

Reeps v BMW of N. America, LLC

2012 NY Slip Op 33030(U)

December 16, 2012

Sup Ct, New York County

Docket Number: 100725/08

Judge: Louis B. York

Republished from New York State Unified Court System's E-Courts Service.
Search E-Courts (<http://www.nycourts.gov/ecourts>) for any additional information on this case.

This opinion is uncorrected and not selected for official publication.

SUPREME COURT OF THE STATE OF NEW YORK NEW YORK COUNTY

PRESENT: LOUIS B. YORK
J.S.C. Justice

PART 2

Sean Reepsian infant

INDEX NO. 100 725/08

-v-

BMW of North America

MOTION DATE _____

MOTION SEQ. NO. 10

The following papers, numbered 1 to _____, were read on this motion to/for _____

Notice of Motion/Order to Show Cause — Affidavits — Exhibits _____ | No(s). _____

Answering Affidavits — Exhibits _____ | No(s). _____

Replying Affidavits _____ | No(s). _____

Upon the foregoing papers, it is ordered that this motion is

FILED

DEC 21 2012

NEW YORK
COUNTY CLERK'S OFFICE

**MOTION IS DECIDED IN ACCORDANCE
WITH ACCOMPANYING MEMORANDUM DECISION**

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE
FOR THE FOLLOWING REASON(S):

Dated: 12/16/12

Luy, J.S.C.

1. CHECK ONE: CASE DISPOSED NON-FINAL DISPOSITION
2. CHECK AS APPROPRIATE: MOTION IS: GRANTED DENIED GRANTED IN PART OTHER
3. CHECK IF APPROPRIATE: SETTLE ORDER SUBMIT ORDER
- DO NOT POST FIDUCIARY APPOINTMENT REFERENCE

LOUIS B. YORK
J.S.C.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X

SEAN REEPS, an Infant by His Mother and Natural
Guardian, DEBRA REEPS,

Plaintiffs,

Index No. 100725/08

-against-

BMW OF NORTH AMERICA, LLC, BMW OF
NORTH AMERICA, INC., BMW(US) HOLDING
CORP., MARTIN MOTOR SALES, INC.,
HASSEL MOTORS, INC.,

Defendants.

FILED
DEC 21 2012
NEW YORK
COUNTY CLERK'S OFFICE

-----X

YORK, J.:

Defendants BMW OF NORTH AMERICA, LLC, BMW OF NORTH AMERICA, INC.,
and BMW(US) HOLDING CORP. (collectively "BMW") move to preclude introduction of
expert testimony in support of plaintiff's theory of causation, or, in the alternative, for a hearing
in accordance with Frye v United States, 293 F. 1013 (1923) to determine whether plaintiff's
expert testimony should be precluded from trial.

BACKGROUND

Sean Reeps was born on May 13, 1992, weighting 8 pounds 7 ounces. His newborn
screening tests and Apgar scores were normal, but in the immediate neonatal period, he
exhibited several anomalies. In her affidavit Dr. Kramer summarized the major adverse birth
outcomes diagnosed in Sean Reeps: microcephaly, severe mental retardation, developmental
delays, spastic quadriparesis (a severe form of cerebral palsy), myopia, and a congenital heart

defect (Kramer Aff., Pl. Exh. H, at ¶4). One of Sean Reeps' doctors found that he had dysmorphic features including a broad nasal bridge, arch-shaped eye-brows, a triangular face, and small, up-slanting palpebral fissures (the separation between the upper and lower eyelids). His genetic evaluation did not show any deviations from the norm.

Plaintiffs attribute Sean Reeds' condition to *in utero* exposure to gasoline vapors his mother Debra Reeps inhaled during the first trimester of her pregnancy, while driving a 1989 BMW 525i. In March 1991 Debra Reeps noticed an odor of gasoline inside her vehicle. An initial inspection by Hassel Motors on March 21, 1991 did not lead to repairs. A second inspection by Hassel Motors on November 1, 1991 showed that a leakage of fuel into the engine compartment was caused by a split fuel line, and the fuel line was replaced. At that time Mrs. Reeps was about 14 weeks pregnant.

This action was commenced on January 16, 2008. On October 21, 2010, plaintiffs served expert disclosures pursuant to CPLR §3101(d). The medical experts included Linda Frazier, M.D., M.P.H.; Cynthia F. Bearer, M.D., Ph.D.; Shira Kramer, Ph.D.; Thomas Sadler, Ph.D.; Daniel Adler, M.D.; and Wendy K. Chung, M.D., Ph.D. Defendant BMW designated as its experts Anthony Scialli, M.D. and Peter Lees, Ph.D.

Shira Kramer attached a detailed report to her disclosure statement. It offered a primer on epidemiology and expressed two opinions. First, she commented on the probability that gasoline vapors cause fetal malformation:

It is my opinion, to a reasonable degree of scientific certainty, that gasoline vapor and specific chemical constituents of gasoline such as toluene and other solvents, individually or in combination, are causally related to an elevated risk of birth defects among children prenatally exposed to these chemicals during early pregnancy.

(Kramer Report, Pl. Exh. D, at ¶79).

She also assessed “causal factors in birth defects experienced by Sean Reeps:

It is my opinion, to a reasonable degree of scientific certainty, that exposure to the chemical constituents of gasoline vapor, individually or in combination, was a substantial causative factor in the birth defects experienced by Sean Reeps, who was exposed to gasoline vapor *in utero* during the first trimester of his development, a period of enhanced susceptibility.

(*id.*, at ¶80)

The expert arrived at her conclusions by using a “weight-of-evidence assessment of the association between exposure to gasoline vapor and/or specific chemical constituents of gasoline vapor and an increased risk of birth defects and other adverse birth outcomes.” The evidence for this assessment came from epidemiological, medical, and toxicological literature.

Dr. Linda Frazier expressed the opinion that at the time of Sean Reeps’ conception and gestation his mother was exposed to developmental hazards due do substances and compounds found in gasoline vapors. Her premise was that “gasoline contains many toxic substances that are capable of severely damaging a developing fetus during the first trimester, including many potent neurotoxicants that are known to harm the brain.”(Frazier Report, Pl. Exh. D, at ¶28) She next determined that the exposure levels of Mrs. Reeps to gasoline was high, based on her reported symptoms of headache, nausea and irritation of the throat. In controlled studies such symptoms occur immediately at gasoline vapor concentrations of at least 1000 ppm (parts per million). Having examined medical histories of Sean Reeps’ mother and father, this expert decided that his parents or he himself had no other health problems or exposures likely to have caused Sean’s congenital malformations and developmental impairments. She concluded by stating that “there is strong scientific support for a toxic etiology of Sean Reeps’ congenital malformations, and that gasoline exposure from Debra Reeps’ automobile is the most likely cause of his birth defects” (*id.*, ¶53).

Other experts brought by plaintiffs concurred in the opinions of Dr. Kramer and Dr. Frazier on the cause of Sean Reeps disease while taking up additional subjects in their disclosure statements. Dr. Bearer planned to expand on these opinions by explaining the mechanisms by which toxicants might affect developing human cells. Dr. Thomas Sandler would describe the embryonic development in the first trimester of pregnancy and particular vulnerability of a fetus to toxins. Dr. Chung would provide testimony about Reeps' medical condition, his family history, and genetic tests she performed on Sean Reeps. It is her opinion that genetic causes of Reeps' condition can be ruled out, and the only explanation for his birth defects and developmental delays is prenatal exposure to gasoline vapors. Dr. Daniel Adler, who examined and evaluated Sean Reeps in 2010, is prepared to testify about details of his multiple illnesses and their permanent character. He deferred to other experts' opinion on the effect of environmental toxins on a fetus and concluded that exposure to gasoline was a substantial cause in producing Reeps' injuries.

In November 2010 defendants BMW and Hassel Motors moved for summary judgment to dismiss the complaint against them, which was denied by order of this court dated July 18, 2011. On August 4, 2011 the current motion followed. It was heard on November 2, 2011. The motion was stayed due to the appeal of the July 18, 2011 order. On April 5, 2012 the Appellate Division, First Department, modified and affirmed the order. Now the court returns to the motion on a Frye hearing.

THE MOTION

Defendant's Argument

Defendant BMW argues that the evidence and methods upon which plaintiffs' experts base their theories of general and specific causation are novel, unorthodox, unreliable and not generally accepted in the relevant scientific communities. (Semprevivo Aff., at ¶26).

Defendant's expert Dr. Anthony Scialli, an obstetrician-gynecologist and reproductive toxicologist, reviewed the medical records and other evidence in the case, along with all the articles, studies and reports identified or cited in plaintiffs' CPLR 3101(d) expert disclosures, and other reports or studies considering consequences of gasoline vapor inhalation. His two objectives were to determine whether the conclusions reached by plaintiffs' experts were (1) generally accepted within the medical and scientific communities and (2) reached by applying methods generally accepted within the relevant medical and scientific communities. He concentrated on expert submissions of Dr. Kramer and Dr. Frazier, since they provided extensive arguments on the causation of Sean Reeps diseases, endorsed by other experts brought by plaintiffs.

As to the first issue, Dr. Scialli concluded that no scientific publication establishes a causal relationship between inhalation of gasoline during pregnancy and the birth defects and developmental abnormalities diagnosed in Sean Reeps. Moreover, he argued there is no study on human subjects (neither a cohort or case control study) showing any association between exposure to gasoline vapor during pregnancy and birth outcomes found in Sean Reeps' case¹ (Scialli Aff, Def. Exh. A, at ¶24). Finally, the published animal studies evaluating the effects of gasoline vapor exposure during pregnancy demonstrated the absence of any adverse developmental outcomes, even with exposure to high levels of gasoline vapor.

¹ In cohort studies, the investigators obtain information about people and their exposures at baseline, let time pass, and then assess the occurrence of outcomes. Investigators commonly make contrasts between individuals who are exposed and not exposed or among groups of individuals with different categories of exposure. In case-control studies, investigators compare exposures between people with a particular disease outcome (cases) and people without that outcome (controls). *See*, PLOS. Medicine. A Peer-Reviewed, Open-Access Journal, available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040297>

Dr. Scialli next evaluated the methodology by which plaintiff's experts arrived at their conclusions. He stated that the generally accepted methods in developmental toxicology for establishing the causal relationship between exposure to chemicals and birth defects are based on standards known as Bradford Hill criteria. They are:

1. Strength of association
2. Consistency
3. Specificity
4. Temporal relationship (temporality)
5. Biological gradient (or dose-response curve)
6. Plausibility
7. Coherence
8. Experiment
9. Analogy

Dr. Scialli criticized Dr. Kramer's reliance on two human case report articles suggesting an association between intentional inhalation of leaded gasoline and birth defects on the ground of specificity, since both exposure (to leaded gasoline) and adverse outcomes, such as miscarriage and morphological deformations, are distinct from those in the Sean Reeps' case. He also objected to the use of experimental animal studies which deal with such outcomes as cancer, increased rate of miscarriage or perinatal death, anemia, and other conditions not relevant to Reeps' circumstances.

Other studies, cited by plaintiffs' experts, show the effect of gasoline's ingredients (such as toluene, ethylbenzene, xylene and benzene) on reproductive and developmental outcomes. These components of gasoline, taken together, account for no more than 2% of gasoline vapor. To inhale a significant amount of these gasoline components Debra Reeps would have had to undergo prolonged exposure to gasoline causing death. Thus the absence in the experts' analysis

of dose assessment capable of producing the observed outcomes in Sean Reeps does not meet the Bradford Hill standard to measure biological gradients.

According to Dr. Scialli, some of Dr. Kramer's conclusions are not consistent with knowledge generally accepted in the medical and scientific communities regarding development of cells in the brain and spinal cord (plausibility and coherence principles). In the early stages of pregnancy, oligodendrocytes that plaintiffs claim were injured by gasoline exposure, had not yet been formed, and thus could not have been damaged by exposure to gasoline.

Finally, Dr. Scialli asserts that plaintiffs' experts failed to follow generally accepted practices for determining causation by ignoring causes other than gasoline vapor inhalation that could have produced the features and developmental delays diagnosed in Sean Reeps.

Intrauterine infection is among the most common causes of cerebral palsy, and Mrs. Reeps had a history of herpes simplex infection, and a rash during her pregnancy.

The second defense expert, Peter Lees, is a specialist in industrial hygiene and environmental health sciences. He assessed the validity of the methods plaintiffs' experts used to determine the quantity of gasoline vapors to which Mrs. Reeps was exposed. No measurements of the concentration of gasoline vapors in Mrs. Reeps' vehicle were made at the time of the leakage, so that there exists no objective, quantifiable data on the issue. Plaintiff's expert Dr. Linda Frazier expressed the opinion that Debra Reeps was exposed to at least 1000 ppm because she reported experiencing nausea and headaches after smelling gasoline. Peter Lees opined that the use of a subject's reported reaction to the smell of gasoline to quantify the magnitude of person's exposure is not consistent with accepted scientific practices and methodology. Studies show that people's reactions to odors may vary greatly independent of

objective measurements of quantities of odor-producing substances, and can result in physical symptoms and complaints at levels far below toxicity.

In the absence of calculations by plaintiff's experts of how extensive the actual gasoline leak had to be to create a vapor concentration of 1000 ppm in the passenger compartment of the car, Peter Lees made his own calculations. He determined that liquid gasoline had to leak and evaporate at a rate of 0.25 gallons per mile to generate 1000 ppm in the engine compartment, and about a gallon per mile to reach the same level in the passenger compartment. There is no evidence to corroborate the existence of such a leak. He concluded that plaintiffs' experts have not correctly identified the concentration of gasoline vapor to which Mrs. Reeps was exposed and that methods they have employed to try to do so were flawed and improper.

Plaintiffs' opposition to a Frye hearing

Plaintiffs contend that a motion for a Frye hearing is precluded by the procedural history of the present case. Defendants have already made and lost the summary judgment motions that raised, *inter alia*, the adequacy of plaintiffs' expert proofs. In opposition to the motion for summary judgment, plaintiffs submitted affidavits of Linda Frazier and Shira Kramer. Plaintiffs assert that this court has already ruled on the sufficiency of plaintiffs' proof of causation.

Turning to the merits of defendants' motion, plaintiffs claim that the methodologies used by their experts are well-established and far from novel (George's Aff. at ¶16). Among these methodologies they list the Bradford Hill criteria, the use of animal studies (*id.* at ¶24), and epidemiology (Pl. Memo of Law, P.8). The disagreements between parties' experts are to be expected, but they are confined to different conclusions on questions of causation or exposure and do not extend to methodologies.

In response to Scialli's and Lees' analyses plaintiffs chose to rely on attorneys' rebuttals in Danielle George's affirmation and a memorandum of law rather than invite their experts to address the issues raised by defendant's experts. They view the present motion as an improper attempt to obtain pretrial expert disclosure not permitted by the CPLR, add unnecessary and substantial extra expense to the prosecution of this action, burdening the court and the parties with time-consuming delay (Pl. Memo of Law, P.3). They suggest that at trial defendants will have every opportunity to object to the opinions of plaintiffs' experts or seek to strike them on Frye grounds.

DISCUSSION

This court did not rule on the sufficiency of medical experts' theory of causation. Issues before the court on defendants' motion for summary judgment were the existence of a specific defect in the car, and defendant's criticisms of plaintiff's experts' theory of causation linking odors in the car to an alleged defect. (see Beadle Reply Aff., Pl. Exh. A) The court noted affidavits of plaintiffs' experts, including medical experts, submitted in opposition to the motion for summary judgment, and accepted them as sufficient to raise an issue of fact to preclude summary judgment. This in itself does not mean that the expert evidence meets scientific standards, an issue on this motion for a Frye hearing. A Frye hearing is evidentiary, separate from dispositive motions, and can be held prior or during the trial. It is appropriate at this junction of the proceedings.

An expert opinion on causation in toxic tort cases should set forth a plaintiff's exposure to a toxin, show that the toxin is capable of causing the particular illness (i.e., general causation), and that the plaintiff was exposed to levels of the toxin sufficient to cause illness (i.e., specific causation) (Parker v Mobil Oil Corp., 7 N.Y.3d at 448, 824 N.Y.S.2d 584; 824 N.Y.S.2d

584[2006]). Plaintiffs' experts expressed opinions on all three required elements of proof of causation. They claim that Sean Reap was exposed to gasoline vapors in the first trimester of Mrs. Reeps' pregnancy, that there is a causal link between *in utero* exposure to gasoline vapor and birth defects of the type diagnosed in Sean Reeps (general causation), and that Mrs. Reeps' and consequently Sean Reeps' exposure was such that it led to his birth and developmental defects (specific causation). Defendants question the approach plaintiffs' experts took to arrive at these conclusions.

Dr. Kramer's report sets forth the general theory of causation, an indispensable part of plaintiffs' case. It is undisputed in this case that there are no scientific publications that explicitly establish that exposure of a human embryo to unleaded gasoline in quantities above a certain threshold leads to birth defects such as cerebral palsy, congenital heart defect, or to severe mental retardation. Plaintiffs' expert sought to establish general causation by a synthesis of the existing literature, applying sound scientific methodology.

The *Frye* test is not concerned with the reliability of a particular expert's conclusions, but rather, with whether the expert[s] deductions are based on principles that are sufficiently established to have gained general acceptance as reliable. 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 v City of New York, 88 AD3d 384, 394; 932 N.Y.S.2d 428 [1st Dept 2011](internal quotations omitted).

This methodology must meet the standards that the scientific community requires, for instance, to accept an article in a peer-reviewed journal. General agreement with the theory advanced by an author of a publication is not a requirement. On the contrary a novel theory is of

particular interest to a professional audience, as long as it is based on recognizable scientific principles. “[T]he court's concern must be limited to making sure that within the scientific field in question, there is a substantive, demonstrable, objective basis for the expert's conclusion. The appropriate question for the court at such a hearing is the somewhat limited question of whether the proffered expert opinion properly relates existing data, studies or literature to the plaintiff's situation, or whether, instead, it is ‘connected to existing data only by the ipse dixit of the expert’” Marsh v Smyth, 12 AD3d 307, 312-13; 785 N.Y.S.2d 440 [1st Dept 2004](Saxe, J., concurring).

It is plaintiff's burden to show that his or her expert's theory is generally accepted in the relevant community Lara v. New York City Health & Hosp. Corp., 305 A.D.2d 106, 757 N.Y.S.2d 740 [1st Dept 2003]. It is also plaintiff's burden to prove that the methodology applied to reach the conclusions will not be rejected by specialists in the field.

Plaintiffs' experts – Dr. Kramer and Dr. Frazier – refer to the Bradford Hill criteria as their guiding principles. This is the methodology widely shared in the field of epidemiology and toxicology where it originated, and applied in teratology (the study of malformations or serious deviations from the normal type in developing organisms). “[T]he test pursuant to *Frye v. United States*, 293 F. 1013 poses the more elemental question of whether the accepted techniques, *when properly performed*, generate results accepted as reliable within the scientific community generally.” People v Wesley, 83 NY2d 417, 422; 611 N.Y.S.2d 97 [1994] (emphasis added). The key issue, on this motion for a Frye hearing, is whether plaintiffs' experts in fact are applying Bradford Hill criteria, or rather pay lip service to them while pursuing a completely different enterprise.

As Sir Austin Bradford Hill characterized his approach, his criteria are applicable when one needs to move from observed association between two phenomena to proof of causation. "Here then are nine different viewpoints from all of which we should study association before we cry causation." Austin Bradford Hill, "The Environment and Disease: Association or Causation?," *Proceedings of the Royal Society of Medicine*, 58 (1965), 295-300. The starting point in causal analysis is the establishment of association.

The court would have been assisted by plaintiffs' experts if they had clearly stated what phenomena they sought to relate to each other. Sean Reeds was diagnosed with multiple debilitating conditions. It is within the professional knowledge of experts, not of the court, whether various symptoms are manifestations of one disease, or whether Sean Reeds is afflicted with several diseases. Dr. Kramer states that "disease classification is a crucial consideration in all epidemiological studies of birth defects, because certain groupings of birth defects may obscure potential associations between specific birth defects and exposure to a potential teratogen." (Kramer Report, at ¶71). In her report Dr. Kramer attempts to establish a relationship between any of Reeds' numerous syndromes and any of the gasoline components, thus dealing with a number of potential associations, not a single association.

Only two case reports, involving a total of eight mothers, exist of fetal abnormalities following inhalation of leaded gasoline during pregnancy. As both Dr. Kramer and Dr. Fraser admit, lead, and not gasoline vapors per se, could have affected the fetal development. However, morphological deformations observed in these newly born were distinct from those in Sean Reeds. Moreover, in 1993 the doctors who diagnosed two of Reeds' condition (microcephaly and spastic quadriplegia) contacted the author of one of the reports by letter and enclosed a photograph of Sean. In her response Dr. Cheryl Greenberg stated that "the phenotype of this

young boy does not at all resemble the babies we have seen who have been exposed to leaded gasoline in pregnancy. Our patients have all been normal to macrocephalic with elongated skulls.” With the usual reservations about syndrome diagnosis from a photograph, Dr. Greenberg concluded that “the likelihood of the specific teratogenic exposure from a faulty fuel line and exhaust system early in pregnancy seems extremely remote” (Def. Exh. M).

The largest part of Dr. Kramer’s report is devoted to description of studies detailing various birth outcomes among women exposed to certain volatile components of gasoline, particularly organic solvents and more specifically the aromatics (benzene, toluene, xylenes). The move from the study of the effect of inhaling unleaded gasoline to the study of inhaling its components is justified by this expert on the ground that gasoline is a mixture of volatile solvents and short-chain hydrocarbons. This is not a generally accepted principle of proof in epidemiological research. In fact, a similar deficiency was noted in Parker v Mobil Oil Corp., at 449-50 (the expert concentrated on the relationship between exposure to benzene and the risk of developing acute myelogenous leukemia (AML) —an association that was not in dispute. Key to the litigation was the relationship, if any, between exposure to gasoline containing benzene as a component and AML).

Dr. Kramer cites numerous epidemiological studies on organic solvents in general that may include benzene and toluene. She broadly includes in her sample studies that deal with occupational exposure to a mixture of solvents, including styrene, polyester resin, organic peroxides, and acetone (Kramer Report, at ¶90), or that simply refer to solvents (*id.*, at ¶¶ 91, 95), or even to chemicals of which the aromatics in general and toluene in particular represented only a small proportion in observed exposure (respectively 19 and 11 out of 174) (*id.*, at ¶94). The outcomes of exposure to solvents are varied -- some related to Reeps’ situation even if

tenuously (developmental retardation, but not severe retardation; neurological consequences, but not cerebral palsy), others not at all related (DNA damage, cancer). The section of Dr. Kramer's report dealing with toluene is distinctive in connecting only one element to adverse birth outcomes. Toluene is a main component of spray paints, glues, and lacquers, often used for solvent abuse (*id.*, at ¶110). Its effect on birth defects has accordingly been well documented in various case reports. Combining both epidemiological studies and case reports Dr. Kramer compiled a list of birth defects and abnormal clinical findings, which, in her terms, are associated with exposure to gasoline vapor or constituents of gasoline during pregnancy (*id.*, at ¶126).

This is the basis of Dr. Kramer's conclusion about general causality: "To a reasonable degree of scientific certainty, the overwhelming majority of studies regarding the effects of gasoline, toluene, and other organic solvents on human health support the conclusion that exposure to gasoline vapor and its chemical constituents is causally related to increased risk of birth defects and adverse birth outcomes."

This conclusion is problematic in several respects. First, it is not a statement on general causation in the case at bar. Relevant to Sean Reeps' case would be an unambiguous statement that exposure to gasoline vapor in the early gestation period is causally related to spastic quadriparesis (or cerebral palsy in general), microcephaly, cardiac disorders of the type Sean Reeps has, or any other of his diagnosed diseases. The expert's imprecision on this point is not accidental. Dr. Kramer concedes that "studies which fail to identify an association between gasoline or solvent exposure and *specific* birth defect(s) typically have very lower (sic) power because of small sample sizes for individual birth defects, and do not address the overall teratogenic potential of the exposure." (emphasis in the original, at ¶129). She adds: "Failure to

detect a statistical association does not establish that there is no association between an exposure and an outcome” (*id.*). At issue in this case are the specific birth defects found in Sean Reeds, and the burden to prove a cause-and-effect relationship between exposure to gasoline and these birth defects falls on the plaintiffs. Intentional inhalation of toluene, a minor component of gasoline vapor, but a substantial part of sprays and lacquers, is not comparable to accidental inhalation of gasoline. The expression “exposure to gasoline vapor and its chemical constituents” is misleading: it conceals that existing studies do not conclusively establish a connection between exposure to unleaded gasoline and birth defects.

Second, neither Dr. Kramer, nor any other of plaintiffs’ experts, assess the threshold level at which maternal exposure to gasoline vapor is capable of producing adverse birth effects in general, or specific effects in this case. Parker v Mobil Oil Corp cited the World Health Organization’s and National Academy of Sciences’ recommendation as to how to establish causation:

(1) determining the plaintiff’s exposure to the particular toxin; (2) general causation, which is proof that the toxin in question can in fact cause the illness, and the amount of exposure required to cause the illness (the dose-response relationship); and (3) specific causation--meaning the likelihood that plaintiff’s illness was caused by the toxin, including eliminating other potential causes of the disease.

Parker v Mobil Oil Corp., at 450, n.2 [2006].

The threshold level of exposure is an element of general causation. The Parker court went on to say “[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” (Parker, at 448). The “dose-response relationship” here means a comprehensive table of correspondence between a range of

doses and a range of responses and a requirement that plaintiff's exposure to a toxin should be placed in a definite cell of this table. It does not mean that the New York courts abolish a general scientific principle that there must be a quantifiable minimum level of exposure which is capable of producing the disease. In a series of cases the First Department rejected plaintiffs' theory of causation for failure to assess the threshold of exposure to a harmful substance. Coratti v Wella Corp., 56 AD3d 343; 867 N.Y.S.2d 421 [1st Dept 2008] (plaintiff's experts did not even attempt to show how much exposure to which chemical or chemicals, whether phenylenediamine, resorcinol or some other substance, will render an individual susceptible to toxic poisoning, the extent of plaintiff's exposure to each chemical or the quantity of each present in defendants' products). Fraser v 301-52 Townhouse Corp., 57 AD3d 416, 420; 870 N.Y.S.2d 266 [1st Dept 2008] (while plaintiffs did offer a measure of the level of mold present in the apartment, their experts did not testify to any threshold level at which mold is capable of causing the injuries of which plaintiffs complain).

Expanding on her conclusion about the cause-and-effect relationship between the gasoline and/or its components and "the elevated risk of birth defects among children prenatally exposed to these chemicals during early pregnancy" Dr. Kramer adds:

Gasoline vapor and specific chemical constituents of gasoline have been associated with a variety of adverse birth outcomes, including: mental retardation, developmental delay, growth retardation, microcephaly, abnormal muscle tone, hyperreflexia, craniofacial defects, skeletal defects, cerebral palsy, behavioral/attentional issues, ocular and vision defects, cardiac defects, gastrointestinal defects, limb defects, kidney defects, major central nervous system defects, and congenital malformations (in general).
(Kramer Report, at ¶79).

The key to this passage is the term “associated.” It is a well-known scientific principle that “association is not causation,” or “correlation is not causation.” Courts are well aware of this principle, and sometimes expressly cite it.

While there is general agreement that indoor dampness and mold are ‘associated’ with upper respiratory complaints, defendants’ experts took the position, consistent with the literature they submitted, that the observed association between such conditions and such ailments is not strong enough to constitute evidence of a causal relationship. In other words, “*‘association’ is not equivalent to ‘causation’*”

Fraser v 301-52 Townhouse Corp., at 417.

Assuming that all harmful effects of gasoline vapor and its chemical components were indeed recorded in the literature, the term “associated” is used by the expert very loosely as she does not use “association” in a statistical sense, that is as a correlation. Dr. Kramer freely combines case reports and epidemiological studies, while in her discussion of epidemiological principles she distinguishes them stating that “case reports are not controlled studies” (Kramer Report, at ¶15). Case reports do not measure the prevalence of a disease in a population. In case reports, “association” suggests the possibility of a link between two observed phenomena, but controlled studies are required to establish such a link. For this reason “[c]ourts have recognized that such observational studies or case reports are not generally accepted in the scientific community on questions of causation.” Heckstall v Pincus, 19 AD3d 203, 205; 797 N.Y.S.2d 445 [1st Dept 2005] (internal citations omitted). In her report, Dr. Kramer moves directly from observations obtained in case studies to conclusions on causality without reference to the role of statistical associations in establishing causality.

Dr. Kramer stated that she would apply Bradford Hill criteria. Courts are familiar with these generally accepted scientific principles. See, for example, description of an expert

testimony that follows the nine-step process proposed by Sir Austin Bradford Hill. Nonnon v City of New York, at 391-93. In the case at bar neither Dr. Kramer, nor Dr. Fraser, who also referred to Bradford Hill criteria, actually applied the nine-step process in arriving at conclusions about causality. Dr. Kramer wrote: "Compelling bases for causation in this case include: consistency of findings across the epidemiological/medical reports and toxicological studies, biological plausibility, and temporality."(*id.*, at 148). These are indeed among Bradford Hill criteria. However, defendants' expert, Dr. Scialli, raised strong reservations concerning plaintiffs' experts' inadequate attention to consistency, gradient, coherence and plausibility. In the court's opinion, the lack of epidemiological studies of the association between *in utero* exposure to gasoline and birth defects raises the question of whether the Bradford Hill criteria are even applicable to this case.

The second plaintiff's expert, Dr. Frazier, did not attempt to present a systematic review of literature. She cites a number of studies, without distinguishing between case reports and epidemiological studies and without relating them to Sean Reeds' circumstances. These studies concern increased rates of miscarriage among women working with petrochemicals, increase of congenital cardiovascular defects among children born to women exposed to hydrocarbon solvents, neurological problems among workers exposed over a period of years to organic solvents, increased rates of childhood cancer among offspring of women exposed to solvents during pregnancy. In the latter example it is sufficient to note that cancer is not among Sean Reeds' multiple abnormalities. Referring to a disease that Sean Reeds actually has, cerebral palsy, Dr. Frazier remarks: "It is entirely plausible that prenatal toxic environmental exposure can cause this condition. Only 14.5% of cerebral palsy cases are caused by intrapartum hypoxia or ischemia" (*id.*, at 42). This is not a statement of causation. The proffered expert opinion "is

connected to existing data only by the ipse dixit of the expert” and does not “properly relate existing data, studies or literature to the plaintiff’s situation” (Marsh v Smyth, at 312-13).

Dr. Frazier’s testimony, however, is central to plaintiffs’ case that Debra Reeds’ exposure to gasoline was equivalent to at least 1000 ppm. Taking this as established fact, Dr. Kramer analogized this exposure to recreational solvent abuse which may match or even exceed the level that, in mathematical models, corresponds to doses administered to rats and producing adverse effect on their offspring (Kramer Aff., at ¶24). Dr. Kramer’s chain of deductions is the only attempt to compare Sean Reeds’ claimed *in utero* exposure to gasoline to a threshold level damaging to the developing fetus, in order to prove specific causation. Defendants’ expert, Peter Lees, explained why the procedure by which Dr. Frazier arrived at the number 1000 ppm is contrary to accepted scientific methodology. Dr. Frazier used a 1942 study that at most reported that a known quantity of gasoline vapor at the level of 1000 ppm may cause the subject to experience nausea and headache. In the opinion of Dr. Lees, shared by this court, it does not follow that a person experiencing nausea and headache after smelling gasoline must have been exposed to 1000 ppm of the substance.

Dr. Frazier also bypasses measuring Debra Reed’s exposure to gasoline vapor by making a sweeping statement: “teratogens² can cause birth defects after a single high exposure during critical periods of fetal development.” (*id.*, at ¶29), citing toxicological studies of rats. She does not explain what “high exposure” means in relation to pregnant women. In connection with the etiology of cerebral palsy, she relies on research demonstrating that cerebral palsy, in which there is damage to the brain’s white matter, results from injury to immature oligodendrocyte brain cells by way of the free radicals that the fetus is unable to detoxify. From this it follows that “an extended first trimester exposure to gasoline components would harm the fetal brain cells

² Substance capable of producing fetal malformation

involved in the pathogenesis of cerebral palsy by striking at a time when these cells are least able to defend themselves.” (*id.*, at ¶45). It is generally accepted in the scientific community that the vulnerability of white matter to injury is related to the presence of pre-oligodendrocytes at gestational age 24–32 weeks in humans ((Hadberg and colleagues. “Models of white matter injury: comparison of infectious, hypoxic-ischemic, and excitotoxic insults.” *Mental Retardation and Developmental Disabilities Research Reviews*, 2002; 8:30-8; Johnston and Hoon. “Cerebral Palcy.” *Neuromolecular Medicine* 2006; 8:435-50). The thesis that the first trimester of pregnancy is the most dangerous for cerebral palsy, crucial for proving general causation in the present case, lacks support in the scientific literature cited to the court by the plaintiffs’ expert herself.

While Dr. Kramer and Dr. Frazier devoted their reports mostly to issues of general causation, of the harmful effect of gasoline and gasoline components on birth defects, they also expressed an opinion on what caused Sean Reeps’ diseases. 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”. Ruling out alternative explanations for the birth defects experienced by Sean Reeps, she expressed a reasonable degree of scientific certainty that exposure to the chemical constituents of gasoline vapor, individually or in combination, was a substantial causal factor in Sean Reeps’ defects at birth (Kramer Report, at ¶152). This conclusion on special causation is subject to the same flaws as the expert’s conclusion on general

causation – 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.

All plaintiffs' medical experts, including Dr. Kramer and Dr. Frazier, conducted the differential diagnosis of Sean Reeds condition and agreed that there was no cause for his malformations and developmental delays apart from *in utero* exposure to gasoline. The disagreement between plaintiffs' and defendants' experts on the quality of this analysis, such as the weight to be given to possible infection during Debra Reeds' pregnancy, is not a proper subject for a Frye hearing. However," in order to be considered as a possible cause, in a differential diagnosis matrix, a given agent must be capable of causing the harm observed." Cornell v 360 W. 51st St. Realty, LLC, 95 AD3d 50, 61; 939 N.Y.S.2d 434 [1st Dept 2012], what was not done in this case.

Dr. Kramer's and Dr. Frazier's opinions do not comport with methodologies prevailing in the epidemiological and toxicological scientific communities and on occasion depart from generally accepted rules of drawing conclusions from premises. They provide insufficient support for the conclusion that exposure to gasoline in some unidentified concentration in the first trimester of pregnancy can cause cerebral palsy, microcephaly or any other condition found in Sean Reeps (general causation), or that such exposure actually led to his illness (specific causation). For this reason their testimony must be precluded. "The Frye's 'general acceptance' test is intended to protect juries from being misled by expert opinions that may be couched in formidable scientific terminology but that are based on fanciful theories " Marso v Novak, 42 AD3d 377, 378-79; 840 N.Y.S.2d 53 [1st Dept 2007] (internal citations omitted). "An expert's inability to show that his or her proffered theories have achieved general acceptance requires that

his or her testimony be excluded. This is in keeping with the "inherent power of all trial court Judges to keep unreliable evidence ('junk science') away from the trier of fact regardless of the qualifications of the expert. A well-credentialed expert does not make invalid science valid merely by espousing an opinion." Styles v Gen. Motors Corp., 20 AD3d 338, 342; 799 N.Y.S.2d 38 [1st Dept 2005](internal citations omitted).

The extensive reports in which experts could fully present their arguments make a separate Frye hearing redundant.

CONCLUSION

For the foregoing reasons, it is

ORDERED that Dr. Kramer's and Dr. Frazier's expert testimonies are precluded from trial.

Dated: 12/16/12

ENTER:

Frye
J.S.C.

FILED
DEC 21 2012
NEW YORK
COUNTY CLERK'S OFFICE

LOUIS B. YERGEN
J.S.C.