

2 Helpful Cases On Specific Causation Expert Testimony

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A plaintiff claiming harm from exposure to a substance generally must prove both general and specific causation. General causation requires proof that the substance can cause the type of harm that the plaintiff suffered. It is most commonly established through epidemiological studies demonstrating a causal connection between exposure to the substance and the particular disease or injury in question. Specific causation requires proof that the harm claimed by the particular plaintiff was caused by the exposure that he or she attributes to the defendant. It requires a fact-specific analysis of the plaintiff's claim, including the nature of the exposure, the nature of the harm claimed by the plaintiff and other possible causes of that harm.

For many substances that are the subject of litigation, an existing body of literature establishing the effects of exposure supports general causation. Accordingly, in many exposure cases — including environmental torts, workplace exposures and products liability — the real hurdle a plaintiff must clear in order to reach the jury (at least with respect to questions of causation) is producing admissible evidence of specific causation. Two recent decisions demonstrate different ways in which such testimony can fail the test of admissibility, likely spelling doom for the plaintiff's claim.

Sean R. v. BMW of North America LLC[1]

Plaintiffs who allege exposure to a toxic substance often have a difficult time proving the extent of their exposure. Unless there is historical testing available or the exposure is ongoing and, thus, can be measured for purposes of litigation, plaintiffs often must attempt to estimate their exposure by analogy to available studies in other contexts or by more creative means. Such estimation methods, like all aspects of opinion testimony, are subject to the admissibility standards for expert testimony in the relevant jurisdiction.

Plaintiffs faced with a challenge to the admissibility of their exposure estimate often argue, or at least imply, that the court should relax the standards for admissibility in light of the practical difficulties they face in estimating a past exposure. In a recent decision, the New York Court of Appeals rejected such an exhortation and confirmed that methods used to estimate exposures are subject to the same admissibility requirements as any other opinion testimony.

In *Sean R.*, the plaintiff alleged that he suffered severe birth defects due to in utero exposure to gas fumes in his parents' automobile. The plaintiff's family had complained of a gas odor in the vehicle and reported symptoms such as nausea, dizziness and headaches when riding in the vehicle. Eventually, the vehicle was found to have a split fuel line that was leaking gasoline into the engine compartment.

In order to show that the resulting exposure to the plaintiff's mother was sufficient to cause the plaintiff's birth defects, the plaintiff's experts used a "symptom threshold" methodology. Studies show that people first experience certain symptoms from exposure to gasoline fumes at particular concentration levels. Because the plaintiff's family had reported those symptoms, the expert inferred that the exposure level must have met the threshold in the studies.

The trial court sustained the defendant's objection to this methodology and the Court of Appeals affirmed. The Court of Appeals began by observing that "[a]lthough it is not always necessary for a plaintiff to quantify exposure levels precisely, we have never dispensed with a plaintiff's burden to establish sufficient exposure to a substance to cause the claimed adverse health effect." Because New York uses the Frye standard for admissibility of expert testimony, the court then asked whether the methods used by the plaintiff's experts "when properly performed, generate results accepted as reliable within the scientific community generally."

The court noted that a similar methodology — using "odor thresholds" to infer an exposure level based on the concentration at which the substance is first capable of olfactory detection — appears to be generally accepted as reliable. It pointed out, however, that the plaintiff had not identified "any text, scholarly article or scientific study ... that approves of or applies [symptom thresholds to determine concentrations], let alone a 'consensus' as to [that method's] reliability." Accordingly, the court affirmed the exclusion of the expert testimony, which will likely result in judgment for the defendant based on the plaintiff's inability to prove specific causation.

Sean R. demonstrates an admirable commitment to rigorous enforcement of the principles that control the admission of expert testimony in a courtroom. The outcome could be different, however, in jurisdictions that have abandoned the Frye standard in favor of the Daubert test. Under Daubert, the touchstone is reliability, and general acceptance is only one factor to be considered in determining whether the methodology in question is reliable. Other reliability factors could well cause a court to conclude that using "symptom thresholds" to estimate concentration levels is sufficiently reliable to allow the testimony to go to the jury.

In re: Lipitor (Atovastatin Calcium) Marketing, Sales Practices & Products Liability Litigation[2]

It is easy for courts to fall into the trap of thinking that general causation plus a temporal relationship between exposure and injury equals specific causation. When there is scientific evidence that exposure to a substance can cause a type of injury, the plaintiff was exposed to that substance and the plaintiff then suffered that type of injury, it is tempting to allow expert testimony attributing the injury to the exposure without further support or analysis. A recent decision of the District of South Carolina in the multidistrict litigation involving the drug Lipitor rejects such fallacious reasoning.

The plaintiffs in the Lipitor MDL allege that their Type 2 diabetes was caused by the cholesterol drug Lipitor. In considering a challenge to the specific-causation testimony in a bellwether trial, the court observed that the plaintiff developed diabetes after taking Lipitor and that there are epidemiological studies finding a causal connection between Lipitor and diabetes. Those studies, however, establish a “relative risk ratio” between Lipitor and diabetes of approximately 1.6.

“The relative risk ratio is the risk of disease or injury among people exposed to an allegedly harmful substance divided by the risk of the disease among those not exposed to the substance.” In other words, the risk that someone taking Lipitor will develop diabetes is 1.6 times higher than the risk for a similarly situated person who is not taking Lipitor. This means, however, that almost two-thirds of people who develop diabetes while taking Lipitor would have developed the disease anyway. Indeed, for any relative risk ratio below 2.0, more than half of the people who are injured following exposure would have suffered the injury anyway. “[T]he question then becomes how does [the plaintiff’s expert] conclude that [the plaintiff] is in the 37 percent that develop diabetes due to Lipitor, rather than the 63 percent that would have done so regardless.”

On this point, the plaintiff’s expert “exclusive[ly] reli[ed] on a temporal relationship” between taking Lipitor and developing diabetes and “was unable to point to a single piece of evidence that she found in [the plaintiff’s] medical files ... that would affect her assessment of whether Lipitor caused the patient’s diabetes.” The expert conceded that the plaintiff had numerous other risk factors for diabetes, some of which had relative risk ratios as high as 12.0. As the court explained, however, “[s]imply because a person takes a drug and then suffers an injury does not show causation. Drawing such a conclusion from temporal relationships leads to the blunder of the post hoc ergo propter hoc fallacy.”

The court further reasoned that the expert could not “simply opine that all present risk factors are ‘substantial contributing factors.’ Risk factors are potential causes of diabetes. Identifying potential causes is the work of general causation and, without more, does not suffice for a specific causation opinion.”

Finally, the expert could not clear the hurdle of admissibility by claiming that she performed a differential etiology because that method “must be reliably applied” and the opinions of an expert who purports to rely on such a methodology “must be supported by sufficient facts and data.” Here, the expert offered no reliable explanation for attributing this plaintiff’s diabetes to Lipitor, a failing that was all the more problematic because the plaintiff had many significant risk factors for diabetes independent of the use of Lipitor. Accordingly, the district court excluded the expert’s testimony, leaving the bellwether plaintiff with no evidence on a critical element of her claim.

While Lipitor is a well-reasoned decision, its utility may be limited. The opinion notes that general causation plus a temporal relationship alone may be enough to prove specific causation in cases where the relative risk ratio is greater than 2.0. In such cases, more than half of those who develop a disease or injury following exposure would not have developed that disease or injury but for the exposure, which some courts have concluded is sufficient to satisfy the plaintiff’s burden to prove specific causation by a preponderance of the evidence. There may be valid grounds for challenging the relative risk ratio identified by the plaintiff in such cases, but when the risk ratio is contended to be greater than 2.0 the Lipitor decision may change from an asset to a liability.

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[1] 2016 WL 527107 (N.Y. Feb. 11, 2016).

[2] 2015 WL 9165589 (D. S.C. Dec. 11, 2015).

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