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 *AMICUS CURIAE*, PRODUCT LIABILITY ADVISORY COUNCIL, INC., IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

HUGH F. YOUNG, JR.
Of Counsel
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Drive, Suite 510
Reston, VA 20191
(703) 264-5300

MARY A. WELLS
Counsel of Record
L. MICHAEL BROOKS, JR.
WELLS, ANDERSON & RACE, LLC
1700 Broadway, Suite 1020
Denver, CO 80290
(303) 830-1212
mwells@warllc.com

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
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QUESTION PRESENTED

Rule 702 of the Federal Rules of Evidence permits admission of expert testimony that is "based upon sufficient facts or data" and "is the product of reliable principles and methods." In *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), this Court reaffirmed the responsibility of district courts to determine whether expert testimony meets these standards, emphasizing that a district court has discretion to exclude "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert" and that "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."

In this case, the district court excluded the opinion proffered by the plaintiffs' causation expert that exposure to benzene was capable of causing a rare form of cancer. Based on flaws in the expert's reasoning and gaps in his data, the district court concluded that the opinion reflected at best unverified "hypotheses." The court of appeals reversed, ruling that the trial court was required to admit the testimony because the expert based his opinion on his "judgment" about the "weight of the evidence." That decision conflicts with *Joiner* and with decisions of at least six other circuits, all of which rule that a district court has discretion to exclude an expert opinion that is not sufficiently tied to reliable underlying data. The question presented is:

QUESTION PRESENTED – Continued

Whether a district court abuses its discretion in excluding expert testimony that draws an inference of potential causation from inconclusive data, merely because the expert asserts that, in his judgment, the weight of the evidence supports his opinion.

PLAC has phrased the question presented in the same manner as Petitioners. By "inconclusive data," PLAC means, and assumes Petitioners mean, data that are inadequate or insufficient to support the proffered conclusion. By this phrasing, PLAC does not suggest that, for expert opinion to be admissible, the available data must be "conclusive" in the sense of supporting only one conclusion.

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INTEREST OF *AMICUS CURIAE*

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit association with 100 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of the law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 900 briefs as *amicus curiae* in both state and federal courts, including more than 75 in this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. Appendix A lists PLAC's corporate members.[1]

[1] Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no person other than *amicus* and its counsel made a monetary contribution to its preparation or submission. Written consent was sought from all parties more than ten days before the due date for this brief. Petitioners' and Respondents' letters consenting to the filing of this brief have been filed with the Clerk's Office.

SUMMARY OF ARGUMENT

The Question Presented in the Petition begins with a quotation from subpart (1) of Rule 702 of the Federal Rules of Evidence, which requires that expert testimony be "based upon sufficient facts or data." The circuit court ignored this text when it reversed the order excluding Dr. Martyn Smith's opinion testimony that Acute Promyelocytic Leukemia (APL) – Plaintiff Brian Milward's disease – can be caused by exposure to benzene. The circuit court repeatedly criticized the trial judge for evaluating whether there was a sufficient basis in the scientific literature to support Dr. Smith's opinions. In so doing, the circuit court failed to give effect to Rule 702(1), which mandates the type of careful gatekeeping the district court performed here.

The last time this Court construed Rule 702 was in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), which was announced a year before Rule 702 was substantially amended to add its three subparts, including subpart (1). That specific subpart has undergone little judicial analysis in the lower federal courts, with many courts assuming, without considering its plain text, that the amendment merely codified *Daubert.* That is what the circuit court did here.

This case presents an opportunity for the Court to clarify the type of sufficiency analysis that is mandated by Rule 702(1) in a case of widespread importance. The case addresses the question of whether benzene is capable of causing a rare type of cancer; no

statistically significant epidemiological evidence links benzene to APL, and there is a vast analytical gap between the animal and cellular studies on which Dr. Smith relies (which relate to *different* diseases and genetic mutations) and the conclusions he proffers. The defendants in this case represent a broadly targeted array of industrial and consumer product manufacturers. But with a substance as ubiquitous as benzene, this case has broad implications for myriad industries and product types. PLAC urges the Court to grant the Petition.

ARGUMENT

I. Under Rule 702(1) of the Federal Rules of Evidence, the district court is required as gatekeeper to evaluate the sufficiency of the facts or data on which an expert opinion is based.

A. This Court has not construed Rule 702 after it was amended in 2000 to require that expert testimony be based on "sufficient facts or data."

Rule 702 of the Federal Rules of Evidence was substantially amended in 2000 in response to *Daubert* and its progeny. With the amended language italicized, Rule 702 provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact

> in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, *if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.*

FED. R. EVID. 702 (emphasis added).[2]

According to the lengthy Advisory Committee Note to the 2000 amendment, the 39-word addition was *not* intended to "codify" the *Daubert* factors of testing, publication, standards, and general acceptance. FED. R. EVID. 702 (advisory committee notes 2000 amendment). The Committee provided an extended summary of the principles articulated in *Daubert*, *Kumho*, and *Joiner*, as well as several lower court decisions. But the Committee was less loquacious in discussing the specific text added to the rule, leading both to scholarly debate about the theoretical basis for the three new subparts and confusion in the courts.[3]

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[2] This Court's trilogy of decisions in *Daubert*, *Joiner*, and *Kumho* construed only the 48 words that precede the italicized language quoted above. *Kumho*, 526 U.S. at 147; *Joiner*, 522 U.S. at 151, n.1; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588 (1993).

[3] *See* 5 CHRISTOPHER B. MUELLER & LAIRD C. KIRKPATRICK, FEDERAL EVIDENCE § 11:8 (3d ed. 2007 & Supp. 2011) (2000 amendment to Rule 702 was a "blockbuster amendment" and

(Continued on following page)

Some circuit and district courts have assumed that the amendment was made to state explicitly what *Daubert* had found by implication, that Rule 702 embodies an evidentiary reliability standard. Other courts, ignoring the Advisory Committee's Notes, have said that the amendment codified aspects of *Daubert*. *E.g.*, *United States v. Mitchell*, 365 F.3d 215, 234 (3d Cir. 2004); *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). Still others have held that the amendment superseded *Daubert*, but that, in the absence of controlling case law on the amended rule, *Daubert* and its progeny remain *persuasive* authority. *E.g.*, *United States v. Parra*, 402 F.3d 752, 758 (7th Cir. 2005); *Huber v. JLG Indus., Inc.*, 344 F. Supp. 2d 769, 773 (D. Mass. 2003).

"perhaps the most significant of all of the amendments to the Rules adopted to date"); 3 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE § 22:15 (2010) (Rule 702(1) embodies a "fit" analysis "as discussed in *Daubert* and *Joiner*"); *see also* Jonathan M. Hoffman, *If the Glove Don't Fit, Update the Glove: The Unplanned Obsolescence of the Substantial Similarity Standard for Experimental Evidence*, 86 NEB. L. REV. 633, 652 (2008) ("In 2000, *Kumho*'s holding was codified by amending Rule 702 to its current form"); William G. Childs, *The Overlapping Magisteria of Law and Science: When Litigation and Science Collide*, 85 NEB. L. REV. 643, 680 n.23 (2007) (embracing the theory that the amended Rule 702 superseded *Daubert*); David G. Owen, *A Decade of Daubert*, 80 DENV. U. L. REV. 345, 362 (2002) ("the amendment (including the Committee Note) to Federal Rule of Evidence 702 does not provide a conclusive roadmap for each specific aspect of expert testimony, but it does provide helpful guidance").

Most lower court opinions merely acknowledge the rule, and then analyze the testimony without any effort to apply the rule's precepts. This is a fundamental error, starkly visible in the circuit court's decision here (as will be discussed *infra*) that deserves this Court's attention. Basic canons of construction require that courts give effect to the full text of the amended rule.[4] In construing such amendments, courts must presume that the changes were intended to have a "real and substantial effect." *Pierce Cnty., Wash. v. Guillen*, 537 U.S. 129, 145 (2003). The unsupported assumption that the amendment did nothing more than ratify the pre-existing case law is contrary to this canon. Further, courts should presume that the amended and original parts were designed to function as an integrated whole, giving effect to both. *See Markham v. Cabell*, 326 U.S. 404, 411 (1945).[5]

The amendment to Rule 702 added three subparts identifying findings the trial court must make to admit expert testimony. Of the three, the latter two rather easily trace their ancestry to *Daubert*'s text, even if the Advisory Committee Note does not provide

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[4] This Court construes Rule 702 using the canons of interpretation applicable to any statute. *Daubert*, 509 U.S. at 587.

[5] The amendment to Rule 702 was not a mere stylistic change. Notably, in a proposed amendment to Rule 702 set to become effective in December 2011, the Committee specifically stated that it was making only "stylistic" revisions. FED. R. EVID. 702 (advisory committee notes to 2011 amendment).

this history. The second subpart requires that "the testimony is the product of reliable principles and methods," FED. R. EVID. 702(2), which mirrors *Daubert*'s focus on the reliability of the expert's "principles and methodology. . . ." 509 U.S. at 595. The third subpart requires that "the witness has applied the principles and methods reliably to the facts of the case." FED. R. EVID. 702(3). This reflects *Daubert*'s overarching focus on reliability; its specific concern about "whether expert testimony proffered in the case is sufficiently tied to the facts of the case," *id.* at 591; and *Joiner*'s holding that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert," so a "court may conclude that there is simply too great an analytical gap between the data and the opinion proffered," 522 U.S. at 146 (citing *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992)).[6]

However, the lineage of the first subpart – that expert testimony must be "based upon *sufficient* facts or data" – is more difficult to pinpoint. Perhaps because of its uncertain parentage, this subpart receives slightly more attention than the other two in the Advisory Committee's Note. Subpart (1) "calls for a quantitative rather than qualitative analysis." FED.

[6] An early draft version of the amended Rule 702(3) was quoted in *Kumho*. 526 U.S. at 157.

R. EVID. 702 (advisory committee notes 2000 amendment).[7] The word "data" as used in the amendment is intended to encompass the reliable opinions of other experts, and the words "facts or data" are broad enough to allow an expert to rely on hypothetical facts that are supported by the evidence. *Id.* Yet all told, the Advisory Committee Notes offer precious little about determining what constitutes "sufficient" facts or data.

Looking beyond the Advisory Committee Notes, it is difficult to find specific language in this Court's case law related to subpart (1)'s requirement of "sufficient facts or data." Again, likely ancestors are *Daubert*'s primary concern with reliability and *Joiner*'s declaration that a district court should not admit opinion "that is connected to existing data only by the *ipse dixit* of the expert" and thus suffers from "too great an analytical gap between the data and the opinion proffered." 522 U.S. at 146 (citing *Turpin*, 959 F.2d at 1360). In a later opinion, this Court relied on *Joiner* in ruling that "[s]cientific evidence and expert testimony must have a *traceable, analytical basis in objective fact* before it may be considered on summary judgment," suggesting that *Joiner* supports a sufficiency evaluation. *Bragdon v. Abbott*, 524 U.S. 624, 653 (1998) (emphasis added). A more distant relative

[7] "The question is whether the expert considered *enough* information to make the proffered opinion reliable." 29 CHARLES ALAN WRIGHT & VICTOR JAMES GOLD, FEDERAL PRACTICE & PROCEDURE § 6266 (Supp. 2011) (emphasis in original).

may be the portion of *Daubert* where the Court discussed the sufficiency of the scientific evidence in referring to district courts' authority to direct verdicts when scientific evidence is "insufficient" to support a finding of causation. 509 U.S. at 596 (citing *Turpin*, 959 F.2d 1349).

B. *Turpin v. Merrell Dow* presents the best explanation for the "sufficient facts or data" requirement of Rule 702(1).

Notably, when this Court spoke about the sufficiency of scientific evidence in both *Daubert* and *Joiner*, it cited with approval the Sixth Circuit's opinion in *Turpin*, one of only two lower court decisions to be cited more than once in this Court's *Daubert* trilogy.[8] PLAC submits that the reasoning contained in *Turpin* presents the most clearly articulated and direct foundation for the "sufficient facts or data" requirement found in Rule 702(1).

Turpin was a Bendectin case, and a predecessor of *Daubert*. The district court granted summary judgment to the defendant manufacturer in part on the basis that the plaintiffs had failed to present sufficient scientific evidence that Bendectin was the source of the plaintiffs' birth defects. *See Turpin v. Merrell Dow Pharmaceuticals Inc.*, 736 F. Supp. 737, 744 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir.

[8] The other is *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), concerning "fit."

1992). The circuit court in *Turpin* engaged in a detailed analysis of the scientific studies on which the plaintiffs' causation case rested, 959 F.2d at 1358-60, like the district court's order here.

Most of the plaintiffs' scientific evidence in *Turpin* consisted of animal (*in vivo*) and cellular (*in vitro*) studies and clinical case analysis, with no statistically significant epidemiology supporting a causal link. *See* 959 F.2d at 1357-59. The court noted that, in general, animal and cellular studies may have value in risk assessment and regulation, but they did not support the conclusion that Bendectin was capable of causing birth defects in humans, stating that the "analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide." *Id.* at 1360. The *Turpin* plaintiffs presented expert testimony from a medical doctor who had examined the animal, cellular, and epidemiological studies, as well as the plaintiffs' medical records, and concluded that Bendectin probably caused the plaintiffs' birth defects. *Id.* In essence, this expert conducted a weight-of-the-evidence analysis, surveying the medical and scientific literature and rendering an opinion on causation. *See id.* The court concluded that this testimony was nothing "more than a personal belief or opinion" because the evidence was "insufficient to meet the plaintiffs' burden of proof." *Id.* The expert used his personal judgment in weighing the evidence and his "conclusions go far beyond the known facts that form the premise for the conclusion stated." *Id.* The court declined to

give any weight to epidemiological data that demonstrated only that it was "possible" that Bendectin caused birth defects, without showing any probability. *Id.* at 1357. By this Court's repeated citation, *Turpin* supports the notion that a threshold review of the *sufficiency* of the facts or data supporting an expert's conclusion must be part of the threshold *reliability* review that is required to admit expert testimony under *Daubert* and now, expressly, Rule 702(1).

C. Rule 702(1) requires an evaluation of what the expert considered and what facts or data were ignored.

Together with *Turpin*, this Court's opinions in *Bragdon* and *Kumho* amplify the need for a sufficiency analysis that is focused on objective analysis, not subjective belief, unsupported speculation, individual judgment calls, or "I know it when I see it" determinations. The presence or absence of objectivity is, in the final analysis, the point of demarcation between subjective, personal opinions of the type excluded by *Turpin* and reliable expert opinions capable of aiding the jury. Two types of analysis are called for under Rule 702(1) to address the sufficiency of the facts or data supporting an expert opinion.

First, under Rule 702(1), an analysis of the sufficiency of the facts or data must necessarily begin with a threshold determination about whether there are facts or data available that are capable of addressing the scientific or technical issue, or whether

the subject of inquiry is simply too novel or unexamined to support any conclusion. *Daubert*, 509 U.S. at 597 (recognizing that the gatekeeping role of the trial judge may require the exclusion of "authentic insights and innovations" where the state of scientific knowledge has not developed enough to support admissibility of opinion evidence); *In re Breast Implant Cases*, 942 F. Supp. 958, 960 (E.D.N.Y. & S.D.N.Y. 1996) (Baer & Weinstein, JJ.) ("We should not rush to judgment where new scientific theories are proposed that lack adequate support or refutation because they are so new."). Even if expert witnesses ground their opinions in sound principles and methods, the court must determine whether their work "yielded facts and data sufficient to support [their] proposed testimony," as "experts' opinions are worthless without data and reasons." *United States v. Mamah*, 332 F.3d 475, 477-78 (7th Cir. 2003).

Second, in a case involving expert evidence on general causation where there is a threshold body of facts or data for an expert to examine, the court must evaluate: (1) whether the expert considered all the pertinent facts or data; and (2) whether there are other facts or data not considered by the expert that "might lead to alternative theories of causation." WRIGHT & GOLD, *supra*, § 6266 (Supp. 2011). While the Advisory Committee's Note states that the analysis directed by Rule 702(1) is "quantitative," the gatekeeper court must necessarily address the degree to which an expert places greater emphasis on some "facts or data," while "discounting the significance of

more relevant criteria." *Mike's Train House, Inc. v. Lionel, L.L.C.*, 472 F.3d 398, 408 (6th Cir. 2006). Otherwise experts could evade gatekeeper review simply by claiming to have "considered" all the facts or data, even though the experts discounted facts or data that did not support their opinions.

As discussed next, the district court in this case correctly performed a sufficiency review under Rule 702(1) and the circuit court erred in concluding that *Daubert* precluded a sufficiency analysis.

II. The First Circuit here not only ignored Rule 702(1)'s requirement of "sufficient facts or data," it chastised the district court judge for following the Rule.

The circuit court here quoted the text of Rule 702, but it merely recited the words without considering their meaning. *Milward v. Acuity Specialty Prods. Group, Inc.*, 639 F.3d 11, 14 (1st Cir. 2011). The rest of the court's opinion is spent eviscerating the "sufficient facts or data" requirement from the Rule. The opinion cuts far deeper than Rule 702(1), striking the very heart of *Daubert* and, in the process, effectively adopting as circuit law Justice Stevens' lone (partial) dissent in *Joiner*.

The circuit court found error in the trial court's conclusion that Dr. Smith did not have a sufficient factual basis for his opinions. *Id.* at 21. Most telling is the circuit court's statement that "the alleged flaws identified by the court go to the weight of Dr. Smith's

opinion, not its admissibility. There is an important difference between what is *unreliable* support and what a trier of fact may conclude is *insufficient* support for an expert's conclusion." *Id.* at 22 (emphasis in original). The circuit court criticized the district court for "repeatedly challeng[ing] the factual underpinnings of Dr. Smith's opinion," claiming that the district court "took sides on questions that are currently the focus of extensive scientific research and debate," and "overstepped the authorized bounds of its role as gatekeeper" by considering the "soundness of the factual underpinnings of the expert's analysis. . . ." *Id.* (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) (decided before Rule 702 was amended)). The circuit court's statements reveal its failure to consider, much less apply, the specific commands of Rule 702. Further, sidestepping *Joiner*'s analytical-gap inquiry, the circuit court declared that exclusion of Dr. Smith's opinions was not required because "the gap was of the district court's making." *Id.* (quoting *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (9th Cir. 1998)).[9]

The application of *Daubert* is one of the most heavily litigated issues in the federal courts. If it

[9] *Kennedy* is, of course, another pre-amendment case. Moreover, in that case, the analytical gap was said to be "of the district court's making" only because the lower court had failed to consider all of the data relied on by the expert, leaving a gap in the evidence that the trial court held against the proponent of the expert testimony. 215 F.3d at 1230. Nothing similar happened here.

were error for a district court to evaluate the foundational strength of the fact or data on which the expert relied, as the district court did here, one would expect to see a deluge of case law disapproving that type of analysis. The reality in many circuits is quite the reverse, both before and after the December 2000 amendment to Rule 702. *See*, *e.g.*, *Mike's Train House*, 472 F.3d at 408 (reversing district court decision admitting expert testimony in part on the basis that the expert failed to rely on sufficient facts or data to support opinion); *Norris v. Baxter Healthcare Corp*., 397 F.3d 878, 885-86 (10th Cir. 2005) (affirming exclusion of expert testimony after finding that case studies were insufficient basis to support general causation findings); *Allison v. McGhan Med. Corp*., 184 F.3d 1300, 1314 (11th Cir. 1999) (affirming exclusion of causation evidence after concluding that animal and cellular studies were insufficient to support causation opinions); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 279 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999) (affirming exclusion of expert testimony based on absence of scientific support for the use of differential diagnosis to determine general causation).

The circuit court also grossly overstated the reliability of Dr. Smith's effort to "weigh the evidence" using his "judgment" to support leaps from various studies regarding other types of leukemia to support his conclusion that benzene can cause APL. It does this first by labeling Dr. Smith's *ipse dixit* a

"methodology," *Milward*, 639 F.3d at 17, but does not end there.

The court then credits Dr. Smith for following "the guidelines articulated by world-renowned epidemiologist Sir Arthur Bradford Hill in his seminal methodological article on inferences of causality." *Id.* The court explained that, "[i]n this mode of reasoning, the use of scientific judgment is necessary" because "'[n]o algorithm exists for applying the Hill guidelines to determine whether an association truly reflects a causal relationship or is spurious.'" *Id.* (quoting RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 cmt. c(3) (2010)).[10] This statement reveals a fundamental misunderstanding of the role of the Bradford Hill Criteria. The Reporters' Notes to the Restatement section cited by the court explain that "[i]n a number of cases, experts attempted to use the Hill guidelines to support the existence of causation in the absence of any epidemiological studies finding an association. . . . The Hill factors were developed for the purpose of determining whether an inference of causation is justified based on a study finding an *association*, and their use to

[10] Comment c to the RESTATEMENT § 28 has been criticized for diluting standards for causation in toxic-tort cases. *See* Victor E. Schwartz & Cary Silverman, *The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts*, 35 HOFSTRA L. REV. 217, 273 (2006) (application of Comment c "could move courts toward to a pre-*Daubert* era, where unsupported expert testimony would be permissible, and juries could be inundated with junk science.").

provide the sole basis for proof of general causation does not reflect accepted epidemiologic methodology." RESTATEMENT § 28 reporters' note cmt. c(3) at 441 (emphasis added). In fact, it is only when the epidemiological research first establishes an association between a substance and a disease that the Bradford Hill criteria become relevant to the evaluation of the strength of the epidemiologic evidence. Bert Black et al., *Guide to Epidemiology*, *in* EXPERT EVIDENCE: A PRACTITIONER'S GUIDE TO LAW, SCIENCE, AND THE FJC MANUAL 73, 98-99 (Bert Black & Patrick W. Lee eds., 1997).

Here, however, the only epidemiological evidence was, in the circuit court's words, "not statistically significant." *Milward*, 639 F.3d at 20. Without statistical significance, these epidemiological studies do not establish an association and, therefore, do not warrant consideration of a causal inference under the Bradford Hill criteria. *See* Black et al., *supra*, at 107.

Regulatory agencies may consider factors similar to the Bradford Hill criteria in evaluating potential public health risks. *See Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1320 (2011). However, the use of public-health risk-assessment methodologies as litigation tools to determine cause-in-fact in a damages action is inherently flawed. The methodologies employed by government agencies engaged in risk regulation "result[ ] from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is reasonably lower than that appropriate

in tort law, which traditionally makes more particularized inquiries into cause and effect and requires a plaintiff to prove that it is more likely than not that another individual has caused him or her harm." *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (criticizing use of "weight of the evidence" methodology to determine causation). Notably, even with their lower threshold of evidence, administrative agencies have evaluated potential health consequences of benzene exposure, but have not arrived at any conclusion as to a causal link between benzene and APL, the disease at issue here.

As the Petition points out, significant conflicts exist within the circuits on the scientific validity of the "weight of the evidence" analysis performed by Dr. Smith. Further, as noted throughout the Petition, there is an irreconcilable conflict between the circuit court's decision and this Court's holding in *Joiner*. The circuit court cited *Joiner*, and then departed completely from its reasoning. Its decision cannot withstand even casual scrutiny under *Daubert* and its progeny; it will wreak havoc among district judges in the First Circuit; and it will infect the reasoning of courts in other circuits if it is not repudiated by this Court.[11]

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[11] Already the opinion is being cited in support of a more hands-off gatekeeping role for the district courts. *E.g.*, *Bertrand v. Gen. Elec. Co.*, No. CIV.A. 09-11948-RGS, 2011 WL 4381014, at *4-6 (D. Mass. Sept. 21, 2011) (admitting expert testimony that defect in oven range burner knob allowed one of the plaintiffs' 18

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III. This case, on its own facts, is of sufficient national importance to justify certiorari review.

A. Benzene is omnipresent and occurs, by fortuity or design, in a vast variety of products and applications.

Benzene is "omnipresent." *Indus. Union Dep't., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 615, 626 (1980). Indeed, the "entire population of the United States is exposed to small quantities of benzene." *Id.* Benzene is a naturally occurring compound found in ambient air, water, and virtually every consumer food product. U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR BENZENE 271-73 (2007), *available at* http://www.atsdr.cdc.gov/toxprofiles/tp3-c6.pdf [hereinafter TOXICOLOGICAL PROFILE]; U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT ON CARCINOGENS 61 (12th ed. 2011), *available at* ntp.niehs.nih.gov/ntp/roc/twelfth/roc12.pdf [hereinafter REPORT ON CARCINOGENS].

The primary route of human exposure to benzene is through ambient air, where exposure is greatest for those who spend significant time in vehicles caught in congested traffic. REPORT ON CARCINOGENS AT 61; TOXICOLOGICAL PROFILE at 278. Smoking and second-hand smoking are major contributors to exposure. REPORT ON CARCINOGENS at 61. Atmospheric benzene occurs

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pet cats to turn on burner and start fire that destroyed family home).

from natural sources such as forest fires and oil seeps, as well as industrial sources such as industrial emissions, hazardous waste sites, fuel evaporation from gasoline filling stations, and automobile exhaust. *Id.* Inhalation exposure also occurs through "off-gassing" from water during showering and cooking. TOXICOLOGICAL PROFILE at 278.

Benzene is present in virtually every consumer food product, including:

> cheddar cheese, cream cheese, margarine, butter, sour cream, ground beef, bologna, hamburger, cheeseburger, pork, beef frankfurters, tuna canned in oil, chicken nuggets, chocolate cake icing, sandwich cookie, chocolate chip cookies, graham crackers, sugar cookies, cake doughnuts with icing, french fries, apple pie, cola carbonated beverages, sweet roll Danish, potato chips, cheese pizza, cheese and pepperoni pizza, mixed nuts, fruit-flavored cereal, fruit flavored sorbet, popsicles, olive/safflower oil, scrambled eggs, peanut butter, popcorn popped in oil, blueberry muffins, coleslaw with dressing, raw banana, avocado, oranges, and strawberries.

Id. at 271-73. In fact, the only food tested that did not contain benzene was American cheese. *Id.* Ingested benzene is particularly problematic because "[a]bsorbed benzene is rapidly distributed throughout the body and tends to accumulate in fatty tissues." U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXGUIDE FOR BENZENE 1 (2007), *available at* www.atsdr.cdc.gov/toxguides/toxguide-3.pdf.

In addition to these quotidian exposures to benzene, as of 1994, more than three million workers were exposed to benzene in the workplace. *Metro-N. Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 434 (1997) (citing U.S. DEP'T OF HEALTH & HUMAN SERVS., SEVENTH ANNUAL REPORT ON CARCINOGENS 71 (1994)). In fact, significant exposure to benzene was found in the following industries and occupations:

> workers at petrochemical plants, petroleum refineries, coke and coal chemicals, tire manufacturers, bulk terminals, bulk plants, drivers of tank trucks, nurses and aides, physicians, technicians, technologists, therapists, dieticians, pharmacists, janitors, gasoline station workers, firefighters, and dry cleaners.

TOXICOLOGICAL PROFILE at 279-81. Consequently, "contacts, even extensive contacts, with serious carcinogens are common." *Buckley*, 521 U.S. at 434.

B. The economic ramifications of benzene regulation, in any form, are staggering.

Despite benzene's omnipresence, because of its "importance to the economy, no one has ever suggested that it would be feasible to eliminate its use entirely, or to try to limit exposures to the small amounts that are omnipresent." *Indus. Union Dep't*, 448 U.S. at 637. Indeed, the Occupational Safety and Health Administration (OSHA), which regulates exposure to benzene in the workplace, mandates warnings only if a mixture exceeds 0.1% benzene; anything

less is not even considered "benzene-containing."[12] 29 C.F.R. § 1910.1028 (2011).

Given benzene's omnipresence and economic significance, this Court has refused to allow a reduction by OSHA in benzene permissible exposure limits (PELs) based on little more than a general notion, unsupported by sound scientific evidence, that exposure to 1 ppm of benzene was significantly safer than exposure to 10 ppm. *Indus. Union*, 448 U.S. at 653-54. The Court noted that even in 1980, such regulation would "require capital investments in engineering controls of approximately $266 million, first-year operating costs . . . of $187 million to $205 million and recurring annual costs of approximately $34 million." *Id.* at 628-29 (citing 43 FED. REG. 5934 (1978)). Moreover, the petroleum refining industry would incur costs of $82,000 per employee, solely for capital costs and first-year operating expenses, and the petrochemical industry would incur the same costs of $39,675 per employee. *Id.* at 629. Further, the proposed tenfold PEL reduction would have benefitted only about 35,000 employees. *Id.*

Projecting these estimates into the cost of implementation in 1992, almost twenty years ago, commentators found costs of between $273 million and $1.1 billion per life saved. *E.g.,* Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533,

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[12] Note that "[b]enzene constitutes 1-2% of most blends of gasoline." TOXICOLOGICAL PROFILE at 277.

1547 (1996). Thus, regulation of benzene, in any form, is enormously expensive relative to its benefits.

1. The cost of regulation by jury, based upon insufficient facts or data, is potentially catastrophic to many industries.

Even more problematic than agency regulation is judicial regulation of benzene. The courts are, indeed, "vigorous regulators" because "[d]amage actions sounding in nuisance, negligence, strict liability, and absolute liability are powerful instruments of regulation." Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 306-07 (1985). Undeniably, "[e]very risk creator and every risk bearer knows that the damage action . . . is potent medicine for regulating public risks." *Id.*

Juries are often "incapable of engaging in the aggregative calculus of risk created and risk averted that progressive public-risk management requires." *Id.* at 278; *see also* Gregory C. Keating, *Pressing Precaution Beyond the Point of Cost-Justification*, 56 VAND. L. REV. 653, 657 (2003); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2173 (2000). Regulation by jury "generates seriously erroneous and inconsistent liability decisions, and results in overdeterrence with respect to regulated products that present complex scientific and technical

questions regarding risk, benefit, and causation." Stewart, *supra*, at 2171. Often jury determinations are directly contrary to "regulatory determinations regarding product risks and benefits, as well as the overwhelming consensus of knowledgeable independent scientists regarding these products' potential to cause harm." *Id.*; *see also* Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 192-93 (1992) ("Erroneous plaintiffs' verdicts and the corresponding overcompensation and over-deterrence are not just academic concerns. The prospect of useful products being driven from the market or of economic resources being diverted from productive uses is real, as the cases of vaccines and Bendectin illustrate.").

Furthermore, just one erroneous plaintiffs' verdict creates a potentially "catastrophic" multiplicity problem because even "an occasional plaintiff's verdict may . . . encourage other suits and increase the settlement value of other cases." Poulter, *supra*, at 193. Considering that, in 2010 alone, 64,367 products-liability actions were filed in the U.S. District Courts, the impact of an erroneous verdict cannot be understated. JAMES C. DUFF, JUDICIAL BUSINESS OF THE U.S. COURTS: 2010 ANNUAL REPORT OF THE DIRECTOR, TABLE S-10 U.S. DISTRICT COURTS – PRODUCT LIABILITY CASES COMMENCED, BY NATURE OF SUIT, DURING THE 12-MONTH PERIODS ENDING SEPTEMBER 30, 2009 AND 2010, *available at* http://www.uscourts.gov/Statistics/JudicialBusiness/2010/tables/ S10Sep10.pdf.

2. Unless the standards for admissibility of scientific expert evidence consistently exclude unreliable testimony, regulation by jury can only be erratic and unpredictable.

What enables or defeats improper regulation by jury is a "regulariz[ation of] the standard for admissibility of scientific evidence." Poulter, *supra*, at 193 (citing numerous cases and commentators). It is well-settled that "[i]n products liability litigation, whether claimants prevail often depends upon expert testimony presented on the issue of causation." Lester Brickman, *On the Relevance of the Admissibility of Scientific Evidence: Tort System Outcomes are Principally Determined by Lawyers' Rates of Return*, 15 CARDOZO L. REV. 1755 (1994); *see also* Barbara J. Rothstein et al., *A Model Mass Tort: The PPA Experience*, 54 DRAKE L. REV. 621, 625 (2006); M. Stuart Madden, *The Duty to Warn in Products Liability: Contours and Criticism*, 11 J. PROD. LIAB. 103, 125 (1988); Kenneth A. Cohen, *Class Actions, Toxic Torts, and Legal Rules*, 67 B.U. L. REV. 581, 595 (1987). Thus, it is "particularly important to see 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." *Joiner*, 522 U.S. at 148-49 (Breyer, J., concurring).

Allowing an unreliable expert opinion that benzene causes a rare form of cancer, despite a complete

lack of epidemiological support (or even support in animal or cellular studies involving the same disease or genetic mutation), creates a cascade effect of regulation by jury and overdeterrence that, given benzene's omnipresence, would reverberate throughout the national economy. Allowing the same approach as to innumerable other substances to which we are all exposed on a daily basis would increase only the societal harm exponentially.

CONCLUSION

For these reasons, PLAC respectfully requests that this Court grant Petitioners' Petition for a Writ of Certiorari.

Respectfully submitted,

HUGH F. YOUNG, JR.
Of Counsel
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Drive, Suite 510
Reston, VA 20191
(703) 264-5300

MARY A. WELLS
Counsel of Record
L. MICHAEL BROOKS, JR.
WELLS, ANDERSON & RACE, LLC
1700 Broadway, Suite 1020
Denver, CO 80290
(303) 830-1212
mwells@warllc.com

APPENDIX

Corporate Members of the Product Liability Advisory Council, Inc.

3M Company

Altec Industries

Altria Client Services Inc.

American Airlines

Astec Industries

Bayer Corporation

Beretta U.S.A. Corp.

BIC Corporation

Biro Manufacturing Company, Inc.

BMW of North America, LLC

Boeing Company

Bombardier Recreational Products, Inc.

BP America Inc.

Bridgestone Americas, Inc.

Brown-Forman Corporation

Caterpillar Inc.

Chrysler Group LLC

Cirrus Design Corporation

CLAAS of America Inc.

Continental Tire the Americas LLC

Cooper Tire and Rubber Company

Crown Cork & Seal Company, Inc.

Crown Equipment Corporation

Daimler Trucks North America LLC

Deere & Company

The Dow Chemical Company

E.I. duPont de Nemours and Company

Emerson Electric Co.

Engineered Controls International, Inc.

Environmental Solutions Group

Estee Lauder Companies

Exxon Mobil Corporation

Ford Motor Company

General Electric Company

General Motors Corporation

GlaxoSmithKline

The Goodyear Tire & Rubber Company

Great Dane Limited Partnership

Harley-Davidson Motor Company

Hawker Beechcraft Corporation

Honda North America, Inc.

Hyundai Motor America

Illinois Tool Works, Inc.

Isuzu North America Corporation

Jaguar Land Rover North America, LLC

Jarden Corporation

Johnson & Johnson

Johnson Controls, Inc.

Kawasaki Motors Corp., U.S.A.

Kia Motors America, Inc.

Kolcraft Enterprises, Inc.

Kraft Foods North America, Inc.

Lincoln Electric Company

Magna International Inc.

Marucci Sports, L.L.C.

Mazak Corporation

Mazda (North America), Inc.

Medtronic, Inc.

Merck & Co., Inc.

Meritor WABCO

Michelin North America, Inc.

Microsoft Corporation

Mitsubishi Motors North America, Inc.

Mueller Water Products

Mutual Pharmaceutical Company, Inc.

Navistar, Inc.

Niro Inc.

Nissan North America, Inc.

Novartis Pharmaceuticals Corporation

PACCAR Inc.

Panasonic

Pella Corporation

Pfizer Inc.

Polaris Industries, Inc.

Porsche Cars North America, Inc.

Purdue Pharma L.P.

Remington Arms Company, Inc.

RJ Reynolds Tobacco Company

Schindler Elevator Corporation

SCM Group USA Inc.

Shell Oil Company

The Sherwin-Williams Company

Smith & Nephew, Inc.

St. Jude Medical, Inc.

Stanley Black & Decker, Inc.

Subaru of America, Inc.

Techtronic Industries North America, Inc.

Thor Industries, Inc.

TK Holdings Inc.

The Toro Company

Toyota Motor Sales, USA, Inc.

Vermeer Manufacturing Company

The Viking Corporation

Volkswagen Group of America, Inc.

Volvo Cars of North America, Inc.

Vulcan Materials Company

Whirlpool Corporation

Yamaha Motor Corporation, U.S.A.

Yokohama Tire Corporation

Zimmer, Inc.