

No. 11-316

---

---

IN THE  
**Supreme Court of the United States**

---

UNITED STATES STEEL CORPORATION, *et al.*,  
*Petitioners,*

v.

BRIAN K. MILWARD AND LINDA J. MILWARD,  
*Respondents.*

---

**On Petition for a Writ of Certiorari  
to the United States Court of Appeals  
for the First Circuit**

---

**BRIEF OF DRI—THE VOICE OF THE  
DEFENSE BAR AS *AMICUS CURIAE*  
SUPPORTING PETITIONERS**

---

CARTER G. PHILLIPS  
JONATHAN F. COHN  
ERIC D. MCARTHUR  
SIDLEY AUSTIN LLP  
1501 K Street, NW  
Washington, DC 20005  
(202) 736-8000

R. MATTHEW CAIRNS\*  
PRESIDENT OF DRI  
55 W. Monroe Street  
Suite 2000  
Chicago, IL 60603  
(312) 795-1101  
cairns@gcglaw.com

TIMOTHY E. KAPSHANDY  
SIDLEY AUSTIN LLP  
1 South Dearborn  
Chicago, IL 60603  
(312) 853-7643

*Counsel for Amicus Curiae*

October 12, 2011

\* Counsel of Record

---

---

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES .....	ii
INTEREST OF <i>AMICUS CURIAE</i> .....	1
INTRODUCTION .....	2
REASONS FOR GRANTING THE PETITION...	3
I. THE “WEIGHT OF THE EVIDENCE” METHODOLOGY APPROVED BY THE COURT OF APPEALS IS NOT A RELI- ABLE BASIS FOR “SCIENTIFIC KNOW- LEDGE” .....	3
II. THE ADMISSIBILITY OF EXPERT TES- TIMONY ON MEDICAL CAUSATION IS AN IMPORTANT AND RECURRING ISSUE THAT MERITS THIS COURT’S REVIEW .....	13
CONCLUSION .....	19

## TABLE OF AUTHORITIES

CASES	Page
<i>Allen v. Pa. Eng'g Corp.</i> , 102 F.3d 194 (5th Cir. 1996).....	11, 13
<i>Amorgianos v. Nat'l Rd. Passenger Corp.</i> , 303 F.3d 256 (2d Cir. 2002) .....	8, 14
<i>Baker v. Dalkon Shield Claimants Tr.</i> , 156 F.3d 248 (1st Cir. 1998) .....	14
<i>Best v. Lowe's Home Ctrs., Inc.</i> , 563 F.3d 171 (6th Cir. 2009) .....	14
<i>Bitler v. A.O. Smith Corp.</i> , 391 F.3d 1114 (10th Cir. 2004) .....	14
<i>Black v. Food Lion, Inc.</i> , 171 F.3d 308 (5th Cir. 1999).....	14
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993).....	<i>passim</i>
<i>Dunn Sandoz Pharms. Corp.</i> , 275 F. Supp. 2d 672 (M.D.N.C. 2003) .....	9
<i>E.I. du Pont de Nemours &amp; Co. v. Robinson</i> , 923 S.W.2d 549 (Tex. 1995).....	10, 16
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997).....	4, 5, 16
<i>Glastetter v. Novartis Pharms. Corp.</i> , 252 F.3d 986 (8th Cir. 2001).....	14
<i>Hardyman v. Norfolk &amp; W. Ry.</i> , 243 F.3d 255 (6th Cir. 2001) .....	14
<i>Heller v. Shaw Indus., Inc.</i> , 167 F.3d 146 (3d Cir. 1999).....	14
<i>Hendrix ex rel. G.P. v. Evenflo Co.</i> , 609 F.3d 1183 (11th Cir. 2010).....	14
<i>Hollander v. Sandoz Pharms. Corp.</i> , 289 F.3d 1193 (10th Cir. 2002).....	14
<i>Joiner v. Gen. Elec. Co.</i> , 78 F.3d 524 (11th Cir. 1996), <i>rev'd</i> , 522 U.S. 136 (1997).....	13
<i>Kennedy v. Collagen Corp.</i> , 161 F.3d 1226 (9th Cir. 1998) .....	14

## TABLE OF AUTHORITIES—continued

	Page
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137 (1999) .....	4, 5, 14
<i>Magistrini v. One Hour Martinizing Dry Cleaning</i> , 180 F. Supp. 2d 584 (D.N.J. 2002), <i>aff'd</i> , 68 F. App'x 356 (3d Cir. 2003) .....	7
<i>McClain v. Metabolife Int'l, Inc.</i> , 401 F.3d 1233 (11th Cir. 2005) .....	14
<i>Merrell Dow Pharms., Inc. v. Havner</i> , 953 S.W.2d 706 (Tex. 1997) .....	13
<i>Moore v. Ashland Chem. Inc.</i> , 151 F.3d 269 (5th Cir. 1998) .....	6, 8, 10, 15
<i>Nelson v. Tenn. Gas Pipeline Co.</i> , 243 F.3d 244 (6th Cir. 2001) .....	14
<i>People v. Leahy</i> , 882 P.2d 321 (Cal. 1994)....	17
<i>Pluck v. BP Oil Pipeline Co.</i> , 640 F.3d 671 (6th Cir. 2011) .....	14
<i>Rider v. Sandoz Pharms. Corp.</i> , 295 F.3d 1194 (11th Cir. 2002) .....	14, 15
<i>Rosen v. Ciba-Geigy Corp.</i> , 78 F.3d 316 (7th Cir. 1996) .....	10
<i>Ruggiero v. Warner-Lambert Co.</i> , 424 F.3d 249 (2d Cir. 2005).....	14
<i>Soldo v. Sandoz Pharms. Corp.</i> , 244 F. Supp. 2d 434 (W.D. Pa. 2003).....	9
<i>State v. O'Key</i> , 899 P.2d 663 (Or. 1995).....	17
<i>Tamraz v. Lincoln Elec. Co.</i> , 620 F.3d 665 (6th Cir. 2010), <i>cert. denied</i> , 131 S. Ct. 2454 (2011) .....	10, 12, 14, 16
<i>Turner v. Iowa Fire Equip. Co.</i> , 229 F.3d 1202 (8th Cir. 2000) .....	14
<i>United States v. Amaral</i> , 488 F.2d 1148 (9th Cir. 1973) .....	17
<i>Westberry v. Gislaved Gummi AB</i> , 178 F.3d 257 (4th Cir. 1999) .....	14

## TABLE OF AUTHORITIES—continued

	Page
<i>Zuchowicz v. United States</i> , 140 F.3d 381 (2d Cir. 1998).....	14
 RULE	
Fed. R. Evid. 702 .....	18
 SCHOLARLY AUTHORITIES	
Joe G. Hollingsworth & Eric G. Lasker, <i>The Case Against Differential Diagnosis: Daubert, Medical Causation Testimony, and the Scientific Method</i> , 37 J. Health L. 85 (2004).....	12, 18
Sheldon Krimsky, <i>The Weight of Scientific Evidence in Policy and Law</i> , 95 Am. J. Pub. Health S129 (Supp. I 2005).....	7, 11
 OTHER AUTHORITIES	
<i>Restatement (Third) of Torts: Physical and Emotional Harm</i> (2010) .....	9, 12, 14, 15
Fed. Judicial Ctr., <i>Reference Manual on Scientific Evidence</i> (2d ed. 2000) .....	11, 15

## INTEREST OF *AMICUS CURIAE*<sup>1</sup>

*Amicus curiae* DRI—The Voice of the Defense Bar is an international organization that includes more than 23,000 attorneys involved in the defense of civil litigation. DRI is committed to enhancing the skills, effectiveness, and professionalism of defense attorneys. Because of this commitment, DRI seeks to address issues germane to defense attorneys and the civil justice system, to promote the role of the defense attorney, to improve the civil justice system, and to preserve the civil jury. DRI has long been a voice in the ongoing effort to make the civil justice system more fair, efficient, and—where national issues are involved—consistent. To promote these objectives, DRI participates as *amicus curiae* in cases raising issues of importance to its members, their clients, and the judicial system.

This is such a case. The decision below significantly and unjustifiably expands the admissibility of expert testimony on medical causation, which is often the key issue in high-stakes toxic-tort and product-liability litigation. The decision does so by requiring that district courts uncritically accept as scientifically reliable an expert’s *ipse dixit* as to the “weight of the evidence,” thereby undermining the essential role district courts play in ensuring that expert testimony rests on a reliable scientific foundation rather than

---

<sup>1</sup> Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution toward the preparation and submission of this brief. Pursuant to Supreme Court Rule 37.2(a), counsel of record for all parties have received timely notice of *amicus curiae*’s intent to file this brief and have consented to the filing of this brief.

subjective belief or unsupported speculation. Left uncorrected, the decision below portends a new era of tort litigation in which lay juries will be asked to decide significant issues of liability based on speculative theories that have not been reliably tested or confirmed. DRI respectfully urges the Court to grant certiorari and reverse the decision below.

### INTRODUCTION

The First Circuit in this case held that district courts not only *may* but *must* admit speculative expert testimony that rests on nothing more than the expert's subjective judgment that an untested hypothesis is supported by the "weight of the evidence." As petitioners have shown, that decision conflicts with this Court's cases and the decisions of other circuits holding that expert testimony is admissible only when it rests on a reliable scientific foundation, and that a district court is not required to accept an expert's *ipse dixit* but must instead carefully examine the methods and data underlying the expert's opinion to ensure that the expert has reliably applied valid scientific principles. Without such an inquiry, the "gatekeeper" function the Federal Rules of Evidence envision for the district court judge becomes meaningless. DRI submits this brief to amplify two important points.

*First*, the weight-of-the-evidence methodology the court of appeals endorsed does not satisfy the criteria this Court has adopted for assessing the reliability of expert testimony. It is neither testable nor falsifiable; it is not governed by any objective standards; and it has not been generally accepted by the scientific community as a means to assess medical causation absent an observed association between the substance and disease at issue. The fact that

regulatory agencies use the methodology to assess risks to public health based on the available data does not mean that it yields “scientific knowledge” admissible under the very different standards governing a court proceeding.

*Second*, the district court’s essential gatekeeping role is particularly important on the issue of medical causation. That issue is often dispositive in toxic-torts and product-liability cases, which can involve enormous stakes not only for the parties, but also for the national economy. The lay jurors who decide these complicated issues are likely to be greatly influenced by testimony that appears to be scientific in nature coming from a witness whom the court has admitted as an expert. The decision below undermines the critical screening function district courts perform to prevent juries from being misled by speculation masquerading as scientific knowledge.

## **REASONS FOR GRANTING THE PETITION**

### **I. THE “WEIGHT OF THE EVIDENCE” METHODOLOGY APPROVED BY THE COURT OF APPEALS IS NOT A RELIABLE BASIS FOR “SCIENTIFIC KNOWLEDGE.”**

1. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court set forth the standard for admission of expert testimony under Federal Rule of Evidence 702. Focusing on Rule 702’s requirement that an expert’s testimony must be based on “‘scientific . . . knowledge,’” the Court held that an expert’s opinion must be “ground[ed] in the methods and procedures of science,” and may not rest on “subjective belief or unsupported speculation.” *Id.* at 590 (omission in original). That is, “in order to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method”

and “must be supported by appropriate validation” based on what is known. *Id.* Only in this way does an expert’s opinion meet Rule 702’s “standard of evidentiary reliability.” *Id.*

Accordingly, before admitting expert testimony, a trial court must ensure that “the reasoning or methodology underlying the testimony is scientifically valid.” *Id.* at 592–93. To assist trial courts in performing this essential “gatekeeping role,” *id.* at 597, the Court identified four factors that bear on the inquiry: (1) whether the theory or technique underlying the expert’s opinion can be and has been tested, *id.* at 593; (2) whether the theory or technique has been subjected to peer review and publication, *id.*; (3) the theory’s or technique’s known or potential rate of error and the existence and maintenance of standards controlling its operation, *id.* at 594; and (4) whether the theory or technique has gained widespread acceptance in the relevant scientific community, *id.* Although the inquiry is “a flexible one” and no single factor is necessarily dispositive, together these factors are designed to ensure “the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission.” *Id.* at 594–95.

Since *Daubert*, this Court has twice reiterated and elaborated these principles, while at the same time emphasizing the broad discretion district courts possess in fulfilling their gatekeeping role and the circumscribed scope of appellate review. See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997) (reversing appellate decision that reversed district court’s exclusion of expert testimony); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999) (same). Of particular relevance here, this Court has held that district courts must rigorously examine the “factual basis,

data, principles, [and] methods” underlying an expert’s opinion, as well as “their application” by the expert. *Kumho*, 526 U.S. at 149. When an expert formulates an opinion by “extrapolat[ing] from existing data,” a district court is not required “to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Joiner*, 522 U.S. at 146. Rather, a “court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Id.*

2. The First Circuit’s decision below disregards this Court’s teachings in *Daubert*, *Joiner*, and *Kumho*. After hearing testimony for four days, the district court concluded that Dr. Smith’s opinion had not been reliably established based on valid scientific principles, but rather amounted to nothing more than a “plausible hypothesis.” Pet. App. 46a; see also *id.* at 48a–49a, 51a, 53a. Following this Court’s instructions, the district court carefully examined the factual basis for each of the conclusions underlying Dr. Smith’s proffered opinion and concluded that the “analytical gap” between the data on which Dr. Smith relied and his conclusion that benzene can cause APL was “simply too great.” *Joiner*, 522 U.S. at 146. Accordingly, the district court held that Dr. Smith’s opinion did “not constitute reliable ‘scientific knowledge’ qualified for admission under Rule 702.” Pet. App. 51a.

In reversing the district court’s decision, the court of appeals did not meaningfully respond to the flaws the district court identified in Dr. Smith’s analysis. Instead, the court concluded that Dr. Smith’s opinion rested on a “scientifically sound and methodologically reliable foundation,” Pet. App. 17a, only because he had applied the so-called “weight-of-the-evidence” methodology. As described by the court of appeals,

this “methodology” involves a mode of reasoning in which an expert “consider[s] all of the relevant available evidence” on an issue and “integrate[s] the evidence using professional judgment to come to a conclusion about the best explanation.” *Id.* at 11a. Although the court acknowledged that “no scientific methodology exists for this process,” it concluded that this did not render the methodology “any less scientific.” *Id.* at 12a (internal quotation marks and alteration omitted).

Remarkably, in reaching this conclusion, the court of appeals did not address any of the *Daubert* factors or otherwise explain how Dr. Smith had employed the methods and procedures of science. In fact, as described by the court of appeals and applied by Dr. Smith, the weight-of-the-evidence methodology satisfies none of *Daubert*’s factors for evidentiary reliability: There is no way to test whether Dr. Smith’s subjective weighing of all the relevant evidence is a reliable way to assess causation, and Dr. Smith’s subjective judgment as to the weight of the evidence has not been subjected to publication or peer review, has no known rate of error or standards controlling its operation, and has not received general acceptance in the scientific community. See *Daubert*, 509 U.S. at 593–94.

Without considering any of these factors, the court of appeals reversed the district court’s thorough and careful opinion, and concluded that the district court had abused its discretion in excluding Dr. Smith’s testimony as speculative. That is exactly backwards: Where, as here, none of the *Daubert* factors exists, “trial courts are *encouraged* to exclude such speculative testimony as lacking any scientific validity.” *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 279 (5th Cir. 1998) (en banc) (emphasis added). They certainly

do not abuse their discretion by excluding an expert opinion that rests on nothing more than the expert's unelaborated personal "judgment."

3. Indeed, it is doubtful whether such a subjective process can be deemed a "methodology" at all. As a leading article on the subject observes, "no canonical frameworks for weighing scientific evidence have emerged." Sheldon Krinsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am. J. Pub. Health S129, S130 (Supp. I 2005). As a result, "[w]e cannot tell whether [weight of the evidence] is used as a methodology, a heuristic, a ranking system, or simply a subjective process of setting a causal threshold for cumulative indirect evidence." *Id.* Absent an accepted standard for combining and weighing various pieces of scientific evidence, the process is necessarily "low on transparency and high on subjectivity," *id.*, and the conclusion it yields "seems to be coming out of a 'black box' of scientific judgment," *id.* at S131. Such an "elusive methodology" is plainly "ripe for Daubert challenges." *Id.*

This is a case in point. Dr. Smith did not identify any standards that governed his weighing of the evidence; nor did he disclose how he went about weighing all the various pieces of evidence to arrive at his opinion. See Pet. App. 62a ("Q. [W]ith regard to how you—what weight you assigned to a piece of evidence that was supportive and the weight that you assigned to a piece of evidence that might not have been supportive, you didn't describe what weight you assigned, correct? A. No; correct."); cf. *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002) ("to ensure that the 'weight-of-the-evidence' methodology is truly a methodology rather than a mere conclusion-oriented selection process that weighs more heavily those studies that

supported an outcome, there must be a scientific method of weighting that is used and explained”), *aff’d*, 68 F. App’x 356 (3d Cir. 2003). Short of independently considering the “fit” between the data the expert relies upon and the ultimate opinion (as the district court did here), it is impossible to “undertake a rigorous examination of . . . the method by which the expert draws an opinion from th[e] facts,” *Amorgianos v. Nat’l Rd. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002), or to obtain an “objective, independent validation of the expert’s methodology,” *Moore*, 151 F.3d at 276. Instead, the district court must simply accept the expert’s *ipse dixit*—precisely what *Joiner* said a district court need not and should not do. The court of appeals’ decision eviscerates *Joiner*.

4. In the face of all this, the court of appeals simply asserted, without explanation or citation of authority, that “[n]o serious argument can be made that the weight of the evidence approach is inherently unreliable.” Pet. App. 13a. The court appears to have based this assertion on the fact that epidemiologists use the weight-of-the-evidence methodology to assess medical causation based on a variety of factors first articulated by Sir Arthur Bradford Hill, see *id.* at 9a–10a, and that doctors use a similar methodology called “differential diagnosis” to diagnose patients in a clinical setting, *id.* at 12a. The court of appeals’ reasoning reflects a fundamental misunderstanding of both the proper use of the Bradford-Hill criteria and the role of scientific evidence in litigation.

Initially, the court of appeals misunderstood the purpose of the Bradford-Hill factors. “The Bradford-Hill criteria ‘were developed as a mean[s] of interpreting an *established association* based on a body of epidemiologic research for the purpose of

trying to judge whether the observed association reflects a causal relation between an exposure and disease.” *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 514 (W.D. Pa. 2003) (alteration in original) (quoting report of court-appointed expert). Here, however, no studies have established an “observed association” between benzene and APL. See Pet. App. 60a (Dr. Smith admitting that no studies “show a statistically significant increase in risk with respect to any of the specific subtypes of AML,” including APL). Absent an observed association, use of the Bradford-Hill factors “to provide the sole basis for proof of general causation does not reflect accepted epidemiologic methodology.” *Restatement (Third) of Torts: Physical & Emotional Harm*, § 28, Reporter’s Note, cmt. c (2010); accord *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 678 (M.D.N.C. 2003) (“[T]he Bradford Hill criteria [are] a method for determining whether the results of an epidemiological study can be said to demonstrate causation and not a method for testing an unproven hypothesis.”).

Furthermore, the methodology approved by the court of appeals did not even properly apply the Bradford-Hill criteria. Rather, it focused almost exclusively on only one of the nine factors—biological plausibility—and essentially ignored all of the rest. That single factor, standing alone, cannot reliably establish general causation. Indeed, as with the weight-of-the-evidence methodology itself, “scientists report that there is no methodology for assessing the strength or reliability of biological-mechanism evidence. It may vary from quite compelling to no more than hypothesis, with little supporting the latter other than some biologic knowledge and a fertile imagination.” *Restatement* § 28, Reporter’s

Note, cmt. c. *Daubert* requires more. See also *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 558 (Tex. 1995) (“a person with a degree should not be allowed to testify that the world is flat, that the moon is made of green cheese, or that the Earth is the center of the solar system”).

More fundamentally, the court of appeals ignored this Court’s instruction in *Daubert* that “there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory.” 509 U.S. at 596–97. Contrary to the court of appeals’ assumption, the mere fact that a methodology is used by scientists for some purposes does not mean that it satisfies Rule 702’s requirement of evidentiary reliability. Scientists routinely generate hypotheses based on their best understanding of existing data; that is an essential part of the scientific method. But those hypotheses do not become admissible as “scientific knowledge” until they have been reliably tested and validated. See *id.* at 593 (“Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.”). As Judge Sutton observed, “what science treats as a useful but untested hypothesis the law should generally treat as inadmissible speculation.” *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010), *cert denied*, 131 S. Ct. 2454 (2011). Or, as Judge Posner memorably put it, “[l]aw lags science; it does not lead it.” *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); see also *Moore*, 151 F.3d at 276 (“[T]he law cannot wait for future scientific investigation and research. We must resolve cases in our courts on the basis of scientific knowledge that is currently available.”).

Moreover, the weight-of-the-evidence methodology is typically used in regulatory contexts where the threshold for decisionmaking is very different than it is in litigation, where propositions must be established by a preponderance of the evidence. See Krinsky, *supra*, at S132–34. An agency like the Food and Drug Administration or the Environmental Protection Agency, for example, might use the weight-of-the-evidence methodology in assessing whether a substance poses an undue risk to the public health. In that setting, the agency must necessarily make its best judgment based on the existing data, even if those data do not reliably support, by a preponderance of the evidence, a firm conclusion on causation. The mere possibility of harm may be reason enough either as a matter of policy or statutory mandate to act given the comparative costs and benefits of the substance at issue. See *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (rejecting the weight-of-the-evidence methodology as unreliable because it “results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances”); Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 33 (2d ed. 2000) (noting that “risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not”).

The same is true of the “differential-diagnosis” method to which the court of appeals compared the weight-of-the-evidence methodology, at least when it is offered as support for an opinion on general causation rather than specific causation.<sup>2</sup> Like

---

<sup>2</sup> General causation refers to whether a substance is capable of causing a disease; specific causation refers to whether the

agencies making determinations about the public health, doctors seeking to diagnose a patient's condition must make the best-informed judgment they can based on the information available to them at the time. "Doctors do not ordinarily make scientifically reliable determinations regarding general causation in their daily clinical practice. Instead, doctors make individualized treatment decisions based on the exigencies of the moment." Joe G. Hollingsworth & Eric G. Lasker, *The Case Against Differential Diagnosis: Daubert, Medical Causation Testimony, and the Scientific Method*, 37 J. Health L. 85, 97 (2004). And like agencies applying the weight-of-the-evidence methodology, physicians "often follow a precautionary principle: If a particular factor *might* cause a disease, and the factor is readily avoidable, why not advise the patient to avoid it?" *Tamraz*, 620 F.3d at 673. "This low threshold for making a decision serves well in the clinic but not in the courtroom, where decision requires not just an educated hunch but at least a preponderance of the evidence." *Id.*

In contrast, an expert witness "cannot satisfy *Daubert* by arguing that he used the 'best methodology' available under the circumstance, or that the expert did the best 'he could with the available data and the scientific literature.'" Hollingsworth & Lasker, *supra*, at 103 (footnote and alteration omitted). Nor is it enough to show that the "limited data available [are] consistent with" the expert's hypothesis. Pet. App. 26a. Rather, because "[o]ur legal system requires that claimants prove their cases by a preponderance of the evidence," "the law should not be hasty to impose liability when

---

substance caused a particular individual's disease. *See Restatement* § 28, cmt. c.

scientifically reliable evidence is unavailable.” *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 728 (Tex. 1997). Accordingly, under *Daubert*, the expert must show by a preponderance of the evidence that his opinion reliably follows from a scientifically valid, testable methodology and is therefore worthy to be called “scientific knowledge.” See *Daubert*, 509 U.S. at 592–93 & n.10. An opinion like the one the court of appeals blessed here, which states that medical causation has been established to some unspecified “reasonable degree of scientific probability,” Pet. App. 61a, based on an unelaborated, subjective weighing of all the evidence that cannot be tested, falsified, or replicated by others, does not meet this standard.

Indeed, as far as we have been able to determine, only one federal appellate decision before this case has endorsed an expert opinion based on the weight-of-the-evidence methodology—the Eleventh Circuit decision this Court swiftly reversed in *Joiner*. See *Joiner v. Gen. Elec. Co.*, 78 F.3d 524, 531–32 (11th Cir. 1996); cf. *Allen*, 102 F.3d at 198 (expressly rejecting the weight-of-the-evidence methodology as not “scientifically acceptable” for demonstrating medical causation). The First Circuit’s decision here should meet the same fate.

## **II. THE ADMISSIBILITY OF EXPERT TESTIMONY ON MEDICAL CAUSATION IS AN IMPORTANT AND RECURRING ISSUE THAT MERITS THIS COURT’S REVIEW.**

Aside from the conflict with this Court’s decisions in *Daubert*, *Joiner*, and *Kumho*, review is warranted because (1) the admissibility of expert testimony on medical causation is an extremely important and recurring issue as to which the lower courts are divided, and (2) the decision below eviscerates the

essential gatekeeping function district courts perform to ensure that juries are not misled by “expertise that is *fausse* and science that is junky.” *Kumho*, 526 U.S. at 159 (Scalia, J. concurring).

1. The question of when expert testimony on medical causation is admissible is an important and recurring issue on which the lower courts are in need of further guidance from this Court. Since this Court’s most recent decision on the issue nearly 14 years ago in *Joiner*, lower courts have continued to devote “a great deal of energy to the issue of causation in toxic-tort cases,” *Restatement* § 28, cmt. c, and the issue continues to garner significant attention at the appellate level.<sup>3</sup> As petitioners have

---

<sup>3</sup> For just a sampling of significant post-*Joiner* appellate decisions grappling with the admissibility of expert testimony on medical causation, see, e.g., *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 676–81 (6th Cir. 2011); *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1193–203 (11th Cir. 2010); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 668–78 (6th Cir. 2010); *Best v. Lowe’s Home Ctrs., Inc.*, 563 F.3d 171, 176–84 (6th Cir. 2009); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 253–55 (2d Cir. 2005); *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1237–55 (11th Cir. 2005); *Bitler v. A.O. Smith Corp.*, 391 F.3d 1114, 1119–25 (10th Cir. 2004); *Amorgianos v. Nat’l Rd. Passenger Corp.*, 303 F.3d 256, 264–70 (2d Cir. 2002); *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1203–13 (10th Cir. 2002); *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197–203 (11th Cir. 2002); *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 988–92 (8th Cir. 2001) (per curiam); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 250–55 (6th Cir. 2001); *Hardyman v. Norfolk & W. Ry.*, 243 F.3d 255, 260–67 (6th Cir. 2001); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1207–09 (8th Cir. 2000); *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152–65 (3d Cir. 1999); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260–66 (4th Cir. 1999); *Black v. Food Lion, Inc.*, 171 F.3d 308, 310–14 (5th Cir. 1999); *Baker v. Dalkon Shield Claimants Tr.*, 156 F.3d 248, 251–54 (1st Cir. 1998); *Zuchowicz v. United States*, 140 F.3d 381, 386–87 (2d Cir. 1998); *Kennedy v. Collagen Corp.*, 161 F.3d

ably demonstrated, the courts of appeals have not achieved consistency in this area, and the First Circuit's decision here, which stakes out the most extreme position to date in favor of admissibility, only adds to the cacophony. See Pet. 21–30.

Medical causation is hotly contested because it is “frequently the crucial issue” in toxic-tort and product-liability cases, “which have aroused considerable controversy because they often entail enormous damage claims and huge transaction costs.” *Reference Manual on Scientific Evidence, supra*, at 32. These cases are often “won or lost on the strength of the scientific evidence presented to prove causation.” *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002). As in *Joiner* and this case, an order excluding the plaintiffs' causation expert is usually followed in short order by an order granting summary judgment to the defendant, because without expert testimony on causation, the plaintiffs cannot satisfy an essential element of their claims. See *Restatement* § 28, Reporter's Note, cmt. c (“the admissibility of an expert's opinion may be determinative as to whether the plaintiff satisfies the burden of production on agent-disease causation”). Conversely, when the trial court admits the plaintiff's expert, the defendant, unable to appeal that ruling immediately, often faces tremendous pressure to settle.

Moreover, these decisions affect more than just the parties to the litigation and can have significant implications for the national economy. Under our system of tort law, a single jury's determination on the question of medical causation may effectively decide whether a useful product will remain on the

---

1226, 1227–31 (9th Cir. 1998); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 274–79 (5th Cir. 1998) (en banc).

market. As Justice Breyer observed in *Joiner*, “modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals.” 522 U.S. at 148 (Breyer, J., concurring). It is therefore essential “that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones.” *Id.* at 148–49. Shirking that responsibility by admitting speculative testimony that “allow[s] the law to get ahead of science” would “destroy jobs and stifle innovation unnecessarily.” *Tamraz*, 620 F.3d at 677–78; see also *id.* at 678 (citing a news article “describing how scientists concluded, after years of litigation, billions in settlements and the bankruptcy of a major manufacturer, that no evidence tied breast implants to health problems”).

2. The district court’s gatekeeping role is also essential because of the significant influence expert testimony has on jurors. As numerous courts and commentators have observed, “[e]xpert witnesses can have an extremely prejudicial impact on the jury, in part because of the way in which the jury perceives a witness labeled as an expert.” *Robinson*, 923 S.W.2d at 553. “A witness who has been admitted by the trial court as an expert often appears inherently more credible to the jury than does a lay witness.” *Id.* And “[w]hile many of these experts undoubtedly hold reliable opinions which are of invaluable assistance to the jury, there are some experts who ‘are more than willing to proffer opinions of dubious value for the proper fee.’” *Id.*

In addition, jurors often give special credence to experts because they testify regarding matters beyond the realm of the typical juror's knowledge. Accordingly, a jury presented with "expert" testimony will be less likely to evaluate the expert's conclusions critically and more likely to give special weight to those opinions merely based on their "scientific" nature. See *Daubert*, 509 U.S. at 595 (an expert's opinion "can be both powerful and quite misleading because of the difficulty in evaluating it") (internal quotation marks omitted); *People v. Leahy*, 882 P.2d 321, 325 (Cal. 1994) ("Lay jurors tend to give considerable weight to "scientific" evidence when presented by "experts" with impressive credentials."); *State v. O'Key*, 899 P.2d 663, 672 (Or. 1995) ("Evidence perceived by lay jurors to be scientific in nature possesses an unusually high degree of persuasive power.").

Because jurors often attribute an "aura of special reliability and trustworthiness" to expert opinion, *United States v. Amaral*, 488 F.2d 1148, 1152 (9th Cir. 1973), testimony that fails to meet *Daubert* standards is likely to confuse the issues, mislead the jury, and result in unfair prejudice. See *Daubert*, 509 U.S. at 595; see also *O'Key*, 899 P.2d at 678 n.20 ("Evidence that purports to be based on science beyond the common knowledge of the average person that does not meet the judicial standard for scientific validity can mislead, confuse, and mystify the jury.").

These concerns are only magnified where, as here, the proffered expert opinion rests on a methodology that purports to be scientific, but in fact bears none of the hallmarks of the scientific method and ultimately amounts to nothing more than the expert's *ipse dixit*. In these circumstances trial courts must be vigilant to prevent the jury from hearing "subjective

judgments and inspired guesswork masquerading as scientific knowledge.” Hollingsworth & Lasker, *supra*, at 104. That is precisely what the district court did here, only to be reversed for supposedly abusing its discretion. But if the district court abused its discretion here, then the critical gatekeeping function district courts perform under *Daubert* will be a dead letter: Trial courts will be *required* to admit speculative testimony on open scientific questions whenever an expert claims that his untested hypothesis is, in his judgment, supported by the “weight of the evidence,” whatever that means.

That is not what the drafters of Rule 702 intended when they provided that an expert may testify if, but only if, “scientific . . . knowledge will assist the trier of fact.” Fed. R. Evid. 702; see also *Daubert*, 509 U.S. at 590 (“The adjective ‘scientific’ implies a grounding in the methods and procedures of science. Similarly, the word ‘knowledge’ connotes more than subjective belief or unsupported speculation.”). Nor is it what this Court envisioned when it instructed trial courts to ensure that an expert’s opinion has “a reliable basis in the knowledge and experience of his discipline.” *Id.* at 592. This Court’s review is again necessary to reaffirm the essential role district courts perform in screening expert testimony to separate the wheat from the chaff and ensure that testimony presented to the jury as “scientific knowledge” in fact rests on a reliable scientific foundation.

**CONCLUSION**

For the foregoing reasons, and those stated by petitioners, the Court should grant the petition for certiorari and reverse the decision below.

Respectfully submitted,

CARTER G. PHILLIPS  
JONATHAN F. COHN  
ERIC D. MCARTHUR  
SIDLEY AUSTIN LLP  
1501 K Street, NW  
Washington, DC 20005  
(202) 736-8000

R. MATTHEW CAIRNS\*  
PRESIDENT OF DRI  
55 W. Monroe Street  
Suite 2000  
Chicago, IL 60603  
(312) 795-1101  
cairns@gcglaw.com

TIMOTHY E. KAPSHANDY  
SIDLEY AUSTIN LLP  
1 South Dearborn  
Chicago, IL 60603  
(312) 853-7643

*Counsel for Amicus Curiae*

October 12, 2011

\* Counsel of Record