

**Court of Appeals
of the
State of New York**

ERIC PARKER,

Plaintiff-Appellant,

-against-

**MOBIL OIL CORPORATION, ISLAND TRANSPORTATION
CORPORATION AND GETTY PETROLEUM MARKETING, INC.,**

Defendants-Respondents.

(For Continuation of Caption See Reverse Side of Cover)

**BRIEF OF AMICUS CURIAE CHAMBER OF COMMERCE
OF THE UNITED STATES OF AMERICA IN SUPPORT
OF RESPONDENTS MOBIL OIL CORPORATION,
ISLAND TRANSPORTATION CORPORATION AND
GETTY PETROLEUM MARKETING, INC**

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GETTY PETROLEUM MARKETING, INC.,

Third-Party Plaintiff-Respondent,

-against-

**MOBIL OIL CORPORATION, EXXON MOBIL CORPORATION
AND NEW YORK OIL PRODUCTS, INC.,**

Third-Party Defendants-Respondents,

**POST AVENUE SERVICE STATION, INC., JOHN CAMPSEY, ROBERT
ADLER, DOUGLAS DARROW, ISLAND TRANSPORTATION
CORPORATION, AMERADA HESS CORPORATION, CROWN CENTRAL
PETROLEUM, HUNTINGTON CREEK ROAD CORP., SEAMUS SERVICE
CENTER LANDVIK REALTY CORPORATION, NORTHVILLE
INDUSTRIES CORP., LOU HALPERIN STATIONS, INC., BAYWAY
REFINING COMPANY-TEXAS AS SUCCESSOR-IN-INTEREST TO PHIBRO
ENERGY-USA, INC. EXXON CORPORATION AND G&L SERVICE
STATION INC.,**

Third-Party Defendants.

ISLAND TRANSPORTATION CORPORATION,

Second Third-Party Plaintiff-Respondent,

-against-

**ATLANTIC STAR TRAILER, HEIL CO., INC., FRUEHAF INC. and WALBASH
NATIONAL INC.,**

Second Third-Party Defendants.

NEW YORK OIL PRODUCTS, INC.

Fourth Third-Party Plaintiff,

-against-

**U.S.A. PETROLEUM PRODUCTS CORP. and ROCKVILLE PETROLEUM,
INC.,**

Fourth Third-Party Defendants.

ISLAND TRANSPORTATION CORPORATION,

Fifth Third-Party Plaintiff,

-against-

KELSEY/HAYES COMPANY LBT, INC. and FRUEHAUF TRAILER CORP.,

Fifth Third-Party Defendants.

CORPORATE DISCLOSURE STATEMENT

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The Chamber of Commerce of the United States of America respectfully submits this brief, accompanied by its motion for *amicus curiae* relief under 22 NYCRR §§ 500.12(e) and 500.23, in support of Defendants-Respondents Mobil Oil Corporation, Island Transportation Corporation, and Getty Petroleum Marketing, Inc. in the above-captioned action.

STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America (the “Chamber”) is the world’s largest business federation, representing more than three million businesses and organizations of every size, in every sector, and from every region of the country. It includes hundreds of associations, thousands of local chambers, and more than 100 American Chambers of Commerce in 91 countries. An important function of the Chamber is to represent the interests of its members in court on matters of significant concern to the business community. In fulfilling that role, the Chamber has filed in excess of 1000 *amicus curiae* briefs in state and federal courts across the country.

The standard by which trial courts decide whether to admit expert scientific evidence is of the utmost importance to the Chamber and its members, who frequently engage in litigation involving expert opinions offered across a wide range of technical or complex scientific areas outside the ken of most lay jurors and judges. Because such expert opinions exert enormous influence over the

outcome of litigation – and, indeed, often determine whether claims survive a motion for summary judgment – the admission of speculative, conclusory, or otherwise unreliable expert testimony poses grave concerns to the Chamber and its membership. Of particular concern is the admission of unreliable expert testimony on the question of causation, which has become one of the most critical yet complex aspects of modern tort litigation.

The Chamber is filing this brief as *amicus curiae* in support of Defendants-Respondents Mobil Oil Corporation, Island Transportation Corporation, and Getty Petroleum Marketing, Inc. because it believes that a reasoned, particularized basis for determining causation is absolutely essential in a legal system that is designed to compensate *individual* plaintiffs for injuries caused by *individual* defendants. New York’s trial courts have a vital role in ensuring that lay juries consider expert scientific testimony attributing a particular plaintiff’s injury to a particular defendant’s product or conduct only when that testimony is based on principles generally accepted as reliable in the relevant scientific field. The Chamber is concerned that there is a need to affirm this basic understanding, and the long-settled precedent upon which it is premised, in view of potential confusion emerging in a minority of this State’s lower courts on this important question. Accordingly, the Chamber respectfully submits this brief as friend of the Court and urges this Court to affirm the decision of the Appellate Division below.

INTRODUCTION AND SUMMARY OF ARGUMENT

Expert testimony is central to litigation today, nowhere more so than in complex product liability and toxic tort cases where even the most basic elements of a plaintiff's claim may fall outside the common realm of a lay jury's experience or understanding. As increasingly complicated cases require evidence concerning increasingly complicated science, jurors are increasingly likely to be swayed by so-called "junk science" or the mere *ipse dixit* of a credentialed expert witness whose words carry the aura of scientific infallibility. The court's role as "gatekeeper" in ensuring that jurors consider only reliable expert testimony therefore has never been more critical.

Although the cause-and-effect relationship between a plaintiff's injury and a defendant's conduct may generally be discernible to a lay jury through application of common sense in a traditional tort context, that is not often true in complex modern tort litigation. Plaintiffs in such cases may have to rely exclusively on expert scientific testimony to show, for example, that exposure to a specific agent caused their injuries. It therefore is crucial that scientific evidence admitted for this purpose be reliable. To be probative, such evidence must meet a threshold of reliability not only with respect to the general question whether substance A may sometimes be linked to condition B, but also with respect to the individualized

question whether a *particular* plaintiff's injury could have been caused by exposure to a *particular* defendant's product.

In addressing such evidence, New York has long adhered to the admissibility standard articulated in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923): a “scientific principle or discovery * * * must be sufficiently established to have gained general acceptance in the particular field in which it belongs.” *Id.* at 1014. The Appellate Division correctly applied this standard to the plaintiff's expert causation testimony in this case, not only with respect to the scientific methodology used to opine that plaintiff's condition (acute myelogenous leukemia) can be caused by the substance at issue (benzene), but that plaintiff's injury *was in fact* caused by his specific exposure to that substance in defendants' product (gasoline). This case provides the Court an opportunity to affirm that (i) *Frye* applies to expert testimony on causation just as it does to all other expert testimony and (ii) such testimony must rely upon principles generally accepted as reliable by the relevant scientific community in showing the *specific* causal connection between plaintiff's injury and the alleged source of that injury.

Failure to uphold these basic principles would have far-reaching negative implications because experts could then rely on speculation or mere *ipse dixit* to persuade a jury that the theoretical causal connection between a known toxin and a disease is sufficient to establish something very different – that a *plaintiff's* injury

was caused by exposure to a *defendant's* product. Such a result would effectively shift the burden to defendants to “disprove” causation, lead to increased frivolous litigation over any product containing any substance with any known toxicity (regardless of concentration or exposure), and turn courtrooms into unscientific laboratories that no longer adhere to the fundamental principle of individualized liability.

ARGUMENT

I. When Expert Scientific Testimony is Necessary to Establish the Causal Connection between the Plaintiff's Alleged Injury and the Defendant's Product or Conduct, the Decision Whether to Admit or Exclude Such Evidence is of Critical Importance

Courts and legal scholars have long recognized the anomalous status of the expert witness, who by definition is an authority in an area beyond the “range of common experience or common knowledge,” *Frye*, 293 F. 1013 at 1014, but whose testimony – like that of any other witness – is subject to evaluation by the lay fact-finder. *See, e.g.*, Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 50-55 (1901) (discussing the “anomaly” of the expert witness); E. Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. Rev. 487, 492 n.22 (1989) (“Our reliance on lay juries to assess the credibility of technical experts is not a problem, of course, if one is willing to assume that

something magical happens in the jury room so that ordinary people can suddenly unravel complex technical and scientific issues that would baffle the rest of us.”).

Perhaps nowhere is the “anomaly” described by Judge Hand any more pronounced – or any more consequential – than in the context of modern tort litigation. Complex product liability and toxic tort cases often (indeed, typically) involve technical or abstruse questions of scientific fact that a plaintiff can address only through expert testimony. Yet it is precisely such expert scientific evidence that a lay jury is both particularly unqualified to assess and particularly likely to find persuasive based on nothing more than the expert’s *curriculum vitae*. See, e.g., *Lara v. N.Y. City Health & Hosps. Corp.*, No. 111751/95, 2003 WL 21171497 (N.Y. Sup. Ct. Sept. 26, 2000) (setting aside \$12 million verdict because plaintiff’s expert’s medical causation theory, which was supported by no reported medical cases or formal studies, failed to meet the general acceptance standard), *aff’d*, 305 A.D.2d 106, 757 N.Y.S.2d 740 (1st Dep’t 2003). Accordingly, the trial court’s gatekeeper role in deciding whether to admit or exclude such expert testimony is of critical importance.

A. The Rise of Complex Product Liability and Toxic Tort Litigation Requires that Plaintiffs Increasingly Rely on Expert Opinions to Show Causation when it is Outside the Experience of Lay Jurors

In a traditional tort case, the cause-and-effect relationship between the defendant’s conduct and the plaintiff’s injury, also known as causation-in-fact, is

usually within the common range of experience of a lay jury. “Often, the cause-and-effect relationship is obvious: A’s vehicle strikes B, injuring him; a bottle of A’s product explodes, injuring B; water impounded on A’s property flows onto B’s land, causing immediate damage.” Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence After Daubert*, 55 U. Pitt. L. Rev. 889, 895 (1994). But that is not so in most product liability or toxic tort cases, like this one, where a plaintiff may allege that chronic low-level exposure to a harmful agent caused his or her disease, injury, or death. In litigation of this sort, “[s]everal factors often obscure the causal pathway between the putative exposures and the diagnosed illness.” Neal C. Stout & Peter A. Valberg, *Bayes’ Law, Sequential Uncertainties, and Evidence of Causation in Toxic Tort Cases*, 38 U. Mich. J.L. Reform 781, 783 (2005). Among the most common of such factors are uncertainty as to the duration and intensity of the plaintiff’s exposure, long latency periods between exposure and illness, and multiple potential confounding causes of the plaintiff’s disease (some of which may occur naturally in the background population) – in addition to the threshold question whether there is a “generally accepted” scientific basis for *ever* linking exposure to agent A with development of condition B. *Id.*

Consequently, “[c]ausation is typically the most problematic element of the toxic tort plaintiff’s case.” Eggen, 55 U. Pitt. L. Rev. at 893. Moreover, “the issue

of causation – whether the alleged exposures actually caused the plaintiff’s injury – is nearly always the central dispute.” Stout & Valberg, 38 U. Mich. J.L. Reform at 781. Plaintiffs therefore often must turn to experts to make out their prima facie case, because even threshold questions concerning such issues as exposure level will normally be outside the realm of experience or comprehension of a lay factfinder. When “the causal mechanism is unknown, establishing causation means providing scientific evidence from which an inference of cause and effect may be drawn.” Federal Judicial Center, *Reference Manual on Scientific Evidence* at 32 (2d ed. 2000). *See also, e.g., Savage v. Union Pac. R.R.*, 67 F. Supp. 2d 1021, 1030 (E.D. Ark. 1999) (“[T]he existence of a causal connection between exposure to a certain chemical and an alleged injury requires specialized expert knowledge and testimony since such matters are not within the common knowledge of lay persons.”).

Plaintiffs in toxic tort cases such as this one thus rely heavily on expert scientific testimony to establish the very essence of their allegations, namely that exposure to the defendant’s product caused their specific injury or condition. Indeed, Judge Weinstein has observed that, “in the mass toxic tort context * * * presentation to the trier of theories of causation depends almost entirely on expert testimony.” *In re “Agent Orange” Prod. Liab. Litig.*, 611 F. Supp. 1223, 1244 (E.D.N.Y. 1985). *See also* M. Neil Brown et al., *The Epistemological Role of*

Expert Witnesses and Toxic Torts, 36 Am. Bus. L.J. 1, 3 (1998) (“[I]n toxic tort cases, expert witness testimony is almost always necessary to prove causation.”).¹ Moreover, increasingly complex theories of causation require reliance on increasingly complex science – only exacerbating the difficulty for the lay jury given the task of evaluating an expert’s scientific opinion once such testimony is admitted. *See, e.g.*, Eggen, 55 U. Pitt. L. Rev. at 891 (“[O]ffers of expert scientific evidence to prove causation have become common and increasingly sophisticated. In areas of great uncertainty – and in some matters of lesser uncertainty – novel techniques and theories of causation have complicated the litigation landscape.”). This centrality of expert testimony means that although plaintiffs should be assured the opportunity to present *reliable* scientific evidence in support of their claims, the *exclusion* of unreliable expert testimony is essential to screen out meritless litigation and reduce the likelihood of insupportable and speculative verdicts.

B. Trial Courts Have an Important “Gatekeeping” Responsibility When Presented With Expert Scientific Testimony

Given the heightened significance of the role that expert opinions necessarily play in modern complex tort litigation, it should be no surprise that

¹ *Cf.* Carol Krafka et al., Fed. Judicial Ctr., *Judge and Attorney Experiences, Practices, and Concerns Regarding Expert Testimony in Federal Civil Trials* 10-11, 14 (2002), available at [http://www.fjc.gov/public/pdf.nsf/lookup/judattex.pdf/\\$file/judattex.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/judattex.pdf/$file/judattex.pdf) (reporting that tort actions constitute by far the largest proportion of cases involving expert testimony, and among the issues addressed by experts, causation is second only to the nature of the injury itself).

state and federal courts – regardless of whether they rely upon *Frye*, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), or some codification of evidentiary standards – stress the important “gatekeeper” role that trial courts have always played when expert testimony is presented. *See, e.g., Gilbert v. DaimlerChrysler Corp.*, 470 Mich. 749, 782 (2004), cert. denied, 126 S.Ct. 354 (2005) (“[P]roperly understood, the court’s gatekeeper role is the same under *Davis-Frye* [the state’s prior “general acceptance” standard] and *Daubert* * * * [B]oth tests require courts to exclude junk science; *Daubert* simply allows courts to consider more than just ‘general acceptance’ in determining whether expert testimony must be excluded.”); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997) (“[W]hile the Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than would have been admissible under *Frye*, they leave in place the ‘gatekeeper’ role of the trial judge in screening such evidence.”).

This Court has repeatedly affirmed that, in determining whether expert testimony should be admitted or excluded, New York employs the *Frye* “general acceptance” test. *See, e.g., People v. Wesley*, 83 N.Y.2d 417, 422 (1994) (“The long-recognized rule of *Frye v. United States* is that expert testimony based on scientific principles or procedures is admissible but only after a principle or procedure has ‘gained general acceptance’ in its specialized field.”); *People v.*

Wernick, 89 N.Y.2d 111, 115 (1996); *People v. Angelo*, 88 N.Y.2d 217, 222-23 (1996); *People v. Lee*, 96 N.Y.2d 157, 162 (2001).² And New York courts have repeatedly recognized the important gatekeeper role that *Frye* confers on trial judges; that role is an aspect of 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.” *Clemente v. Blumenberg*, 183 Misc.2d 923, 932, 705 N.Y.S.2d 792, 799 (Sup. Ct. 1999). *See, e.g., DeMeyer v. Advantage Auto*, 9 Misc.3d 306, 310, 797 N.Y.S.2d 743, 747 (Sup. Ct. 2005) (“Under the “*Frye*” test, courts, in effect, perform a gatekeeper function by making an initial determination as to whether or not the basis of expert opinion has gained sufficient general acceptance in a particular field in order to be considered reliable, and to justify admission at trial.”); *Ficic v. State Farm Fire & Cas. Co.*, 9 Misc.3d 793, 799, 804 N.Y.S.2d 541, 545 (Sup. Ct. 2005) (“The role of the trial judge as the ultimate gatekeeper of admissible [expert] testimony was affirmed by the Court of Appeals . . .”).

² Although the U.S. Supreme Court in *Daubert* concluded that the *Frye* general acceptance test was no longer the governing standard in the federal courts because it had been superseded by the Federal Rules of Evidence, New York remains one of several continuing *Frye* jurisdictions. For a geographical taxonomy of *Frye* versus *Daubert* states, *see, e.g.,* Edward K. Cheng & Albert H. Yoon, *Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards*, 91 Va. L. Rev. 471, 473 (2005).

When acting in this gatekeeping capacity, a trial court that is “asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist.” *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) (Posner, J.). This ensures that “when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work.” *Id.* To serve that function, courts have emphasized that “[t]his gatekeeper role applies to *all stages* of expert analysis” and that “[c]areful vetting of all aspects of expert testimony is especially important when an expert provides testimony about causation.” *Gilbert*, 470 Mich. at 782 (emphasis in original). Otherwise, juries may be influenced by the aura of infallibility that naturally accompanies scientific expert testimony, particularly on complex questions that are otherwise completely outside lay experience. *See, e.g., United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974) (“[S]cientific proof may in some instances assume a posture of mystic infallibility in the eyes of a jury of laymen.”); *O’Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1389 (C.D. Ill. 1992) (noting that scrutiny by a trial court is required because “an expert’s opinion ‘bears an aura of reliability and trustworthiness’”).

Screening out unreliable expert testimony serves a crucial role in preserving the health of the litigation system. Admission of such evidence would allow insubstantial claims to survive motions for summary judgment, impose substantial

discovery costs on defendants, and often lead defendants to settle even insubstantial claims for fear of enormous liability – thus encouraging plaintiffs to bring more meritless suits in the first place. And “ensuring the reliability of expert evidence is particularly important in products liability and toxic tort cases, where the economic stakes to the parties and to society are extremely high * * * The only way to protect society’s overall interests in toxic tort and products liability litigation is to enforce a standard that ensures the reliability of expert evidence, whether that standard be *Daubert*’s reliability test or the *Frye* general acceptance test.” David E. Bernstein, *Frye, Frye, Again: The Past, Present, and Future of the General Acceptance Test*, 41 *Jurimetrics J.* 385, 396 (2001).

II. This Court Should Affirm the Appellate Division Because Expert Causation Testimony is Subject to the Same Standard as all Other Scientific Evidence and is Admissible Only if it Relies upon Generally Accepted Principles to Show a Link Between Plaintiff’s Injury and Defendant’s Product or Conduct

The principle outlined above is by now well settled: courts must exercise a gatekeeper role in policing the introduction of expert testimony, applying the *Frye* or related standards to assure that such evidence is reliable. The question here is whether there should be an exception to this rule when the expert opines on issues of causation. *Amicus* submits that no such exception should be recognized. We accordingly urge the Court to affirm the decision of the Appellate Division because the court below properly (i) applied the *Frye* general acceptance admissibility

standard to the plaintiff's expert scientific testimony on causation and (ii) required that such testimony rely on principles generally accepted as reliable by the relevant scientific community to show a causal connection between plaintiff's injury and the specific alleged source of that injury. Although nearly all of the lower courts in this State – including the Appellate Division below – have correctly held that the *Frye* standard applies to expert scientific testimony on the issue of causation just as it would to other expert testimony, *amicus* urges the Court to expressly reaffirm that proposition because a minority of outlier opinions that have apparently taken a contrary view may lead to confusion on this critical issue.

A. This Court Should Clarify that There is No “Causation Exception” to the Standard for Admitting Expert Testimony Under *Frye*

In arriving at its decision below, the Appellate Division relied upon a straightforward articulation of the long-held standard for admission of expert scientific evidence initially set out in *Frye* and adopted by this Court: “Expert testimony is admissible provided that the principles and methodology relied upon by the expert have gained general acceptance as being reliable within the scientific community.” *Parker v. Mobil Oil Corp.*, 16 A.D.3d 648, 650, 793 N.Y.S.2d 434, 436 (2005) (citing *Frye* and *Wesley*, 83 N.Y.2d at 422-23).

The court below determined that the testimony of plaintiff's experts should have been excluded under this standard because the experts “failed to make a

causal connection, based upon a scientifically-reliable methodology, between the plaintiff's specific level of exposure to benzene in gasoline and his AML." *Parker*, 16 A.D.3d at 653, 793 N.Y.S.2d at 439. To that end, the court discussed a three-step process that would have constituted such a scientifically reliable methodology:

This three-step process includes: (1) a determination of the plaintiff's level of exposure to the toxin in question, (2) from a review of the scientific literature, proof that the toxin is capable of producing the illness, or general causation, and the level of exposure to the toxin which will produce that illness (*i.e.*, the dose-response relationship) must be ascertained, and (3) establishment of specific causation by demonstrating the probability that the toxin caused the particular plaintiff's illness, which involves weighing the possibility of other causes of the illness.

16 A.D.3d at 651, 793 N.Y.S.2d at 437.

There should be no doubt that the central insight of the decision below is correct. If *Frye* is meant to "protect juries from being misled by expert opinions that may be couched in formidable scientific terminology but that are based on fanciful theories," *Styles v. Gen. Motors Corp.*, 20 A.D.3d 338, 342, 799 N.Y.S.2d 38, 42 (1st Dep't 2005) (concurring opinion) (citations omitted), then the *Frye* general acceptance standard must apply equally when such opinions are offered to establish causation as when offered to establish any other aspect of a plaintiff's case. Indeed, as already discussed, given the increasing scientific complexity and centrality of expert causation testimony in tort litigation today, it would be particularly odd to carve out a "causation exception" to the long-held *Frye* general

acceptance standard. Decisions from each Department consistently have refused to do so.³

³ See, e.g., *Heckstall v. Pincus*, 19 A.D.3d 203, 204, 205, 797 N.Y.S.2d 445, 447 (1st Dep't 2005) (finding that "plaintiff failed to adequately show causation" when no showing under *Frye* standard that expert's "theory of causation has gained general acceptance in the scientific community") (citations omitted); *Pauling v. Orentreich Med. Group*, 14 A.D.3d 357, 357, 787 N.Y.S.2d 311, 312 (1st Dep't 2005) ("Plaintiff failed to meet her burden of proof at the *Frye* hearing that her theory of causation is generally accepted in the medical community.") (citations omitted); *Selig v. Pfizer, Inc.*, 290 A.D.2d 319, 320, 735 N.Y.S.2d 549, 551 (1st Dep't 2002) ("In the absence of any clinical data supporting their expert's theory that there is a causal link between the use of the drug Viagra and heart attacks in men with pre-existing coronary artery disease, it was incumbent upon plaintiffs to set forth other scientific evidence based on accepted principles showing such a causal link."); *Zito v. Zabarsky*, 28 A.D.3d 42, 44, 812 N.Y.S.2d 535, 537 (2d Dep't 2006) ("The trial court correctly concluded that the medical opinion in this case, that there was a causal connection between the allegedly excessive dose of Zocor and the onset of polymyositis, was a novel one, such that a *Frye* hearing was warranted."); *Lewin v. County of Suffolk*, 18 A.D.3d 621, 622, 795 N.Y.S.2d 659, 660 (2d Dep't 2005) ("The plaintiffs failed to meet their burden at a *Frye* hearing of establishing that their theory of causation is generally accepted in the medical and scientific community.") (citations omitted); *Del Maestro v. Grecco*, 16 A.D.3d 364, 366, 791 N.Y.S.2d 139, 141 (2d Dep't 2005) ("[T]he plaintiffs failed to meet their burden of proof of establishing that their expert's theory of causation was generally accepted in the medical community.") (citations omitted); *Saulpaugh ex rel. Saulpaugh v. Krafte*, 5 A.D.3d 934, 936, 774 N.Y.S.2d 194, 196 (3d Dep't 2004) ("Absent any controlled studies, clinical data, medical literature, peer review or supportive proof indicating that [the expert's causation] theory was generally accepted by the relevant medical community, Supreme Court properly excluded testimony regarding that theory.") (citations omitted); *Norberg v. Pepsi Cola Buffalo Bottling Corp.*, 10 A.D.3d 740, 742, 781 N.Y.S.2d 538, 539 (3d Dep't 2004) (finding an "absence of a [generally accepted] scientific foundation for the [causation] opinion of claimant's expert"); *Kaczor v. Vanchem, Inc.*, 262 A.D.2d 1041, 1042, 691 N.Y.S.2d 831, 832 (4th Dep't 1999) ("In the absence of a generally accepted basis in the scientific community for a medical opinion

In a case very similar to the one at bar, in which a plaintiff alleged that his leukemia was caused by exposure to benzene contained in bottled water, a federal court explained why this is so. Upholding the exclusion of plaintiff's expert testimony on the issue of causation, the court specifically acknowledged the "especially sensitive" gatekeeping role for judges in cases "where the plaintiff claims that exposure to a toxic substance caused his injury, [because a] jury may blindly accept an expert's opinion that conforms with their underlying fears of toxic substances without carefully understanding or examining the basis for that opinion." *Sutera v. Perrier Group of Am., Inc.*, 986 F. Supp. 655, 660-61 (D. Mass. 1997) (quoting *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995)).

Despite the clarity of this principle, however, at least one summary decision and another concurring opinion from the First Department have suggested that *Frye* may be inapplicable, or have a limited applicability, when causation is at issue. *In re N. Y. City Asbestos Litig.*, 24 A.D.3d 375, 375-76, 806 N.Y.S.2d 531, 532 (1st Dep't 2005) ("Since the parties argued over causation, no novel scientific technique or application of science was at issue, and a *Frye* hearing was not warranted."); *Marsh v. Smyth*, 12 A.D.3d 307, 311, 785 N.Y.S.2d 440, 444 (1st

regarding causation, such opinion amounts to nothing more than personal speculation.") (internal quotation marks omitted) (citation omitted).

Dep't 2004) (Saxe, J., concurring) (“[I]n a case such as this, where the proposed expert testimony concerns a claim that the plaintiff’s injury was caused by the actions taken by the defendants, the whole concept of the *Frye* analysis is of limited applicability.”). Because of the importance of this matter, this Court should clarify that there is no “causation exception” to *Frye*.

To the extent that these opinions merely affirm the unremarkable proposition that *Frye* does not apply if there is simply a dispute over the ultimate factual issue of causation and *not* over the scientific reliability of plaintiff’s causation evidence, the seeming disagreement in the lower courts is illusory. *See Marsh*, 12 A.D.3d at 312, 785 N.Y.S.2d at 444-45 (Saxe, J., concurring) (noting “it is exactly that which is often the primary point of contention in a personal injury action, where the plaintiff offers an opinion that the defendant’s conduct caused the injury, and the defendant denies any such conduct and counters that the injury resulted from some other causative agent, unrelated to defendant”). *Frye* applies only if the dispute centers on the methodology employed by an expert witness in forming a causation opinion – specifically, whether the expert relied on scientific principles generally accepted as reliable by the relevant scientific community.⁴

⁴ A narrow interpretation of Justice Saxe’s concurring opinion in *Marsh* would be supported by his joining in a unanimous panel opinion the following year in *Heckstall*, 19 A.D.3d at 205, 797 N.Y.S.2d at 447, which applied the *Frye* test to an expert’s causation opinion and held that the expert’s methodology was “not

These opinions could, however, be taken to stand for the proposition that, because causation is ultimately a question of fact for the jury, there is *no* threshold admissibility standard for expert scientific testimony offered as evidence for the jury to consider when making its determination regarding specific causation. If that is the view of these decisions, they ignore long and widely held concerns about the potentially undue influence of unreliable expert testimony on lay jurors,

generally accepted in the scientific community on questions of causation.” Justice Saxe noted in his concurring opinion in *Marsh* that “[t]he *Frye* test, used in a classic context, considers whether the court should allow testimony involving a recently introduced process such as DNA testing, polygraph tests, or post-hypnotic recollection.” 12 A.D.3d at 310, 785 N.Y.S.2d at 443-44 (citations omitted). When setting out the *Frye* standard as adopted by this Court, however, Justice Saxe acknowledged that the purpose of *Frye* is “to ensure that courts do not rely upon an expert’s testimony regarding a novel *procedure, methodology or theory* unless it has been ‘generally accepted’ within the relevant scientific community as leading to reliable results.” *Id.* (emphasis added). While the original application and subsequent formulations of the *Frye* test state that this standard applies to *novel* scientific evidence, the relationship between “novelty” and “general acceptance” essentially becomes tautological once one moves beyond the “classic context” from which the *Frye* test emerged, as Justice Saxe agrees New York’s courts have done – in other words, an expert opinion divorced from “generally accepted” scientific principle, methodology or theory must by definition be “novel.” *See, e.g., DeMeyer*, 9 Misc.3d at 311, 797 N.Y.S.2d at 748 (“A court is only required to conduct an inquiry, concerning general acceptance, pursuant to *Frye*, in situations in which a party seeks to rely upon novel scientific, technical or other concepts involving expertise. Otherwise stated, if a principle theory or methodology forming the basis for an expert opinion has been generally accepted in the relevant scientific community, it would not be novel, and therefore, not require a hearing or other inquiry by the court.”) (internal citations omitted).

undermine the well-accepted gatekeeper role of the trial judge, and run contrary to the great weight of authority in this jurisdiction as well as in other *Frye* states.⁵

B. To be Admissible, Expert Causation Testimony Must be Based on Generally Accepted Principles Showing that the Plaintiff's Particular Injury Resulted from Plaintiff's Particular Exposure to the Defendant's Particular Product

By articulating a generally accepted three-step scientific methodology for expert testimony proffered to show that plaintiff's exposure to the substance at issue caused his injury, the court below also applied a related proposition that this

⁵ Sister *Frye* jurisdictions similarly have applied the standard general acceptance test to expert causation testimony. *See, e.g., Hawkins v. State*, No. 4D03-4628, 2006 WL 1083394, at *4 (Fla. Dist. Ct. App. Apr. 26, 2006) (recognizing “the need for expert testimony to establish the causation element” and overturning defendant’s conviction because the medical examiner’s testimony was not based on generally accepted scientific principles); *Cerna v. S. Fla. Bioavailability Clinic, Inc.*, 815 So. 2d 652, 655-56 (Fla. Dist. Ct. App. 2002) (holding that trial court properly excluded expert testimony on the issue of causation); *Kaelbel Wholesale, Inc. v. Soderstrom*, 785 So. 2d 539, 547-50 (Fla. Dist. Ct. App. 2001) (holding that the trial court erred in allowing expert testimony on the issue of causation because it did not meet the applicable *Frye* test); *Kane v. Motorola, Inc.*, 779 N.E.2d 302, 309 (Ill. App. Ct. 2002) (holding that it was proper for trial court to exclude expert causation testimony for failing to meet the *Frye* standard); *Craig ex rel. Craig v. Oakwood Hosp.*, 684 N.W.2d 296, 307-08 (Mich. 2004) (holding that the lower court erred in failing to conduct a *Frye* hearing to determine whether the expert’s causation theory was based on generally accepted scientific principles); *McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. Ct. App. 2004) (same); *Schafersman v. Agland Coop*, 631 N.W.2d 862, 870-71 (Neb. 2001) (reversing trial court and holding that expert testimony failed to meet the *Frye* standard); *Blum ex rel. Blum v. Merrell Dow Pharms., Inc.*, 764 A.2d 1, 4 (Pa. 2000) (upholding reversal of lower court and finding that expert testimony on causation did not satisfy either the *Frye* or the *Daubert* standard); *Grant v. Boccia*, 132 Wash. App. 1016 (Ct. App. 2006) (upholding lower court’s exclusion of expert testimony on causation under the *Frye* standard).

Court should likewise affirm: to be admissible under *Frye*, expert causation testimony must rely upon generally accepted scientific principles to establish both “general” and “specific” causation. To hold otherwise would set aside a fundamental precept of our tort system – individualized liability. *See, e.g.*, Richard J. Pierce, Jr., *Causation in Government Regulation and Toxic Torts*, 76 Wash. U. L.Q. 1307 (1998) (“By contrast [to a regulatory context], in a tort case, the court must decide whether a *particular* manufacturer of substance A is legally and financially responsible for a *particular* injury to a *particular* individual.”) (emphasis added).

Establishing specific causation is, of course, essential to making out a plaintiff’s case.⁶ In a toxic tort suit such as this one, plaintiff’s experts accordingly

⁶ Courts in federal and state jurisdictions across the country, including New York, have clearly recognized that both general and specific causation are essential to a plaintiff’s case. In *Heckstall*, for example, the First Department reversed a trial court’s denial of summary judgment and dismissed the complaint because plaintiff’s experts did not meet the *Frye* test and thus plaintiff did not submit “sufficient evidence as to either general or specific causation.” 19 A.D.3d at 205, 797 N.Y.S.2d at 447. The court recognized that in order “to prevail against [the defendant], plaintiff must tender evidence in admissible form demonstrating ‘general causation,’ i.e., that Bupropion can cause an arrhythmia, and also ‘specific causation,’ i.e., that decedent’s ingestion of two doses of Bupropion created or aggravated the arrhythmia that caused her death.” *Id.* at 204, at 447 (citing *Devito v. SmithKline Beecham Corp. d/b/a GlaxoSmithKline*, 2004 U.S. Dist. LEXIS 27374, *5 (N.D.N.Y. 2004)). *See also, e.g.*, *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1164 (E.D. La. 1997) (“Proof of causation has two components, general and specific. General causation deals with whether the substance at issue * * * can cause diseases or disorders in people in general. Specific causation

must provide the jury with scientifically reliable testimony that the substance at issue is not only *capable* of causing the condition in question (that is, general causation), but also that this plaintiff's *particular* injury was caused by plaintiff's *particular* exposure to this defendant's *particular* product (that is, specific causation). *See, e.g., Stout & Valberg*, 38 U. Mich J.L. Reform at 784, 872; *Eggen*, 55 U. Pitt. L. Rev. at 896-97 (“Nowhere has the bifurcation of the standard of causal proof between general causation, based on probabilities, and specific causation, based on individualized factual connections, been as pronounced as it is in the toxic tort case.”).

focuses upon whether the substance * * * was in fact the cause of the ailments or symptoms in the particular patient.”); *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1132 (D. Ariz. 2001) (“Plaintiff must show both general and specific causation”) (citing *Raynor v. Merrell Pharms., Inc.*, 104 F.3d 1371, 1376 (D.C. Cir. 1997)); *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997) (“To raise a fact issue on causation and thus to survive legal sufficiency review, a claimant must do more than simply introduce into evidence epidemiological studies that show a substantially elevated risk. A claimant must show that he or she is similar to those in the studies. This would include proof that the injured person was exposed to the same substance, that the exposure or dose levels were comparable to or greater than those in the studies, that the exposure occurred before the onset of injury, and that the timing of the onset of injury was consistent with that experienced by those in the study.”), *applied in Matt Dietz Co. v. Torres*, No. 04-05-00552-CV, 2006 WL 1406586, at *3-*4 (Tex. App. May 24, 2006) (dividing the expert inquiry into “general causation” and “specific causation” inquires under *Havner*); *Norfolk S. Ry. Co. v. Rogers*, 621 S.E.2d 59, 69 (Va. 2005) (recognizing the distinction between general and specific causation, and holding that the plaintiff failed to establish specific exposure to enough silica dust to cause injury).

Determining the reliability of specific causation evidence may require a wholly different inquiry from that bearing on general causation. Indeed, the relevant scientific field in which “general acceptance” must be attained under *Frye* may not be the same for each aspect of the expert testimony on these subjects. For example, as the Reference Manual on Scientific Evidence states:

Epidemiology is concerned with the incidence of disease in populations and does not address the question of the cause of an individual’s disease. This question, sometimes referred to as specific causation, is beyond the domain of the science of epidemiology. Epidemiology has its limits at the point where an inference is made that the relationship between an agent and a disease is causal (general causation) and where the magnitude of excess risk attributed to the agent has been determined; that is, epidemiology addresses whether an agent can cause a disease, not whether an agent did cause a specific plaintiff’s disease.

Federal Judicial Center, *Reference Manual on Scientific Evidence* (2d ed. 2000), at 381-82. *Frye*’s standard, therefore, must be separately applied to evidence addressing general and specific causation.

This means that the gatekeeper judge must do more than assure that the scientific methodology underlying an expert’s opinion making a general causal connection between the substance and condition at issue is accepted as reliable; the judge also must examine the reliability of the scientific methodology supporting the expert’s opinion that the individual plaintiff’s exposure to the defendant’s specific product caused that plaintiff’s injury. Otherwise, “[a]llowing testimony based solely on the acceptance of an expert’s general methodology risks opening

the floodgates to junk science. Epidemiology, DNA testing, and other methodologies are generally accepted by the scientific community, but only if the relevant studies or tests are conducted properly, and *only if the person relying on the methodology has extrapolated (or reasoned) in a generally accepted way from the study or test results to a conclusion.*” Bernstein, 41 Jurimetrics J. at 398 (emphasis added). Failure to do so is tantamount to “fuzzy science at its worst.” *Nonnon v. City of N. Y.*, --- N.Y.S.2d ---, 2006 WL 1529293, at *8 (1st Dep’t., June 6, 2006) (Andrias, J., dissenting).

The plaintiff’s experts failed to do that here. Whatever the reliability of the conclusion that the substance at issue (benzene) may sometimes be linked to the condition in question (acute myelogenous leukemia), the experts failed to establish in a scientifically reliable way that plaintiff’s particular injury was caused by his particular exposure to defendants’ particular product (gasoline). *Parker*, 793 N.Y.S.2d at 439. In explaining why this is so, the Appellate Division applied the three-part inquiry, described above, which looks to the plaintiff’s level of exposure to the toxin, proof that the toxin is capable of causing the illness, and a demonstration of the probability that the toxin caused *the plaintiff’s* illness. That approach is widely used by courts across the country.⁷ *But see Nonnon*, 2006 WL

⁷ “The existence of a dose-response relationship has been described as ‘the most fundamental and pervasive concept in toxicology.’” Joe G. Hollingsworth & Eric

1529293, at *9 (declining to apply the *Parker* test “to the facts here because no scientist could make an accurate measurement of the doses of the combined carcinogens to which these plaintiffs were exposed”).

E. Lasker, *The Case Against Differential Diagnosis: Daubert, Medical Causation Testimony, and the Scientific Method*, 37 J. Health L. 85, 93 (2004) (quoting David L. Eaton & Curtis D. Klaassen, *Principles of Toxicology*, in *Cassarett & Doull’s Toxicology: The Basic Science of Poisons* 17-18 (Curtis D. Klaassen ed., 2001)). In addition to the federal court decisions cited by the Appellate Division, several other *Frye* jurisdictions have also held that dose-response relationship and exposure analysis are key elements of expert causation testimony. *See, e.g., Lofgren v. Motorola, Inc.*, No. CV 93-05521, 1998 WL 299925, at *18, *25 (Ariz. Super. Ct. June 1, 1998) (holding that the plaintiffs’ experts’ methodologies were not generally accepted because they failed to take into account dose-response factors, that “knowledge of the amount and duration of exposure are essential elements to a valid toxicological opinion determining whether a chemical caused certain reactions,” and that “[s]cientific methodology dictates that comparison of the known or estimated exposure to established reactive dose levels is the cornerstone of toxicology”) (internal quotation marks omitted) (brackets omitted); *Graham v. Lautrec, Ltd.*, No. 01 031717 CE, 2003 WL 23512133, at *3 (Mich. Cir. Ct. July 24, 2003) (excluding plaintiff’s expert in part because of the expert’s failure to address an “important factor in establishing causality,” which “is the presence of a dose-response relationship between risk of disease and varying levels of a potentially harmful agent”); *Goeb v. Tharaldson*, No. CX-98-2275, 1999 WL 561956, at *6 (Minn. Ct. App. Aug. 3, 1999) (upholding the exclusion of an expert in part because the expert failed to quantify exposure sufficiently under the dose-response method), *aff’d on other grounds*, 615 N.W.2d 800 (Minn. 2000); *Trach v. Fellin*, 817 A.2d 1102, 1113 & n.12 (Pa. Super. Ct. 2003) (observing “that there is no question that the scientific community has generally accepted the * * * ‘Dose Response’ principle” and recognizing “the venerability of th[e] principle” that “the dose determines the poison”) (internal quotation marks omitted) (citation omitted); *Skoogfors v. Haverstick-Borthwick Co.*, No. 93-23217, 2000 WL 573453, at *3 n.14 (Pa. Ct. Com. Pl. Jan. 13, 2000) (listing “a dose-response relationship” as one of several “criteria that must be evaluated in order to establish causation in a particular case” and excluding plaintiff’s expert, who did not evaluate those criteria, under the general acceptance standard).

Whether or not this Court endorses all of the particulars of the analysis used below, the central point of the Appellate Division plainly was correct: *Frye* applies to expert causation testimony, and the methodology used to develop the expert's opinion on both general and specific causation must be generally accepted as reliable by the scientific community. When, as in this case, the experts offer *no* real methodology (let alone one that is generally accepted in the relevant field) in order to make a connection between the plaintiff's exposure and his disease, expert testimony on specific causation should be excluded.

III. Failure to Preserve the Standard for Admission of Expert Causation Testimony Would Subvert the Fairness of the Trial Process, Produce Insupportable Results, and Impose Significant Burdens on the Judicial System

Failure to affirm that expert scientific testimony on causation is subject to the *Frye* general acceptance standard in the same way as all other expert testimony, and that *Frye* governs expert evidence relating to both general and specific causation, could have potentially far-reaching negative consequences for litigants, the court system, and the public. Experts would be free to rely on speculation or mere *ipse dixit* (bolstered by the aura of scientific infallibility) to persuade juries that the general causal connection between a toxin and a disease justifies the inference that a particular plaintiff's injury was caused by exposure to a given defendant's product – regardless of any facts pertaining to the duration or intensity of that particular plaintiff's exposure, concentration levels of the toxin in the

particular product at issue, or other potential causes of the plaintiff's particular injury. Such a regime would effectively shift the burden to the defendant to disprove causation, while overburdening the courts with claims that cannot be established reliably through the science on which the litigation ostensibly is premised.

This danger is very real. If reliable evidence of specific causation is not needed, any product that contains a substance with a general epidemiological link to the plaintiff's condition could be the subject of a lawsuit. Under such a scheme, any plaintiff with cancer would be entitled to reach a jury with any claim involving exposure to a known carcinogen, whether or not there is any scientifically reliable basis to conclude that plaintiff's condition was in fact caused by the defendant's product. For example, "[b]oth orange juice and coffee contain known animal carcinogens." *Pierce*, 76 Wash. U. L.Q. at 1313 (citations omitted). Without applying a meaningful admissibility standard to expert testimony on specific causation, any plaintiff with a condition linked to the carcinogenic agents in these everyday products and who regularly had a cup of juice or coffee with breakfast would have a triable claim against producers of those products. There is no reason to doubt that many of these plaintiffs, if they had sympathetic stories and articulate experts, would prevail.

Toxic tort plaintiffs, like all tort plaintiffs, have the burden of proving that a defendant more likely than not caused their injuries. *See, e.g., In re "Agent Orange,"* 611 F. Supp. at 1262 (concluding that toxic tort plaintiffs were required to "offer evidence that causation was more than [fifty] percent probable"). If courts were to allow lay juries to infer specific causation in scientifically complex cases without the aid of reliable expert testimony, it would "inappropriately shift the plaintiff's burden of proof onto the defendant. Instead of requiring the plaintiff to indicate why the injury occurred, we would in effect be forcing defendants to disprove causality." *Lasley v. Georgetown Univ.*, 688 A.2d 1381, 1387 (D.C. 1997). *See also Nonnon*, 2006 WL 1529293, at *13 (Andrias, J., dissenting) (noting that "the court improperly shifted the burden of proof to the City when it found that the City had not provided 'any evidence to indicate that the plaintiffs did not get their diseases from the landfill'"). This would turn one of the most basic precepts of our judicial system on its head, undermining fundamental notions of fairness and, in essence, converting lay jurors into regulators. *See Pierce*, 76 Wash. U. L.Q. at 1308 (A regulatory "agency does not have to find a causal relationship between substance A and any particular case of cancer. By contrast, in a tort case, the court must find that it is more probable than not that substance A caused plaintiff B's cancer to award damages to B.").

Such a regime also would have broader, systemic consequences. If all it took to put complex scientific questions of causation before a lay jury was reliable expert testimony of general causation – that there may be a connection between substance A and condition B – innumerable benign and beneficial products could be driven from the market even in the absence of any reliable showing of an individualized link to injury in a specific case. *See id.* at 1316 (“[T]here are 48,523 unregulated synthetic chemicals used in commerce. Eighty percent of those chemicals have not been subjected to any toxicity tests. Fifty percent of all substances that have been tested to date have been shown to be animal carcinogens. A high percentage of all products available in the United States contain one or more of the 38,818 unregulated and untested synthetic chemicals.”) (citations omitted).

Indeed, carcinogens are “known to exist in all wine, beer, lettuce, root beer, apples, mushrooms, pears, plums, peanut butter, tea, celery, carrots, bread, and chlorinated water.” *Id.* at 1315-16 (citing Lois Swirsky Gold et al., *Rodent Carcinogens: Setting Priorities*, 258 *Science* 261, 262-63 (1992)). As recognized by the so-called father of chemical pharmacology, Paracelsus: “What is there that is not poison? All things are poison and nothing [is] without poison. Solely the dose determines that a thing is not a poison.” Hollingsworth & Lasker, 37 *J. Health L.* at 93 (citing David L. Eaton & Curtis D. Klaassen, *Principles of*

Toxicology, in Cassarett & Doull's Toxicology: The Basic Science of Poisons 13
(Curtis D. Klaassen ed., 2001).

The end result would be a free-for-all in front of the jury, increased litigation costs, and an overburdened judicial system. Perhaps most troubling is the prospect of turning courts into un-scientific laboratories in which speculative, conclusory, or otherwise unreliable “expert” theories about what caused a specific plaintiff’s injury could be validated by lay jurors before the methodology used by an expert has been generally accepted in the applicable scientific field. As Judge Posner noted, “the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.” *Rosen*, 78 F.3d at 319. *See also Clemente*, 183 Misc.2d at 934, 705 N.Y.S.2d at 800 (“Courts are not laboratories in which to try out new theories to ascertain whether jurors will believe them or not * * * It is the role of the judge to spend time screening a novel theory or technique before having it presented to a jury.”). The plaintiff’s attempt here to turn that principle upside down should be rejected.

CONCLUSION

Because the Appellate Division below properly applied the well-settled *Frye* general acceptance standard to the plaintiff’s expert scientific testimony, both with respect to general causation and with respect to the specific causal nexus between *this particular plaintiff’s injury and his particular exposure to these particular*

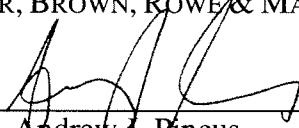
defendants' products, amicus curiae respectfully urges this Court to affirm the decision below.

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Respectfully submitted,

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