



December 11, 2014

New York State Court of Appeals
20 Eagle Street
Albany, NY 12207

Re: *Sean Reeps v. BMW of North America LLC et al.*, APL-2014-00215

To the Honorable Judges of the Court of Appeals:

The American Association for Justice (“AAJ”), through its counsel, respectfully submits this Amicus Curiae letter brief in support of Plaintiff-Appellant Sean Reeps.

I. THE IDENTITY AND INTEREST OF AMICUS CURIAE.

The American Association for Justice is a national bar association dedicated to securing meaningful access to the courts for persons seeking legal redress for wrongful injury and to safeguarding the right to trial by jury. The American Association for Justice is deeply concerned that the decisions below undermine these fundamental principles. Specifically, the decisions by the trial Court and the Appellate Division impose unfair, unscientific, and ill-advised restrictions on the scientific evidence that may serve as the foundation for expert opinion. Such overly-stringent requirements do not reflect the practice of scientists, conflict with well-

reasoned authority from across the nation, and usurp the role of the jury as the constitutionally designated finder of fact.

At issue in this case is the proffered testimony of two of Plaintiff's experts that inhalation of gasoline vapors by Debra Reeps while driving during the first trimester of her pregnancy can and did cause Sean Reeps' severe birth defects. The Supreme Court precluded Dr. Kramer and Dr. Frazier from testifying as to general and specific causation. (*Reeps v. BMW of N. Am., LLC*, No. 100725/08, 2012 WL 6729899 [NY Dec. 12, 2012]) ("Trial Order"). It then denied plaintiff's motion for reargument or reconsideration in *Reeps ex rel. Reeps v. BMW of North America, LLC* (39 Misc 3d 1234[A], 972 NYS2d 146 [2013]) ("Reconsideration"), and the Appellate Division affirmed in a short opinion. (*Sean R. v. BMW of N. Am., LLC*, 981 NYS2d 514, 115 AD3d 432 [1st Dept 2014]).

II. THE PRECLUSION OF CAUSATION TESTIMONY BY PLAINTIFF'S EXPERTS IS INCONSISTENT WITH THE WEIGHT OF REASONED AUTHORITY.

The American Association for Justice is concerned that the rulings below rest on errors of law that not only deprived a severely injured plaintiff of his opportunity to present the merits of his case to a jury, but if allowed to stand, would also unfairly disadvantage wrongfully injured persons in a wide variety of cases that depend upon the well-founded testimony of scientists applying generally accepted methods.

A. The Lower Court Erred in Requiring That the Testimony of Plaintiff’s Experts on General Causation Be Based on Epidemiological Studies.

Implicit in the motion Court’s ruling is the notion that the testimony of plaintiff’s experts regarding general causation is insufficient in the absence of epidemiological studies demonstrating an association between a pregnant woman’s inhalation of gasoline vapors and the types of birth defects suffered by Sean Reeps. The motion Court wrote that “there are no epidemiological studies on the effect of *in utero* exposure to gasoline vapors and the kind of diseases found in Sean Reeps, or, more generally, birth defects.” (Reconsideration at *2). The Court’s “central objection to experts’ methodology” was that, in “the absence of epidemiological studies on the subject . . . no association between exposure to gasoline vapor in pregnancy and palsy, microcephaly, or congenital heart disease has ever been demonstrated.” (*Id.*). The Court faulted Plaintiff’s experts for reliance on sources including toxicological studies and case reports, writing that such sources “are not controlled epidemiological studies, and cannot establish association in the statistical sense used in epidemiology.” (*Id.*).

This Court has stated that a plaintiff in a toxic torts case is required to offer an expert opinion “that the toxin is capable of causing the particular illness (general causation) and that the plaintiff was exposed to sufficient levels of the toxin to cause

the illness (specific causation).” (*Parker v. Mobil Oil Corp.*, 7 NY3d 434, 448, 824 NYS2d 584, 857 NE2d 1114, 1120 [2006]). But this Court has never held that epidemiological studies are the sole method of establishing general causation, nor have scientists or courts nationwide endorsed such an approach.

By way of background, “epidemiology” is a branch of science and medicine which applies the scientific method to human populations by “observ[ing] the effect of exposure to a single factor upon the incidence of disease in two otherwise identical populations.” (*DeLuca v. Merrell Dow Pharm., Inc.*, 911 F2d 941, 945 [3d Cir 1990], quoting Bert Black & David E. Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation*, 52 Fordham L Rev 732, 755 [1984]). Such comparisons of an exposed group of humans to a control group can yield strong inferences regarding general causation. However, this particular scientific tool is also subject to major limitations.

Epidemiologic studies may be experimental or observational. In an experimental study, the researcher exposes individuals to an agent and compares the results to a non-exposed control group. (Black & Lillienfield, *supra*, at 755-56.) Where an epidemiologist can closely monitor exposure, experimental clinical trials finding an association between an exposure and an outcome are deemed highly reliable. (*Id.* at 756). For obvious ethical reasons, however, experimental studies

cannot intentionally expose human beings to suspected toxins. (*See, e.g., Ethyl Corp. v. EPA*, 541 F2d 1, 26 [DC Cir], *cert. denied*, 426 US 941 [1976]) (leaded gasoline emissions). They are therefore “not commonly encountered in toxic tort litigation.” (Black & Lilienfeld, *supra*, at 756).

Instead, scientists may design observational epidemiological studies that use “statistical methods to detect abnormally high incidences of disease in a study population and to associate these incidences with unusual exposures to suspect environmental factors.” (Michael Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 Harv Envt’l L Rev 429, 431 [1983]). Such epidemiological studies provide circumstantial evidence of causation. “[E]pidemiologic evidence can justify an inference that an agent causes a disease . . . [but] cannot deductively prove causation. (Federal Judicial Center, *Reference Manual on Scientific Evidence* 553 n.8 [3d ed. 2011] (“Reference Manual”); *see also Ethyl Corp. v. EPA*, 541 F2d 1, 26 [DC Cir 1976]) (“Epidemiology . . . can only draw inference from observed correlations rather than prove cause and effect relationships.”).¹

¹ Indeed, the motion Court suggested that observational studies without control groups would also be insufficient as a basis for expert opinion as to causation. “In case reports, ‘association’ suggests the possibility of a link between two observed phenomena, but controlled studies are required to establish such a link.” (Trial Order at *27). That reasoning would limit plaintiffs to proving causation based

Because the epidemiologist does not control exposure or other conditions, observational studies may also be subject to biases and confounding variables that make interpretation difficult. (Marcia Angell, *The Interpretation of Epidemiologic Studies*, 323 *New England J of Med* 823, 824 [1990]). In addition, due to the limits of statistical tools, “epidemiological studies are inherently capable of detecting only comparatively large increases in the relative risk.” (EPA Final Guidelines for Carcinogen Risk Assessment, 51 *Fed Reg* 33992, 33995-96 [Sept. 24, 1986]). Importantly, for present purposes, “[n]egative results cannot prove the absence of [causation].” (*Id.* See also Office of Science and Technology Policy, *Chemical Carcinogens: A Review of the Science and its Associated Principles*, 50 *Fed Reg* 10372, 10377 [Mar. 14, 1985]) (“A high-quality negative epidemiological study, while useful, cannot prove the absence of an association. . . .”).

on studies that deliberately expose subjects to suspected toxins—a virtual impossibility in cases like the instant one, where exposing a group of pregnant women to gasoline vapors would be ethically intolerable. (See, e.g., *Globetti v. Sandoz Pharms. Corp.*, 111 *F Supp 2d* 1174, 1180 [ND Ala 2000]) (“one cannot ethically experiment on human beings, exposing them to the near certainty of some number of deaths, simply to satisfy some evidentiary standard”).

In view of these limitations, the overwhelming weight of authority from across the country, including both *Frye*² and *Daubert*³ jurisdictions, holds that epidemiological studies are not essential to expert opinion on causation that is otherwise based on generally accepted methodology. New York courts have held that “‘general causation’ is not limited to the results of epidemiological studies.” (*Rosati v. Brigham Park Co-operative Apts.*, 36 Misc 3d 1214[A], 961 NYS2d 361, at *22 [NY 2012]). In addition, a “quite substantial body of case law and commentary rejects an epidemiologic threshold for sufficient proof of general causation,” particularly where such evidence “is not reasonably available to the plaintiff when other, reasonably probative evidence exists.” (*Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28, Reporter’s Note to comment c (“Reporter’s Note”), citing numerous federal and state cases). (See, e.g., *Benedi v. McNeil-P.P.C., Inc.*, 66 F3d 1378, 1384 [4th Cir 1995]) (“We do not read *Daubert* as restricting expert testimony to opinions that are based solely upon epidemiological data”); *Kennedy v. Collagen Corp.*, 161 F3d 1226, 1229 [9th Cir 1998]) (abuse of discretion to exclude expert testimony based on reliable

² *Frye v. United States*, 293 F 1013 (DC Cir 1923).

³ *Daubert v. Merrell Dow Pharms., Inc.*, 509 US 579 (1993).

methodology simply because there were no epidemiological studies); *Robertson v. Doug Ashy Bldg. Materials, Inc.*, 77 So 3d 339, 359 [La Ct App 2011], *writ denied*, 77 So 3d 972 [2012]) (“[W]e cannot find, nor have we been directed to, any authority for the trial court’s determination that epidemiological evidence is *required* to establish causation of an individual’s disease.”)).

The Restatement Reporter observed that occasionally “courts have suggested or implied that a plaintiff cannot meet the burden of production on causation without epidemiologic evidence.” (Reporter’s Note, *supra*). Comment c rejects that view as “overreliance on scientific thresholds,” and states that “almost all courts employ a more flexible approach to proof of causation—except in those cases with a substantial body of exonerative epidemiologic evidence.” (*See, e.g., Norris v. Baxter Healthcare Corp.*, 397 F3d 878 [10th Cir 2005]) (holding opinions of experts who ignored a substantial body of contrary epidemiologic evidence were properly ruled inadmissible). The case before this court is not such a case. The American Association for Justice urges this Court to make clear that, particularly where epidemiological studies precisely mirroring the plaintiff’s exposure and injury are unavailable, expert testimony on general causation may be based on other accepted methodologies. (*See also* David L. Faigman *et al.*, *How Good Is Good Enough?: Expert Evidence Under Daubert and Kumho*, 50 Case W Res L Rev 645, 663 [2000])

("It is now clear that courts will not exclude causal opinions based on non-epidemiological evidence in situations where a body of such data does not exist.").

B. The Lower Court Erred in Requiring That Expert Testimony on General Causation Be Based Solely on Evidence Linking Maternal Exposure to Gasoline Vapors to the Specific Birth Defects Afflicting Plaintiff.

In addition to requiring that expert testimony as to general causation be based on epidemiological studies, the motion Court also required that such testimony be based on evidence linking *in utero* exposure to the exact defects afflicting the plaintiff: "At issue in this case are the specific birth defects found in Sean Reeds [sic], and the burden to prove a cause-and-effect relationship between exposure to gasoline and these birth defects falls on the plaintiffs." (Trial Order at *22-23). The motion Court demanded that Plaintiff's expert render "an unambiguous statement that exposure to gasoline vapor in the early gestation period is causally related to spastic quadriplegia (or cerebral palsy in general), microcephaly, cardiac disorders of the type Sean Reeps has, or any other of his diagnosed diseases." (*Id.* at *22). The Court faulted Dr. Kramer and Dr. Frazier for relying on "studies which fail to identify an association between gasoline or solvent exposure and *specific* birth defect(s)." (*Id.*) (emphasis in original).

New York law is to the contrary:

When applying the *Frye* test to assess the reliability of an expert's theory of causation, "it is not necessary 'that the underlying support for the theory . . . consist of cases or studies considering circumstances exactly parallel to those under consideration in the litigation. It is sufficient if a synthesis of various studies or cases reasonably permits the conclusion reached by the . . . expert.'"

(*LaRose v. Corrao*, 963 NYS2d 712, 713-14, 105 AD3d 1009 [2d Dept 2013], quoting *Zito v. Zabarsky*, 812 NYS2d 535, 537, 28 AD3d 42, 44 [2d Dept 2006]).

The motion Court's insistence upon "specificity" of findings also ignores the reality that many birth anomalies, including injuries from which Sean Reeps suffers, are extremely rare. The rarity of such conditions makes it extraordinarily difficult, if not impossible, to design an epidemiological study large enough to reflect an increase in relative risk.

Accordingly, courts applying the *Frye* test commonly recognize that extrapolation from existing data and scientific literature is a generally accepted methodology used by scientists to arrive at new or different conclusions. For example in *Duran v. Cullinan* (677 N.E.2d 999 [Ill Ct App 1997]), the plaintiff alleged that her child suffered multiple birth defects due to her use of the Ovulen-21 oral contraceptive. The court held that the plaintiffs' experts could rely on studies indicating that oral contraceptives have a teratogenic effect, rejecting defense arguments that "the literature does not mention the exact defects suffered by

Lindsay.” Under *Frye*, the court stated, “we do not believe that the plaintiffs were required to present an epidemiological study showing the exact type of defect as long as the plaintiffs’ experts’ methodology in reaching their conclusions as to causation was sound.” (*Id.* at 1004, citing *Ferebee v. Chevron Chemical Co.*, 736 F2d 1529, 1535-36 [DC Cir 1984]). (*See also Donaldson v. Cent. Ill. Pub. Serv. Co.*, 730 NE2d 68, 76 [Ill Ct App 2000], *aff’d*, 767 NE2d 314 [Ill Ct App 2002] (discussing *Duran* case with approval)). Federal courts following *Daubert* have also adopted similar reasoning. (*See, e.g., Ambrosini v. Labarraque*, 101 F3d 129, 138 [DC Cir 1996] (error to exclude testimony of plaintiff’s expert that mother’s ingestion of prescription drug Depo-Provera could cause plaintiff’s birth defects; although none of the studies relied upon specifically concluded that the drug caused the type of birth defects suffered by plaintiff, expert testified that he arrived at that conclusion using traditional methodology of experts in his field)).

The limitation imposed by the court below permits a tortfeasor to keep a toxic-tort case from the jury by simply demanding ever greater specificity in the foundation of causation expert’s opinion. In *Anderson v. Akzo Nobel Coatings, Inc.* (260 P3d 857 [Wash 2011] (en banc)), the plaintiff alleged that her son was born with neurological birth defects due to her exposure to organic paint solvents while pregnant. Plaintiff introduced expert testimony that such toxic solvents are fat

soluble, pass easily through the placenta, and may damage the developing brain of a fetus within the uterus. The Washington Supreme Court rejected the defendant's contention that the plaintiff must also establish acceptance of the causal connection between the solvents "and the specific polymicrogyria birth defect" affecting the child. (*Id.* at 866). The court explained that if courts require general acceptance "of each discrete and evermore specific part of an expert opinion, virtually all opinions based upon scientific data could be argued to be within some part of the scientific twilight zone." (*Id.*).

In the area of congenital defects, scientists generally accept and courts following *Frye* therefore permit, extrapolation from animal and *in vitro* studies to support expert opinion that an agent is a human teratogen. In *Castillo v. E.I. DuPont de Nemours & Co., Inc.* (854 So 2d 1264 [Fla 2003]), an action seeking damages for birth defects due to *in utero* exposure to the fungicide Benlate, the Florida Supreme Court held that expert general causation testimony, based on extrapolation from *in vivo* tests (animal toxicology) and *in vitro* tests (showing effects on isolated cell systems) to conclude that Benlate is a human teratogen was admissible, where the expert relied upon principles of qualitative extrapolation generally recognized in toxicology and pharmacology. (*Id.* at 1273). Likewise, the court in *Roberti v. Andy's Termite & Pest Control, Inc.* (6 Cal Rptr 3d 827 [Cal Ct App 2003]), applying

California's *Frye* test, held that the trial judge erred in excluding testimony by plaintiff's expert that plaintiff's brain damage was caused by in utero exposure to the pesticide Dursban. The expert's use of animal studies to extrapolate to effects on humans was a methodology that is accepted in the scientific community, and defendant's disagreement with the expert's conclusion "pertains to the weight of the underlying bases for the expert opinion, not its admissibility." (*Id.* at 834).

The ruling in this case presents an example of making "evermore specific" demands on the expert's foundation to defeat the plaintiff's right to present her case to the jury. As the Supreme Court explained,

Dr. Kramer presented a table comparing Sean Reeps' medical condition at birth with those reported in the literature as associated with *in utero* exposure to gasoline, toluene, and other organic solvents. All twelve symptoms found in Sean Reeps are among those listed. She concluded: "The concordance between the birth outcomes experienced by Sean Reeps and those seen in children exposed to gasoline, toluene, and other organic solvents supports the causal association between exposure to these chemicals and Sean Reeps' birth defects."

(Trial Order at *32). Despite the extraordinarily close correspondence drawn by the expert from existing data to plaintiff's injuries, the Court nevertheless precluded Dr. Kramer from testifying, due to "lack of specificity, the absence of quantitative assessment of the threshold exposure to toxins sufficient to produce particular diseases, and inappropriate use of case reports to establish causality." To allow this

ruling to stand, AAJ submits, will deprive wrongfully injured parties of their day in court because extrapolation that is accepted by scientists in the field is deemed inadequate for experts in the courtroom.

C. The Appellate Division Erred Insofar as it Held That Studies Showing the Reproductive Toxicity of Gasoline Constituents, Including Toluene, Cannot Provide a Reliable Basis for Expert Opinion That Gasoline Vapors Are Reproductively Toxic.

The Appellate Division in this case wrote:

Plaintiff's experts' testimony was properly precluded. The motion court properly determined that the medical and scientific literature submitted by plaintiffs' experts does not support the proffered theory that exposure to gasoline fumes caused plaintiff's birth defects. Rather, the literature shows that some of the constituent chemicals contained in gasoline, and presumably those chemicals' vapors, can cause birth defects. However, plaintiff failed to show how exposure to those constituent chemicals, constituted as unleaded gasoline vapors, could have caused his injuries (*see Parker*, 7 NY3d at 449-50, 824 NYS2d at 590-91, 857 NE2d at 1121-22).

(*Sean R. v. BMW of N. Am., LLC*, 115 AD3d 432, 981 NYS2d 514, 515 [1st Dept 2014]). (*See also* Reconsideration at *2 (criticizing Dr. Frazier's causation testimony as "not deal[ing] with gasoline vapor at all, but with toluene."); (Trial Order at *20, citing *Parker*, 7 NY3d at 449-50, 824 NYS2d at 550-51, 857 NE2d at 1121-22) ("The move from the study of the effect of inhaling unleaded gasoline to the study

of inhaling its components . . . is not a generally accepted principle of proof in epidemiological research.”)).

This appears to be based on a misreading of dicta in this Court’s *Parker* decision, which was confined to the question of proving specific causation. On the issue of general causation, expert opinion that exposure to a mixture can cause adverse effects based on the known adverse effects of a component would seem unremarkable. For example, in *Curtis v. M&S Petroleum, Inc.* (174 F3d 661 [5th Cir 1999]), refinery workers sought damages for various health problems caused by exposure to Heavy Aromatic Distillate processed at the refinery. The court held it an abuse of discretion to exclude plaintiffs’ expert’s “general causation opinion that exposure to benzene,” a component of HAD, “would cause the injuries suffered by Plaintiffs.” (*Id.* at 670).

With respect to general causation, however, the Supreme Court stated, “It is a standard practice in toxicology that common commercial mixtures, such as gasoline, are evaluated for toxicity a whole, not as a sum of its components.” (Reconsideration at *4, citing the FJC Reference Manual at 673). The Reference Manual in the same paragraph also describes two other accepted means of evaluating the toxicity of commercial mixtures of several agents. In one, “the known toxicological effect of one agent is used to explore the mechanism of action of another agent.” (*Id.*). A third

approach “is based on an understanding of the basic mechanism of action of the individual components of the mixture, thereby allowing prediction of the combined effect.” (*Id.*). Dr. Frazier’s use of this accepted methodology was improperly rejected by the motion Court.

The American Association for Justice asks this Court to make clear that the foundation for expert opinion as to general causation is not subject to artificial limitations “provided that whatever methods an expert uses to establish causation are generally accepted in the scientific community.” (*Parker*, 7 NY3d at 448, 824 NYS2d at 590, 857 NE2d at 1121).

D. The Motion Court Erred in Ruling That Weight-of-the-Evidence Methodology Is Insufficient Foundation for Causation Opinion.

Plaintiff’s experts here employed a weight-of-the-evidence methodology, taking account of the timing and duration of exposure, molecular structure of the toxins, animal studies, human case reports, epidemiological studies germane to Plaintiff’s exposures and injuries, and review of the extensive peer-reviewed scientific literature to arrive at the conclusion that exposure to gasoline vapors, and their toxic components, can and did cause Sean Reeps’ congenital birth defects. (*See* Plaintiff’s Letter Br. at 15-16).

The term “weight of the evidence” is used “to characterize a process or method in which all scientific evidence that is relevant to the status of a causal

hypothesis is taken into account.” (See Sheldon Krimsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am J Pub Health S129, S129 [2005]). The motion Court, however, improperly denigrated this methodology as “a fall-back solution when [plaintiff’s experts] do not find supporting epidemiological evidence.” (Reconsideration at *3). In the Court’s view, their use of the term amounted to no more than “a colorful way” for experts to say they have examined a body of evidence “using a method we have not described.” (*Id.*).

The crux of the issue, however, is not whether the *Court* deems this methodology reliable, but whether it is a methodology that is generally accepted by scientists in the relevant field. In that respect, the Reference Manual, which the supreme court otherwise deemed authoritative, provides illumination:

It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine, the National Research Council, and the National Institute for Environmental Health Sciences) consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence. In applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed.

(*Id.* at 19-20). (See also Carl F. Cranor, *A Framework for Assessing Scientific Arguments: Gaps, Relevance and Integrated Evidence*, 15 JL & Pol’y 7, 23 [2007])

(explaining that “weight-of-the-evidence” is used in “both scientific and regulatory contexts”)).

Courts have admitted expert testimony based on the weight-of-the-evidence methodology in toxic torts cases. (*See, e.g., In re Chantix (Varenicline) Prods. Liab. Litig.*, 889 F Supp 2d 1272, 1293 [ND Ala 2012] (finding that “Dr. [Shira] Kramer’s weight of evidence methodology is persuasive”); *Milward v. Acuity Specialty Prods. Group*, 639 F3d 11, 17-20 [1st Cir 2011], *cert. denied sub nom., U.S. Steel Corp. v. Milward*, 132 S Ct 1002 [2012] (discussing the reliability of the weight-of-the-evidence methodology and holding that the trial court abused its discretion in excluding plaintiff’s expert’s opinion that exposure to benzene caused plaintiff’s Acute Promyelocytic Leukemia, which was based on that methodology); *King v. Burlington N. Santa Fe Ry. Co.*, 762 NW2d 24, 39-40 [Neb. 2009] (finding reversible error in excluding plaintiff’s expert on causation, noting that “government agencies and some experts use a weight-of-the-evidence methodology” and that “the Environmental Protection Agency uses this methodology to assess risks”); *Ambrosini v. Labarraque*, 101 F3d 129, 140 [DC Cir 1996] (plaintiff’s expert permitted to rely on review of “totality of the data” to conclude that prescription drug Depo-Deprova was a cause of birth defects)).

As the First Circuit concluded, “No serious argument can be made that the weight of the evidence approach is inherently unreliable.” (*Milward*, 639 F.3d at 18-19). One commentator has stated that cases such as *Milward* “teach[] that it may be possible for experts to draw inferences of general causation even if they do not rely on experimental or observational evidence that tests the hypothesis directly. The legal requirement of fit, although it depends on science, should not be framed in scientific terms so restrictive that it becomes a straitjacket.” (Steve C. Gold, *A Fitting Vision of Science for the Courtroom*, 3 *Wake Forest JL & Pol’y* 1, 39 [2013]).

E. The Motion Court Erred by Excluding Plaintiff’s Expert Testimony Regarding Specific Causation on Grounds That the Expert’s Calculations, Based on Odor Threshold Methodology, “Just Don’t Add Up”.

On the issue of specific causation, Plaintiff proffered expert testimony that Debra Reeps was continuously exposed to at a minimum 1000 parts per million of gasoline vapors while she was driving throughout her first trimester, based on the threshold at which people detect the odor of gasoline, and display symptoms which Ms. Reeps and other passengers experienced. (*See* Plaintiff’s Letter Br. at *6-7 (summarizing testimony of Dr. Linda Frazier)).

It is well recognized that “[o]nly rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes [and] it is usually difficult, if not impossible, to quantify the amount of exposure.” (Reference

Manual at 639-40). Courts do not deprive the plaintiff of her day in court simply because the basis for her expert's opinion on specific causation was not as precise as contemporaneous air quality monitoring. As this Court has acknowledged, "often, a plaintiff's exposure to a toxin will be difficult or impossible to quantify by pinpointing an exact numerical value." (*Parker*, 7 NY3d at 448, 824 NYS2d at 590, 857 NE2d at 1120). In such cases,

[I]t is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship, provided that whatever methods an expert uses to establish causation are generally accepted in the scientific community.

(*Id.*). This Court itself suggested that "[t]here could be several other ways an expert might demonstrate causation." (*Id.* at 449, 824 NYS2d at 590, 857 NE2d at 1121). (See also *Sunnycalb v. CSX Transp., Inc.*, 926 F Supp 2d 988, 993-94 [SD Ohio 2013] (Where exact measurements are not available, "this circuit and others have held that evidence of the precise level of chemical exposure is not necessary when other evidence supports the claim.")).

One of those approaches is odor threshold methodology. For example, in *Lewis v. Airco, Inc.* (No. A-3509-08T3, 2011 WL 2731880, at *7 [NJ Super Ct App Div July 15, 2011]), although a manufacturing facility no longer existed, an expert was permitted to opine that worker had been exposed to 2,000 ppm of the carcinogen

vinyl chloride monomer, based on threshold at which workers smelled VCM. (*See also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F Supp 2d 584, 613-14 [DNJ 2002], *aff'd*, 68 Fed Appx 356 [3d Cir. 2003] (denying defense motion to exclude expert testimony, based on odor threshold methodology, that plaintiff had been regularly exposed to at least 200 ppm of perchloroethylene)). The *Magistrini* court determined that odor threshold methodology “has been subject to peer review and is a generally accepted way of estimating exposure levels in the absence of air sampling.” (*Id.* at 614).

However, rather than inquire whether this methodology is generally accepted by scientists in the field, the motion Court engaged in its own calculations and concluded that the expert’s “numbers simply do not add up.” (Reconsideration at *4). The flaws in the defense consultant’s analysis, which the motion Court echoed, are addressed in Plaintiff’s letter brief. For present purposes, AAJ would simply note that it was clearly not Dr. Frazier’s methodology, but her conclusion that caused the court to exclude her testimony.

The court for the Appellate Division, First Department correctly set out the standard for assessing the foundation for expert testimony in *Nonnon v. City of New York* (819 NYS2d 705, 32 AD3d 91 [1st Dept 2006], *aff'd*, 9 NY3d 825, 874 NE2d 720 [NY Ct App 2007]), where plaintiff sought to recover for injuries caused by

toxins illegally dumped in a landfill. The court made clear that the *Frye* test assesses an expert's methodology and technique, not his or her conclusions:

Here, plaintiffs' experts laid a proper foundation for the introduction of their opinions [as to causation]. They followed generally accepted methods for the collection and analysis of evidence and applied proper techniques to reach their conclusions.

(*Id.* at 104, 819 NYS2d at 714).

By way of example, the court cited its decision in *Marsh v. Smyth* (785 NYS2d 440, 12 AD3d 307 [1st Dept 2004]), where the motion court had disallowed the testimony of plaintiff's two experts regarding the cause of plaintiff's injury on the grounds that the experts' conclusions were not accepted in the field:

We reversed, holding that *Frye* is not concerned with the reliability of a certain expert's conclusions, but instead with whether the experts' deductions are based upon principles that are sufficiently established to have gained general acceptance as reliable.

(*Nonnon*, 819 NYS2d at 713-14, 32 AD3d at 103 (internal quotation omitted)). As the court subsequently restated,

General acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion, but that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in reaching their conclusions.

(*Nonnon*, 932 NYS2d at 435, 88 AD3d at 394 (internal quotations omitted)).

Other jurisdictions that follow *Frye* similarly hold that the “general acceptance” standard applies only to the principles and methodology relied upon by the expert; it is for the jury to decide whether the expert’s conclusions are credible.

For example, the Supreme Court of Illinois has stated:

“[G]eneral acceptance” does not concern the ultimate conclusion. Rather, the proper focus of the general acceptance test is on the underlying methodology used to generate the conclusion. If the underlying method used to generate an expert’s opinion are reasonably relied upon by the experts in the field, the fact finder may consider the opinion—despite the novelty of the conclusion rendered by the expert.

(Donaldson v. Central Ill. Pub. Serv. Co., 767 NE2d 314, 324 [Ill 2002], abrogated on other grounds by, In re Commitment of Simons, 821 NE2d 1184 [Ill 2004]).

Similarly, the Florida Supreme Court has held that, where the parties’ experts disagreed whether physical trauma can cause fibromyalgia, “the trial court abused its discretion in not allowing the jury to determine the weight to give the opinion testimony.” (*Marsh v. Valyou, 977 So 2d 543, 558 [Fla 2007]*). (*See also Berry v. CSX Transp., Inc., 709 So 2d 552, 567 [Fla Dist Ct App 1998]* (Under *Frye*, when expert opinion is “based upon generally accepted scientific principles and methodology, it is not necessary that the expert’s opinion be generally accepted as well.”)).

The New Jersey Supreme Court has stated that in a toxic-torts case,

[I]t is not essential that there be general agreement with the opinions drawn from the methodology used. There must merely be some expert consensus that the methodology and the underlying data are generally followed by experts in the field.

(*Rubanick v. Witco Chem. Corp.*, 593 A2d 733, 748 [NJ 1991]). The *Rubanick* court cautioned that “[g]reat difficulties can arise when judges, assuming the role of scientist, attempt to assess the validity of a complex scientific methodology.” (*Id.*). Consequently, the inquiry “is not the reliability of the expert’s ultimate opinion . . . nor whether the court thinks that the expert’s reliance was reasonable. The proper inquiry is whether comparable ‘experts in the field [would] actually rely’ on that information.” (*Id.* at 749 (internal citations omitted)).

Even in *Daubert*, which authorized federal courts under Federal Rule of Evidence 702 to inquire into the reliability of expert opinion, the Court explained that the “focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.” (509 U.S. at 595). The Court subsequently suggested that “conclusions and methodology are not entirely distinct from one another.” (*General Electric Co. v. Joiner*, 522 US 136, 146 [1997]). However, the Court made clear that its concern was with expert opinion based on no methodology whatever, but “connected to existing data only by the *ipse dixit* of the expert.” (*Id.*).

Thus any objection that an expert's opinion is based on mistaken calculations goes to the weight of the expert's testimony, not its admissibility. (*See, e.g., Lewis v. Airco, Inc.*, No. A-3509-08T3, 2011 WL 2731880, at *23-24 [NJ Super Ct App Div July 15, 2011] (objections to the calculations by plaintiff's expert regarding level of toxic exposure go to weight, not admissibility); *Turner v. Williams*, 762 NE2d 70, 82 [Ill Ct App 2001] (objection that plaintiff's expert did not include certain information in his calculations did not render testimony inadmissible as lacking foundation, but rather was a matter that "could have been adequately brought to light before the jury on cross-examination."); *Milward*, 639 F3d at 23-24 (where defense expert asserted that plaintiff's opinion was based on "faulty calculations" but "both experts' opinions are supported by evidence and sound scientific reasoning, the question of who is right is a question for the jury.")).

III. UNWARRANTED RESTRICTIONS ON THE ADMISSIBILITY OF EXPERT TESTIMONY UNDERMINE THE CONSTITUTIONAL RIGHT TO TRIAL BY JURY.

The People of the State of New York have guaranteed for themselves the right to trial by jury, providing in their constitution that this fundamental right "shall remain inviolate forever." (NY Const, art I, § 2). This Court has observed that the right of a jury trial in legal actions is the "most important" of the rights of a civil litigant, and that "expediency alone does not warrant the denial of this fundamental

right.” (*Kaminsky v. Kahn*, 20 NY2d 573, 583, 232 NE2d 837, 841 [NY Ct App 1967]).

“New York has protected the right to a jury trial from the very beginning of its history.” (Matthew Tulchin, *An Analysis of the Development of the Jury’s Role in A New York Criminal Trial*, 13 JL & Pol’y 425, 454 [2005]). The jury right is specifically directed at the “otherwise autocratic power and authority of the judge.” (*Granfinanciera S.A. v. Nordberg*, 492 US 33, 83 [1989], White, J., dissenting). The drafters of New York’s first constitution sought to protect against “[j]udges [who] often exerted pressure on juries to ensure that the verdicts they rendered conformed to government policy.” (Tulchin, *supra*, at 449). They incorporated “the unfettered right to a jury trial” into the constitution “to protect the individual liberties and freedoms” of the citizens of New York. (*Id.*).

Scholars have noted that the rules of evidence, specifically more restrictive rules concerning expert witnesses, have allowed judges to assert greater control over juries and threaten to diminish the role of the jury in the American justice system. (See Allan Kanner & M. Ryan Casey, *Daubert and the Disappearing Jury Trial*, 69 U. Pitt. L. Rev. 281, 314-16 [2007]; Nancy Jean King, *The American Criminal Jury*, 62 Law & Contemp. Probs. 41, 49 [1999]).

Judges who assume the role of “amateur scientists,” examining theories, gathering opposing facts and making judgments about which conclusion is correct, “might very well be said to undermine the . . . right to a jury trial.” (Kanner & Casey, *supra*, at 291-92). Indeed, empirical studies indicate that the increasingly more stringent judicial barriers to the admissibility of scientific expert testimony have had a measurable “chilling effect” on the ability of injured parties to seek legal redress. (Kanner & Casey, *supra*, at 329, citing Lloyd Dixon & Brian Gill, RAND Institute for Civil Justice, *Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision* [2001], available at <http://www.rand.org/publications/MR/MR1439/MR1439.pdf>.)

This result not only deprives wrongfully injured victims of legal redress, but makes corporate defendants less accountable and therefore less inclined to avoid reckless conduct or to invest in safety. (*Id.* at 315-16).

This Court has held that it would be “inappropriate to set an insurmountable standard that would effectively deprive toxic tort plaintiffs of their day in court.” (*Parker*, 7 NY3d at 447-49, 824 NYS2d at 590, 857 NE2d at 1120). The American Association for Justice believes that that lower Court has done so in this case. Its view is “overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence,

and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” (*Daubert*, 509 US at 596). (*See also Barefoot v. Estelle*, 463 US 880, 899 n.7 [1983]) (“Petitioner’s entire argument . . . is founded on the premise that a jury will not be able to separate the wheat from the chaff. We do not share in this low evaluation of the adversary process.”).

For these reasons, the American Association for Justice urges this Court to reverse the decision below.

Respectfully submitted,

A handwritten signature in blue ink that reads "Robert S. Peck". The signature is written in a cursive, flowing style.

Robert S. Peck
Jeffrey R. White

Attorney for Amicus Curiae
American Association for Justice