposure is to a high level for a short period of time or to a low level over a long period of time. Id. at 11. The plaintiff, however, was exposed "on a relatively few occasions to an uncertain (albeit low) level" of 1,1,1-Tri. Id. The available scientific literature only addressed exposure to 1,1,1-Tri at high levels. Further, as a factual matter, the court found that "much of the general population of the United States is exposed to low levels of 1,1,1-Tri" through "background" exposure. Id.

The court described the task of the plaintiff's expert as follows:

First, an evaluation is made of the chemicals to which the individual might have been exposed, and of the concentrations of these chemicals in air breathed by the individual. The second step involves an evaluation, based on the published scientific literature, of the exposures necessary to produce the adverse effects associated with the chemicals to which individuals may be exposed. These two evaluations are then combined in the final step of the risk assessment to provide an estimate of the likelihood that any of the harmful properties of any or all of the chemicals might have been expressed in the exposed individual.

Id. at 26. Because all chemicals can cause health problems at some level or concentration of exposure, the task of the expert "is to identify a dose-response relationship for a particular chemical (or chemical mixture) and illness and analyze the results to determine whether the duration and concentration of exposure in a given instance could have caused the alleged harm." Id.

Plaintiff's expert in Reiter failed to make the requisite causal connection in a scientifically reliable way. The court found that plaintiff's expert, without accounting for plaintiff's low dose of 1,1,1-Tri and without any knowledge of the chemical composition of the product plaintiff used at work, concluded that plaintiff's MCS was caused by the defendant's 1,1,1-Tri because, among other things, "the literature discusses that type of effect being caused by a closely related compound," and because certain inconclusive laboratory results indicated an increase in certain biological markers. Id. at 17, 22.

The Reiter court rejected the expert's conclusions, finding that she had relied on "inadequate and inconclusive data regarding plaintiff," that she had not "followed established and accepted scientific methodology in analyzing that data," and that she "failed to show support in peer reviewed literature and published studies for the conclusions" she reached. Id. at 31. Finding the trial court's opinion to be "comprehensive and well reasoned," the Appellate Division affirmed. A-6686-97T3 (Slip Op., January 16, 2000.)

D. Can causation be proven by differential diagnosis?

Generally, in making a differential diagnosis, a physician reaches a conclusion by considering all of the plausible diagnostic candidates that could produce the observed symptoms and signs, and then by comparing the expected clinical findings with the findings actually observed. See Henifin, et al., “Reference Guide on Medical Testimony,” in Fed. Jud. Ctr., Reference Manual on Scientific Evidence 463, 481 (2d ed. 2000). Because many diagnostic entities do not imply any specific etiology, the process of differential diagnosis will often be unable to advance the inquiry about specific causation in an individual. For instance, if clinicians were to weigh the diagnostic possibilities of migraine and brain tumor in a given patient, and reach a diagnosis of brain tumor, they have not shed any particular light on the causation of the tumor. Many, if not most, diseases of ordinary life, such as most cancers, autoimmune diseases, and cardiovascular diseases have an established prevalence in the general population and no unique causal associations with toxic exposures.

Differential diagnosis cannot establish a new diagnostic entity in a patient and it cannot establish general causation between an exposure and a disease, when the disease is otherwise prevalent in the general population. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1412-14 (D. Or. 1996). For such diseases of ordinary life, the differential diagnostic process will not advance the inquiry into what caused the occurrence of the disease in a particular patient.

A few exceptional diagnoses imply unique etiologies. Asbestosis is caused ex hypothesi by asbestos; berylliosis by beryllium. If the differential diagnostic process leads to a diagnosis such as asbestosis, then it yields both a diagnosis and an etiology.

New Jersey courts have not directly addressed the various confusions and issues surrounding the use and misuse of differential diagnosis to prove causation. In Bloedorn, discussed above in Section C, there was an attempt to rush the “gate” with what appears to be a physician’s differential diagnosis, but the trial and appellate courts rejected the effort as unsupported and conjectural.

E. What is the appropriate procedure for challenging the admissibility of expert testimony in our state courts?

The Rubanick case clearly announced that the proper procedure for determining the soundness of an expert’s methodology is in a Rule 104 hearing outside the presence of the jury. Rubanick, 242 N.J. Super. 36, 46-47 (App. Div. 1990), aff’d, 125 N.J. 421 (1991). The timing and procedures of the Rule 104 hearing, however, are not well defined. In Reiter, the trial judge permitted the defendants to file their challenges to plaintiffs’ experts after completing their pre-trial depositions of plaintiffs’ experts, but before plaintiffs were allowed to conduct depositions of defendants’ experts. Reiter, Slip Op. at 3 (1998).

In Rosetti v. N.J. Transit Rail, A-1913-97T2 (App. Div. Sept. 1, 1999), Slip Op. at 14, the court remanded for a full Rule 104 evidentiary hearing, notwithstanding that counsel had “cavalierly” agreed to an in limine ruling on the papers and oral argument. In the opinion of the Appellate Division, the issue whether occupational trauma causes Carpal Tunnel Syndrome required a complete record, which should have included viva voce testimony from both sides’ experts, or at the very least, a summary judgment motion with all expert reports to guide the trial court in its gatekeeping function. Id. at 14.

The appellate standard of review of a trial court’s gatekeeping decisions is not clear.³

F. To what extent has Kumho and its progeny been applied by our state courts?

In non-toxic tort cases, New Jersey courts appear reluctant to depart from the general acceptance test articulated in Kelly. In re Commitment of R.S., 339 N.J. Super. 507, 534 (App. Div. 2001). In criminal cases, the courts seem particularly determined to retain the general acceptance test. State v. Dishon, 297 N.J. Super. 254, 276 (App. Div.) certif. denied, 149 N.J. 144 (1997). This institutional reluctance begs the question whether the 1993 adoption of Rule 702 changed the applicable standard to “helpfulness” or “reliability” for all expert witness testimony. The reluctance also appears to overlook the distinction between novel scientific devices and scientific fields, and unreliable opinions that purport to have a scientific basis of facts and data.

The New Jersey Supreme Court has begun to move slowly towards addressing these open issues. In State v. Fortin, 162 N.J. 517, 525 (2000), the Court affirmed the exclusion of linkage-analysis testimony under the Kelly test. The excluded expert in Fortin sought to provide identification evidence from his analysis of the characteristic facts of the alleged criminal’s modus operandi. Importantly, the Court rejected the prosecution’s argument that expert testimony based upon knowledge and experience did not have to satisfy the standard for scientific testimony. Id. at 525. The Court seemed particularly troubled by the inability to replicate the expert’s results, and the lack of peers to test his theories. Id. at 527. By analyzing the scientific testimony for its underlying testing and reproducibility (or falsifiability), the Supreme Court moved away from the strictly “nose-counting” approach implied by the general acceptance test.

³ Daubert did not address the standard of review to be applied by an appellate court. The issue was addressed in General Electric Co. v. Joiner, 522 U.S. 136 (1997), where the Supreme Court instructed the appellate courts to use an “abuse of discretion standard” when reviewing a trial judge’s decision to admit or exclude expert testimony. Joiner, 522 U.S. 136, at 139. According to Joiner, the appellate court must determine whether there was a reasonable basis for the trial court’s decision, not decide whether, based upon the evidence, it would have admitted or excluded the proffered expert testimony. Joiner, at 144. If the trial judges’ ruling is supported by evidence, the appellate court should defer to the trial court and affirm. Joiner, 522 U.S. 136, 139.