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publication in the New York Reports.

No. 3
Sean R., &c.,
 Appellant,
 v.
BMW of North America, LLC, et
al.,
 Respondents.

Steven J. Phillips, for appellant.
Philip C. Semprevivo, for respondents BMW of North
America, LLC et al.
Leslie McHugh, for respondent Martin Motor Sales, Inc.
Haydn J. Brill, for respondent Hassel Motors, Inc.
American Association for Justice, amicus curiae.

PIGOTT, J.:

Plaintiff Sean R. was born with severe mental and
physical disabilities, which he attributes to *in utero* exposure
to unleaded gasoline vapor caused by a defective fuel hose in his
mother's BMW. The question on this appeal is whether the courts
below properly precluded two of plaintiff's expert witnesses from

testifying at trial as to causation. Because the experts did not rely on generally accepted principles and methodologies in concluding that plaintiff was exposed to a sufficient concentration of gasoline vapor to cause his injuries, we affirm.

I.

In May 1989, plaintiff's father, Guy R., purchased a new BMW 525i for his wife, Debra. She was the only person to drive the car and used it primarily for running local errands.

In the spring of 1991, Debra began to notice a smell of gasoline in the vehicle. She stated the odor "came and went" and that it would often dissipate as she drove. Debra said she could tolerate the smell in the summer when she was able to drive with the windows down, but that at other times it was so strong it caused her headaches, dizziness and throat irritation. Debra's family members also noticed the odor when they rode in the vehicle, and Debra's mother said it made her nauseous and dizzy. Eventually, the couple began to smell the odor in their home from the attached garage where they parked the car at night.

That March, Debra took the car to Hassel Motors complaining of the gasoline odor. Hassel could not identify any problem with the vehicle, however, and made no repairs. Debra continued driving the vehicle, despite the persistent odor of gasoline, when she became pregnant with plaintiff in July or August of 1991. Her husband took the vehicle back to Hassel in November, at which time Hassel discovered a fuel leakage into the engine compartment caused by a split fuel hose. In total, Debra

had driven 6,458 miles in the eight months that she smelled gasoline in the vehicle.

Plaintiff was born without difficulty on May 13, 1992. Although his initial Apgar scores were 9 and 10 at one and five minutes after birth, respectively, subsequent testing revealed that plaintiff suffered from severe mental and physical disabilities. He was diagnosed with, among other things, spastic quadriparesis (a form of cerebral palsy), developmental delays, ventricular asymmetry, delayed myelination, microcephaly, aortic stenosis, malformed bicuspid valve, tracheomalacia and impaired visual function.

Two years later, BMW of North America, LLC issued a recall of all 525i vehicles made between 1989 and 1991, due to defects in the feed fuel hoses. It described the defective hoses as being able to "harden and 'set' over time due to engine compartment temperatures," making it "possible that seepage between the hose and the fitting could result because the clamp cannot provide sufficient sealing force to compensate for the hardening of the hose." The recall report noted that customers had associated the defect with a "conspicuous fuel odor."

Plaintiff commenced this personal injury action in January 2008 against defendants BMW of North America, LLC, BMW of North America, Inc., BMW (US) Holding Corp. (collectively, "BMW"), Martin Motor Sales and Hassel. He alleged that the vehicle's defective fuel hose, and Hassel's failure to timely discover and fix the defective hose, caused his injuries by

exposing him *in utero* to toxic gasoline vapor.

In furtherance of his claims, plaintiff served notice of his intent to rely on the testimony of ten expert witnesses at trial, including Linda Frazier, M.D., M.P.H. and Shira Kramer, M.H.S., Ph.D. As plaintiff's primary causation experts, Dr. Frazier and Dr. Kramer were prepared to testify that plaintiff's *in utero* exposure to gasoline vapor proximately caused his birth defects. For her part, Dr. Frazier concluded that plaintiff's mother inhaled 1,000 parts per million (ppm) of gasoline vapor based on the fact that "she and others experienced symptoms of acute toxicity during exposure, such as headache, nausea and irritation of the throat and mucous membranes. In controlled studies, for symptoms such as these to occur immediately, a gasoline vapor concentration of at least 1000 ppm . . . is required." Dr. Frazier then utilized the "Bradford Hill criteria" to conclude that unleaded gasoline vapor is capable of causing the types of birth defects plaintiff suffered based on the link between exposure to the constituent chemicals of gasoline and adverse birth outcomes. Finally, after ruling out other possible causes, Dr. Frazier concluded that Debra's "high peak exposure[]" to gasoline vapor during the first trimester of her pregnancy was the most likely cause of plaintiff's injuries.

Dr. Kramer reached similar conclusions with respect to causation. Using a "weight of the evidence" analysis, she explained that "gasoline vapor and/or [the] specific chemical constituents of gasoline vapor" -- specifically toluene and

benzene -- are "causally related to an elevated risk of birth defects." Based on the symptoms that plaintiff's mother said she experienced and Dr. Frazier's estimate that plaintiff was exposed to 1,000 ppm of gasoline vapor, Dr. Kramer further concluded that plaintiff's exposure to unleaded gasoline vapor was a substantial causative factor in plaintiff's birth defects.

BMW and Hassel moved for summary judgment in November 2010, alleging, as relevant here, that the opinions of plaintiff's causation experts lacked a proper foundation. Supreme Court denied summary judgment, holding that plaintiff's experts provided a foundation for their opinions. The Appellate Division modified on grounds not pertinent to this appeal, and otherwise affirmed (94 AD3d 475, 475 [1st Dept 2012]).

Defendants then moved to preclude plaintiff's causation experts from testifying at trial or, alternatively, to hold a hearing in accordance with Frye v United States (293 F 1013 [DC Cir 1923]). In support of their motions, defendants included the expert affidavits of Anthony Scialli, M.D. and Peter Lees, Ph.D., which challenged the opinions of Dr. Frazier and Dr. Kramer for reaching novel conclusions and not using generally accepted principles and methodologies.

After reviewing lengthy submissions and a number of supplemental expert reports, Supreme Court granted defendants' motion to the extent that it precluded the testimony of Drs. Frazier and Kramer. As relevant here, the court determined that those experts did not rely on generally accepted methodologies in

concluding that *in utero* exposure to unleaded gasoline vapor caused plaintiff's injuries. After granting plaintiff's motion for reargument, Supreme Court adhered to its original decision.

The Appellate Division unanimously affirmed and certified the following question to this Court: "Was the order of the Supreme Court, as affirmed by this Court, properly made?" (115 AD3d 432 [1st Dept 2014]).

II.

In toxic tort cases, an expert opinion on causation must set forth (1) a plaintiff's exposure to a toxin, (2) that the toxin is capable of causing the particular injuries plaintiff suffered (general causation) and (3) that the plaintiff was exposed to sufficient levels of the toxin to cause such injuries (specific causation) (see Parker v Mobil Oil Corp., 7 NY3d 434, 448 [2006]). Although it is "not always necessary for a plaintiff to quantify exposure levels precisely" (id.), we have never "dispensed with a plaintiff's burden to establish sufficient exposure to a substance to cause the claimed adverse health effect" (Cornell v 360 W. 51st Realty, LLC, 22 NY3d 762, 784 [2014]). "At a minimum, . . . there must be evidence from which the factfinder can conclude that the plaintiff was exposed to levels of th[e] agent that are known to cause the kind of harm that the plaintiff claims to have suffered" (id., quoting Wright v Willamette Indus., Inc., 91 F3d 1105, 1107 [8th Cir 1996]).

Not only is it necessary for a causation expert to establish that the plaintiff was exposed to sufficient levels of

a toxin to have caused his injuries, but the expert also must do so through methods "found to be generally accepted as reliable in the scientific community" (Parker, 7 NY3d at 449). This "general acceptance" requirement, also known as the Frye test, governs the admissibility of expert testimony in New York. It asks "whether the expert's techniques, when properly performed, generate results accepted as reliable within the scientific community generally" (People v Wesley, 83 NY2d 417, 423 [1994]). Although unanimity is not required, the proponent must show "consensus in the scientific community as to the [methodology's] reliability" (id. at 437 [Kaye, J., concurring]).

Plaintiff and his experts have failed to make that showing in this case. Dr. Frazier and Dr. Kramer concluded that plaintiff was exposed to a sufficient amount of gasoline vapor to have caused his injuries based on the reports by plaintiff's mother and grandmother that the smell of gasoline occasionally caused them nausea, dizziness, headaches and throat irritation. Plaintiff and his experts have not identified any text, scholarly article or scientific study, however, that approves of or applies this type of methodology, let alone a "consensus" as to its reliability. Therefore, the courts below properly granted defendants' motion to preclude their testimony at trial.¹

¹ Due to the procedural posture of this case, our analysis and holding are limited to the Frye inquiry of whether the experts' techniques are generally accepted in the scientific community. We express no opinion on the "separate and distinct" question of whether there was a proper foundation for their

Dr. Frazier claims that it is accepted practice in occupational medicine to use standardized studies of symptoms as a guide when assessing exposures retrospectively. For support, she cites to the documentation report for gasoline by the American Conference of Governmental and Industrial Hygienists (ACGIH), which synthesizes the results of controlled studies and states that the threshold for immediate, mild toxic effect is approximately 1,000 ppm. She also cites to a 1991 study in which subjects exposed to known quantities of toluene and ethanol experienced an increase in headaches as their exposure level increased, as well as a 2008 report on the safety of n-Butyl alcohol in cosmetic products.

None of those sources, however, establish that Dr. Frazier's methodology, "when properly performed, generate[s] results accepted as reliable within the scientific community generally" (Wesley, 83 NY2d at 423). They merely support her conclusion that there is a dose-response relationship between exposure to the chemical constituents of gasoline and symptoms of toxicity. In Dr. Frazier's own words, the ACGIH report lists the known "exposure levels which cause people to report symptoms such as nausea and headache because, on the whole, controlled exposure studies are reliable." We don't disagree with the scientific validity of controlled studies or their ability to measure symptoms in response to a given exposure. But those controlled

opinions (Parker, 7 NY3d at 447).

studies do not support the inverse approach Dr. Frazier employed in this case -- working backwards from reported symptoms to divine an otherwise unknown concentration of gasoline vapor. Dr. Frazier has not identified on this record any study, report, article or opinion that admits or employs such a methodology.

Dr. Frazier's methodology is also fundamentally different from the true "odor threshold" analysis that has been admitted in other toxic tort cases. The odor threshold of a substance is the level at which the substance is capable of olfactory detection (Manuel v Shell Oil Co., 664 So 2d 470, 477 [5th Cir 1995]). Concentrations below the odor threshold are, by definition, not detectable by human smell (see Dickens v Oxy Vinyls, LP, 631 F Supp 2d 859, 863 [WD Ky 2009]). Causation experts have used odor thresholds to determine, for example, that a plaintiff was occupationally exposed to 60 ppm of hexane where hexane cannot be detected below that concentration and the plaintiff testified that he smelled hexane while working (see Beckner v Bayer Cropscience, LP, 2011 WL 805788 *6 n 8 [SD W Va, Mar. 2, 2011, No. 2:05-0530]). Similarly, the expert in Magistrini v One Hour Martinizing Dry Cleaning (180 F Supp 2d 584 [D NJ 2002], affd 68 Fed Appx 356 [3d Cir 2003]) calculated a plaintiff's occupational exposure to perchloroethylene (PCE) based on the chemical's odor threshold, coupled with other employment information, the cubic footage of the workspace and industrial literature (id. at 613-614).

Odor thresholds can be particularly helpful in

occupational exposure cases, where the odor threshold of a substance exceeds permissible workplace safety standards (see Beckner, 2011 WL 805788 at * n 8 [noting that if "one detects the odor of hexane, there is necessarily an exposure exceeding the limit set by the National Institute for Occupational Safety and Health . . . of 50 ppm"]). In some cases, however, the odor threshold of a substance is far below toxicity. Indeed, as one of plaintiff's sources explains:

"Smelling organic solvents is not indicative of a significant exposure, as the olfactory nerve can detect levels as low as several parts per million, which is not necessarily associated with toxicity. As an example, the odor threshold of toluene is 0.8 parts per million, whereas the [threshold limit value] is 100 parts per million."

(McMartin et al, Pregnancy Outcome Following Maternal Organic Solvent Exposure: A Meta-Analysis of Epidemiologic Studies, 34 American Journal of Industrial Medicine 288-292, 289 [1998]).

Defendants state, and plaintiff does not dispute, that unleaded gasoline in the early 1990s had a very low odor threshold of between 0.50 and 0.76 ppm. Assuming that is correct, a person would have been able to detect the odor of unleaded gasoline vapor at less than 1 ppm. Had Dr. Frazier applied a true odor threshold methodology in this case, like the experts in Beckner and Magistrini, the only conclusion she could have reached was that plaintiff was exposed to at least 1 ppm of unleaded gasoline -- the minimum level at which gasoline is detectable by human smell. Instead, Dr. Frazier averred that

there is a minimum threshold of gasoline vapor beneath which individuals do not experience headache, nausea or dizziness. And because Debra experienced headaches, nausea and dizziness, Dr. Frazier concluded she must have been exposed to at least that concentration. Plaintiff has not shown that such a "symptom-threshold" methodology, unlike the odor threshold methodology admitted in other cases, has been generally accepted in the scientific community.²

Although it is sometimes difficult, if not impossible, to quantify a plaintiff's past exposure to a substance, we have not dispensed with the requirement that a causation expert in a toxic tort case show, through generally accepted methodologies, that a plaintiff was exposed to a sufficient amount of a toxin to have caused his injuries (see Joseph V. Rodricks, Reference Guide on Exposure Science, in Federal Judicial Center, Reference Manual on Scientific Evidence at 539 [3d ed 2011] ["The methodological tools necessary to 'reconstruct' the plaintiff's past exposure are identical to those used to estimate current exposures, but

² Plaintiff's reliance on Allen v Martin Surfacing (263 FRD 47 [D Mass 2008]) is similarly misplaced. The expert in that case "did not rely alone on [the plaintiff's] symptom accounts in forming his opinion" about plaintiff's exposure to toluene (id. at 56 [emphasis added]). The expert also considered the known amount of volatile organic compounds that were used in the resurfacing process, the manner in which those compounds would have dissipated in the gymnasium -- including the weather at the time the solvents were used -- and the pathways of exposure in concluding that plaintiff's exposure approached the threshold limit value for toluene (id. at 55-56). Moreover, the defendant in Allen did not challenge the general acceptance of the expert's methodology, as defendants do here.

the availability of the data necessary to apply those methods may be limited or, in some cases, nonexistent"])). It was plaintiff's burden to show that the methodology his experts employed was generally accepted in the scientific community. Having failed to meet that burden, the courts below properly precluded Dr. Frazier's and Dr. Kramer's testimony that plaintiff's exposure to gasoline vapor caused his injuries.

Accordingly, the order of the Appellate Division should be affirmed, with costs, and the certified question answered in the affirmative.

* * * * *

Order affirmed, with costs, and certified question answered in the affirmative. Opinion by Judge Pigott. Judges Rivera, Abdus-Salaam, Stein and Fahey concur. Chief Judge DiFiore and Judge Garcia took no part.

Decided February 11, 2016