No. 11-

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

PETITION FOR A WRIT OF CERTIORARI

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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," rather than reliable scientific conclusions. 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:

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.

PARTIES TO THE PROCEEDING

Petitioners, defendants-appellees in the proceeding below, are United States Steel Corporation, Acuity Specialty Products, Inc., American Grease Stick Company, Berryman Products, Inc., Boyle-Midway, Inc., Braskem America Inc., The Clorox Company, CRC Industries, Inc., Henkel Corporation, NCH Corporation, Nu-Calgon Wholesaler, Inc., Radiator Specialty Company, Rust-Oleum Corporation, The Sherwin-Williams Company, The Steco Corporation, Sunnyside Corporation, USX Corporation, and WD-40 Company.

The following parties were initially named as defendants but were later dismissed from the case and did not participate in the proceeding in the court of appeals: Bostik, Inc., La-Co-Industries, Inc./Markal, LPS Industries, Inc., Sunoco, Inc., Zep Manufacturing Company, and Nicus Corporation.

Respondents are Brian K. Milward and Linda J. Milward, plaintiffs-appellants below.

CORPORATE DISCLOSURE STATEMENT

The shares of United States Steel Corporation are publicly traded. United States Steel Corporation does not have a parent corporation, and no publicly-held company owns 10% or more of United States Steel Corporation's stock.

Acuity Specialty Products, Inc., is incorrectly identified in the pleadings as "Acuity Specialty Products Group, Inc." Acuity Specialty Products, Inc. d/b/a Zep Sales & Service, f/k/a Acuity Specialty Products Group, Inc., d/b/a Zep Manufacturing Company, is a wholly-owned subsidiary of Zep Inc., which is a publicly traded corporation.

American Grease Stick Company has no parent corporation and no publicly-held company owns 10% or more of its stock.

Braskem America, Inc. (formerly known as Aristech Chemical Corporation, Sunoco Chemicals, Inc., and Braskem PP Americas Inc.) is a wholly-owned subsidiary of Braskem, S.A. Braskem S.A. is publicly traded on the Sao Paulo Exchange and the Madrid Exchange, and its American Depositary Receipts are traded on the New York Stock Exchange.

Berryman Products, Inc. has no parent corporation and no publicly-held company owns 10% or more of its stock.

Boyle-Midway, Inc.'s successor by merger is Reckitt Benckiser Inc. (formerly known as Reckitt & Colman Inc.). Reckitt Benckiser Inc., a Delaware corporation, converted itself into a Delaware limited liability company under the name Reckitt Benckiser LLC as of January 1, 2011. Reckitt Benckiser LLC is an indi-

rect subsidiary of Reckitt Benckiser Group plc, a publicly-held foreign company.

The Clorox Company has no parent corporation and no publicly-held company owns 10% or more of its stock.

The parent corporation of CRC Industries, Inc. is Berwind Industries, LLC. No publicly-held company owns 10% or more of CRC Industries, Inc.'s stock.

Henkel Corporation is a wholly-owned indirect subsidiary of Henkel of America, Inc., which is in turn a wholly-owned indirect subsidiary of Henkel KGaA.

NCH Corporation has no parent corporation and no publicly-held company owns 10% or more of its stock.

Nu-Calgon Wholesaler, Inc., has no parent corporation and no publicly-held company owns 10% or more of its stock.

Radiator Specialty Company has no parent corporation and no publicly-held company owns 10% or more of its stock.

The parent corporation of Rust-Oleum Corporation is RPM Consumer Holding Company, which is a subsidiary of RPM International, Inc., which is publicly traded.

The Sherwin Williams Company has no parent corporation and no publicly-held company owns 10% or more of its stock.

The Steco Corporation has no parent corporation and no publicly-held company owns 10% or more of its stock.

Sunnyside Corporation has no parent corporation and no publicly-held company owns 10% or more of its stock.

USX Corporation, which plaintiffs named as a defendant as a successor to United States Steel Corporation, was never served with process in this case. United States Steel Corporation changed its name to USX Corporation in 1986. USX Corporation merged into United States Steel LLC in 2001, and United States Steel LLC is now known as United States Steel Corporation. The "USX Corporation" that was formerly a successor to United States Steel Corporation therefore no longer exists and has no shareholders.

WD-40 Company has no parent corporation and no publicly-held company owns 10% more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners United States Steel Corporation, *et al.*, respectfully petition for a writ of certiorari to review a judgment of the United States Court of Appeals for the First Circuit.

OPINIONS BELOW

The court of appeals' decision (App. 1a-29a) is reported at 639 F.3d 11. The district court's decision excluding respondents' proffered expert testimony (App. 33a-53a) is reported at 664 F. Supp. 2d 137.

JURISDICTION

The court of appeals' judgment was entered on March 22, 2011. App. 1a. Rehearing was denied on April 14, 2011. App. 55a. On June 24, 2011, Justice Breyer extended the time for filing a petition for certiorari to Sunday, September 11, 2011. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

RELEVANT RULE

Rule 702 of the Federal Rules of Evidence provides:

> 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.

STATEMENT

1. Petitioners make and sell various industrial and consumer products. Respondents Brian and Linda Milward sued petitioners for negligence, alleging that Brian Milward, who worked as a refrigerator technician in the Boston area for over thirty years, was injured by exposure to "'products manufactured and/or sold by [petitioners] which included benzene as an ingredient or contaminant.'" App. 34a. The complaint alleged that "'[a]s a direct and proximate result of [his] exposure to benzene … and other benzene-containing products,'" Mr. Milward developed a rare form of cancer known as

acute promyelocytic leukemia (APL). *Id.* (alterations in original).[1]

Leukemia is a cancer that results from the malignant mutation of blood cells. There are numerous different forms of leukemia, many of which are classified based on the type of cell that has mutated ("myeloid" or "lymphoid") and how quickly the mutated cells accumulate ("acute" or "chronic"). App. 7a-8a. Leukemic disorders involving rapid accumulation of mutated myeloid cells are classified as acute myeloid leukemias, or AMLs. App. 7a. AML is not a single disease, but rather a broad classification that, by convention, includes eight distinct subtypes, one of which is APL. App. 8a.

AMLs as a category are rare, with an annual incidence of only 3.5 cases per 100,000 people, and the APL subtype accounts for only five to ten percent of all cases of AML. App. 8a. APL differs from all other AML subtypes because it involves an excess of immature cells called promyelocytes and a unique genetic mutation. App. 8a & n.4. There is no scientific consensus regarding the cause or causes of APL. App. 8a-9a, 44a.

2. After initial discovery, which included declarations, reports, and depositions of five expert witnesses, petitioners challenged the admissibility of the Milwards' proffered expert testimony regarding causation. *See* Fed. R. Evid. 702; *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The district

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[1] The complaint also alleged that Mr. Milward was exposed to benzene "during the course of performing repairs and other work to vehicles owned by him and others, and during the performance of work and maintenance on his home." C.A.J.A. 53 ¶31. It also alleged exposure to other "toxins and carcinogens" during Mr. Milward's years as a refrigeration technician. *Id.* ¶30.

court held an initial *Daubert* hearing limited to the threshold issue of "general" causation—namely, "the general [assertion] that exposure to benzene *can* cause APL." App. 38a (emphasis added).[2]

That hearing, which lasted four days, turned on the admissibility of the opinion of the Milwards' toxicologist, Dr. Martyn Smith. Dr. Smith acknowledged, as he had in his deposition, that no study had actually found a causal relationship between benzene exposure and APL. App. 62a-63a; App. 89a ("there are no specific studies of APL and benzene exposure that I can rely on"). Nonetheless, he proposed to testify to a conclusion of general causation based on the "weight of the evidence." App. 38a, 85a.

Dr. Smith described the "weight of the evidence" approach as one in which he "look[ed] at all of the evidence and weigh[ed] the positives and negatives as part of that evidence." App. 58a. In support, he relied in part on an article on the "weight of the evidence method" (*see* App. 85a-86a), which states that "there is no algorithm or canonical methodology for determining [weight of the evidence]" where relevant studies are not definitive. Krimsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am. J. Pub. Health S129, S134 (2005) (C.A.J.A. 3154). The same article also notes that "weight of the evidence" may "refer[] to nothing more than a subjective assessment on the part of a reviewer," taking the evidence into account, and can take the form of a "Seat-of-the-Pants Qualitative Assessment." *Id.* at S129, S132 (C.A.J.A. 3149, 3152).

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[2] The district court deferred any consideration of "specific" causation—*i.e.*, whether benzene exposure caused *Mr. Milward's* APL. App. 2a.

Dr. Smith also testified that he reviewed the data in light of the "Bradford Hill considerations," which he described as "a broad framework to help evaluate the various types of evidence relevant to the general causation question." App. 58a, 86a.[3] Dr. Smith admitted that "application of those factors to a particular causal hypothesis, and the relative weight to assign each of them, is both context-dependent and subject to the independent judgment of the scientist reviewing the available body of data." App. 87a. He did not explain how he went through the process of choosing and weighing the data in arriving at his opinion in this case, other than asserting that he considered relevant factors and concluded "to a reasonable degree of scientific probability" that benzene exposure can cause APL. App. 88a. Indeed, he did not describe "what weight [he] assigned to a piece of evidence that was supportive and the weight that [he] assigned to a piece of evidence that might not have been supportive." App. 62a.

Dr. Smith based his opinion on four categories of data:

First, Dr. Smith testified that numerous scientific studies show that benzene exposure can cause some *other* types of leukemia that are classified as AML subtypes. App. 14a, 42a. He admitted that no study has reached that conclusion regarding APL in particular, and that about 80% of all leukemia cases have no discernible cause. App. 61a. Nonetheless, he opined that

[3] These considerations, named after Sir Austin Bradford Hill, include "the strength of an association between the exposure and a particular disease, consistency of the association, specificity of the association, temporality, biological gradient or dose-response, plausibility, coherency of the association, any relevant experimental data and analogy." App. 86a; *see also* App. 9a.

the "weight of the evidence" supported the conclusion that benzene exposure can cause *all* subtypes of AML, including APL. App. 58a-59a. He concluded that it is "scientifically probable" that benzene "will produce all forms of AML," including APL, by damaging the DNA of what he believed was a common leukemia-initiating cell. App. 60a; *see also* App. 14a-15a.[4]

Second, Dr. Smith observed that 95% of all APL patients have a signature genetic mutation called a "t(15;17) translocation," meaning that a gene on chromosome 17 has switched places with a gene on chromosome 15. App. 8a n.4, 40a.[5] Dr. Smith admitted that his own extensive studies had failed to link benzene to the t(15;17) translocation, and that he knew of no study showing that benzene could lead to the t(15;17) translocation; the most he could venture was that "with some of the new breakthroughs in biology, we'll be able to" look for such a link. App. 65a-66a, 68a. He opined, however, that because benzene has been shown to produce certain *other* genetic mutations, the weight of the evidence suggested that it was "biologically plausible" that benzene could cause the t(15;17) translocation as well. App. 87a-88a.

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[4] The court of appeals' opinion refers to "five bodies of evidence" (App. 14a) because it separates this category into two components: (1) evidence that benzene causes some AML subtypes and (2) Dr. Smith's opinion that all AML subtypes derive from a common genetically-damaged cell.

[5] The other 5% of APL cases feature different translocations of the same chromosome 17 gene, also known as the retinoic acid receptor-alpha gene. App. 8a n.4. Mr. Milward's medical records reflect that he had the t(15:17) translocation at the time he was diagnosed with APL. C.A.J.A. 2916.

Under questioning by the district court, Dr. Smith agreed that, although the t(15;17) translocation appeared in almost all patients with APL, it was at most a necessary, but not sufficient, condition for the development of APL. App. 66a-67a. Indeed, even if benzene were able to cause a t(15;17) translocation, only 10% of people with the t(15;17) translocation ever develop APL. App. 40a.

Third, Dr. Smith testified that benzene can inhibit the function of an enzyme called topoisomerase II ("topo II"), which allows DNA to replicate without damage. App. 49a. He testified that benzene's inhibition of topo II can lead to genetic changes that cause other forms of AML. When asked whether "any chemical agent that inhibits [topo II] is capable of producing AML," Dr. Smith responded "I think it's a cause for concern and something for science to follow up on, and I think that's essentially what's happening." App. 59a. Nonetheless, he concluded that the evidence was "highly consistent" with the possibility that benzene's inhibition of topo II could cause APL. *Id.*

Fourth, Dr. Smith considered certain epidemiological studies. He acknowledged that these were not statistically significant regarding APL. App. 60a. Yet he testified that "available APL-specific material supports my conclusion and is certainly not inconsistent with it." *Id.* On cross-examination, Dr. Smith admitted that the way in which he counted the cases of APL in one epidemiological study for purposes of his litigation opinion was inconsistent with his treatment of the same study in his own published peer-reviewed work. App. 63a-64a.

In addition to Dr. Smith's testimony, the Milwards proffered the testimony of Dr. Carl Cranor, a professor of philosophy. He testified that the weight of the evi-

dence approach involves "accumulating all potentially relevant evidence" and "making a subjective judgment on the strength of the evidence." App. 71a.

Petitioners called three witnesses of their own. Dr. David Pyatt, a toxicology expert, testified that some topo II inhibitors have shown no association with any form of leukemia at all, including APL. App. 83a-84a. Dr. Pyatt also testified that APL is "distinct … from the other subtypes of AML" in its treatment mechanisms and risk factors—for instance, he noted that studies associate smoking with the development of AML but not of APL—and that assumptions about APL based on AML data are thus "too simplistic." App. 80a-82a. Dr. John Bennett, a hematologist, agreed that APL is a "unique and distinct disease." App. 79a. Finally, Dr. David Garabrant, an epidemiologist, testified that Dr. Smith's inferences from the epidemiological studies were based on erroneous, inconsistent, "speculati[ve]," "arbitrary," and invalid assumptions and calculations, and accordingly that his inferences were "unreliable" and "no better than other guesses." App. 72a-73a, 75a-78a.

3. After carefully considering these submissions, the district court ruled that "Dr. Smith's proffered testimony that exposure to benzene can cause APL lacks sufficient demonstrated scientific reliability to warrant its admission under Rule 702." App. 34a.

The district court recognized its duty to consider "'the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie'" Dr. Smith's testimony, and not to exclude the testimony "simply because the trial judge is not persuaded that the witness's conclusions are correct." App. 36a-37a (quoting *Daubert*, 509 U.S. at 594). It also recog-

nized, however, that this Court has cautioned against admitting "'opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.'" App. 37a (quoting *General Elec. Co.* v. *Joiner*, 522 U.S. 136, 146 (1997)). To guard against that risk, "it may be necessary for the trial judge to evaluate whether the conclusions drawn by the expert have adequate support in the scientific principles upon which the expert purports to rely." App. 37a-38a.

The district court concluded that Dr. Smith's purported "weight of the evidence evaluation" (App. 42a) rested on a series of unwarranted extrapolations from the scientific data, thus rendering any ultimate inference of causation unduly speculative and inadmissible.

a. With respect to Dr. Smith's testimony that all AML subtypes originated from a common leukemia-initiating cell—so that the finding that benzene causes some AML subtypes would support a conclusion that it causes all AML subtypes—the district court noted that "clear differences exist among AML subtypes that may make inappropriate a broad extrapolation from AML generally to APL specifically." App. 42a-43a. In particular, APL is the only AML subtype associated with the t(15;17) translocation, as Dr. Smith admitted. App. 43a.

The court noted that Dr. Smith sought to explain this difference by saying that benzene exposure creates genetic mutations at a very early stage of cell development, so that "this mutation has the potential to impact all myeloid cell lineages and all subtypes of AML." App. 43a. Countering that position, however, several recent scientific papers suggested that leukemia-inducing mutations may occur at later stages of blood cell development, thus making it impossible to conclude

that benzene could be responsible for the mutation. App. 43a-45a.

The court concluded that, "[b]ased on the present state of 'scientific knowledge,' Dr. Smith's theory is at best a plausible hypothesis; it might be true. There are other plausible hypotheses that might be true as well, including the hypothesis that the genetic mutation that leads to APL occurs in relatively mature cells, not in a common progenitor cell of all myeloid lineages." App. 46a. Accordingly, Dr. Smith's opinion that a causal link between benzene and some other AML subtypes sufficiently supported a causal connection between benzene and APL was not "based on sufficient facts and data to be accepted as a reliable scientific conclusion, as distinguished from an hypothesis." *Id.*

b. The district court next addressed Dr. Smith's opinion that, because benzene exposure has been linked with certain genetic mutations, it is "biologically plausible" that it causes the specific t(15;17) translocation that is present in almost all cases of APL (as well as in many individuals who never develop APL). App. 47a. As the district court pointed out, a study co-authored by Dr. Smith concluded that benzene exposure causes "selective" mutations, *i.e.*, mutations at specific chromosomal locations, rather than random mutations—a finding that "tend[s] to defeat the generalization that because it has been shown that benzene causes damage to some chromosomes, it is 'biologically plausible' that it causes damage to other chromosomes." App. 48a. Thus, because "general extrapolation is not justified" and there was no evidence of benzene exposure causing the specific t(15;17) translocation characteristic of APL, Dr. Smith's opinion on this point was "simply an hypothesis, not a reliable scientific conclusion." App. 49a.

c. The district court found similar flaws in Dr. Smith's conclusion that, because benzene exposure could inhibit the DNA-protecting function of topo II, it could cause the t(15;17) translocation associated with APL. As the court noted, scientific evidence showed that "[t]here are different classes of topo II inhibitors," and the different classes have been associated with different genetic mutations and different AML subtypes. App. 49a. One article specifically concluded that "the topo II inhibition effected by benzene metabolites is *affirmatively different* from that effected by other classes of topo II inhibitors." App. 50a. Thus, Dr. Smith's assertion that "all topo II inhibitors act similarly to cause a similar effect … does not appear to be based on reliable scientific knowledge." *Id.* The court concluded that Dr. Smith's opinion that benzene could cause APL by inhibiting topo II was "at best a theory and at worst an error. It does not constitute reliable 'scientific knowledge' qualified for admission under Rule 702." App. 51a.

d. Finally, the court ruled that the epidemiological studies Dr. Smith cited did "not give [his opinion] the support he claims." App. 51a. Even Dr. Smith admitted that no study actually showed any causal link between benzene exposure and APL. App. 89a. The court further concluded that, as Dr. Garabrant "convincingly demonstrated," Dr. Smith "made unduly favorable assumptions in reinterpreting the [epidemiological] studies" and made "faulty calculations" with regard to two of the studies. App. 52a.

The court observed that even if some of the reported epidemiological data could properly be interpreted to suggest a positive "association" between benzene and APL, those results were not statistically significant and thus could not demonstrate causation. *Id.*

Although the Milwards did not "seriously contend otherwise," they argued that evidence of a statistically insignificant association would "suggest[]" a causal relationship. *Id.* The court rejected that argument as insufficient to warrant admission of an expert opinion regarding causation:

> A "suggestion" may give rise to a plausible hypothesis, but not a reliable inference. That is why scientists are careful only to rely on data that is shown to have statistical significance. In this case, Dr. Smith's attempt to support his conclusion with data that concededly lacks statistical significance is a deviation from sound practice of the scientific method. In short, what Dr. Smith has is an epidemiological hypothesis to go with his biological hypothesis. What is lacking is sufficient evidence—whether biological or epidemiological—to warrant a reliable scientific inference.

App. 53a.

The court concluded that Dr. Smith's various hypotheses, while perhaps plausible, "remain hypotheses, the validity of which has not been reliably established." App. 53a. Accordingly, they were "not admissible as 'scientific knowledge' under Rule 702." *Id.*

Following the exclusion of Dr. Smith's testimony, the Milwards consented to entry of judgment for petitioners. App. 3a; C.A.J.A. 1263-1270.

4. The court of appeals reversed. App. 1a-29a. Purporting to apply an abuse-of-discretion standard, it ruled that the district court was required to admit Dr. Smith's "weight of the evidence" opinion on general causation, leaving the data gaps and methodological

flaws the trial court had identified to be argued to and evaluated by the jury. App. 3a, 17a.

The court of appeals recognized that, although APL "has been the subject of extensive research, there is not yet a scientific consensus as to the causes of the genetic translocation that induces APL." App. 9a.[6] The court ruled that Dr. Smith's reliance on a "weight of the evidence" methodology made his testimony on APL causation admissible. It characterized "weight of the evidence" testimony as involving "a mode of logical reasoning often described as 'inference to the best explanation.'" App. 11a. Citing the Milwards' philosophy expert, Dr. Cranor, the court described "inference to the best explanation" as requiring a scientist to "consider all of the relevant evidence" and "integrate the evidence using professional judgment to come to a conclusion about the best explanation." *Id.* It reasoned that the "use of judgment in the weight of the evidence methodology is similar to that in differential diagnosis," which courts had found to be "a reliable method of medical diagnosis." App. 12a.

Having accepted Dr. Smith's "weight of the evidence" methodology as generally reliable, the court of

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[6] The court's claim that the t(15;17) translocation "induces APL" (App. 10a) is an overstatement. Dr. Smith admitted that "the t(15;17) translocation by itself does not necessarily lead to the development of APL." App. 65a. The court of appeals' opinion, as originally issued on March 22, 2011, contained significant additional errors. For example, the court originally asserted that "benzene is known to cause the type of chromosomal damage characteristic of APL" (App. 31a), which is manifestly incorrect, as even Dr. Smith admitted (App. 65a-66a). After petitioners pointed out these errors in a petition for rehearing, the court of appeals issued an "errata sheet" (App. 31a), but did not acknowledge that the errors had any effect on its reasoning.

appeals framed the issue as whether Dr. Smith applied the methodology in his testimony "with 'the same level of intellectual rigor' that he uses in his scientific practice." App. 14a (quoting *Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 152 (1999)). It sought to answer that question only by summarizing the data that Dr. Smith claimed to have "tak[en] into account" and the conclusions he sought to draw from them:

> Dr. Smith explained that taking into account all of the evidence described above—the fact that benzene causes AML as a class, that all subtypes of AML likely have a common etiology, that benzene is known to cause the general types of cellular damage that are known to cause APL, that benzene is known to inhibit an enzyme whose inhibition is known to cause APL, and that APL has been reported in benzene-exposed workers in a number of epidemiological studies—he reached the opinion that the weight of the evidence supports the conclusion that benzene exposure is capable of causing APL. Dr. Smith's opinion rests on a scientifically sound and methodologically reliable foundation, as is required by *Daubert*.

App. 17a.

The court of appeals did not describe or evaluate the process by which Dr. Smith chose and "weigh[ed]" the evidence or address the logical inconsistencies and evidentiary insufficiencies identified by the district court. Rather, it criticized the district court for engaging in a judicial "evaluation of the weight of the evidence, which is an issue that is the province of the jury." App. 17a. It reasoned that the trial court should not have "treated the separate evidentiary components

of Dr. Smith's analysis atomistically, as though his ultimate opinion was *independently* supported by each." App. 22a. In the First Circuit's view, "[t]he hallmark of the weight of the evidence approach" was instead "reasoning to the best explanation for all of the available evidence." App. 23a. Despite the significant gaps in evidence and flaws in reasoning identified by the district court, the court of appeals compelled admission of Dr. Smith's opinion because he had selected certain evidence, taken that evidence "into account," and "reached [an] opinion" based on his own unspecified evaluation of its "weight"—a process the court of appeals called "scientifically sound and methodologically reliable." App. 17a.

The court of appeals specifically dismissed the district court's concerns regarding Dr. Smith's reliance on epidemiological evidence. In its view, Dr. Garabrant's criticism of "faulty calculations" in Dr. Smith's approach to two studies—which the district court found convincing (App. 52a)—merely created a situation where "both experts' opinions are supported by evidence and sound scientific reasoning," leaving "the question of who is right … for the jury" (App. 24a). As for the lack of any statistically-significant epidemiological evidence showing a causal relationship between benzene exposure and APL, the court of appeals held that the district court was required to tolerate Dr. Smith's reliance on admittedly inconclusive data because of "the rarity of APL and difficulties of data collection in the United States." App. 25a. Under the "weight of the evidence methodology," the court concluded, Dr. Smith was entitled to rely on statistically insignificant epidemiological evidence as "consistent with, and suggestive of" the causal relationship he hypothesized on other grounds. App. 27a; *see also* App. 24a n.17.

REASONS FOR GRANTING THE PETITION

This Court should grant certiorari and reverse the court of appeals' erroneous application of Rule 702. The court's decision implicates an important federal question, resolves it in a way that conflicts with this Court's cases and with decisions of at least six other circuits, and improperly restricts district courts' ability to fulfill their gatekeeping role by identifying critical gaps between an expert's asserted opinion and the underlying scientific data.

The court of appeals ruled that, because Dr. Smith claimed to apply a "weight of the evidence" approach, the district court abused its discretion in considering the quality of that evidence and the reliability of Dr. Smith's reasoning. But the district court followed the same course as this Court in *Joiner*, namely analyzing the separate proffered bases for the expert's opinion and concluding that they "were not sufficient, whether individually or in combination, to support [the expert's] conclusions." *General Electric Co.* v. *Joiner*, 522 U.S. 136, 146-147 (1997). Incantation of the phrase "weight of the evidence," or invocation of the related concept of "differential diagnosis," does not automatically transform "the *ipse dixit* of the expert" into a reliable methodology, reliably applied to "sufficient facts or data." *Id.* at 146; Fed. R. Evid. 702.

In addition to misinterpreting Rule 702 and conflicting with *Joiner*, the decision below conflicts with decisions in the Second, Fifth, Sixth, Eighth, Tenth, and Eleventh Circuits, which have recognized that district courts should—and at the very least may—scrutinize the scientific foundation underlying expert assertions about general causation and exclude opinions that are based only on hypotheses, not actual evidence.

Contrary to the rule in other circuits, the First Circuit treated Dr. Smith's invocation of a "weight of the evidence" approach as sufficient to require admission of expert speculation where the data are concededly sparse and inconclusive.

Unless this Court intervenes, district courts in the First Circuit will be not only allowed but *compelled* to admit speculative testimony, whenever an expert can state that he has "weighed" particular evidence and applied his "judgment" to it. Trial courts will be constrained to disregard logical flaws, errors in calculation, and result-oriented reinterpretations of underlying data—all of which the district court identified in Dr. Smith's testimony here—and leave those matters to the jury. That approach constricts the critical judicial gatekeeping role that this Court recognized in *Joiner* in a way that will require the admission of almost any expert testimony on any open scientific issue. Commentators have already recognized that the First Circuit's decision departs markedly from the rule laid down by this Court in *Joiner* and by other circuits. That conflict among the lower courts on an issue of widespread significance warrants further review by this Court.

I. THE COURT OF APPEALS' DECISION CONFLICTS WITH THIS COURT'S DECISION IN *JOINER*

The district court here did exactly as Rule 702 and this Court's case law direct: it considered whether every "inference or assertion" offered by Dr. Smith was "derived by the scientific method" and "supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert* v. *Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993). This standard requires that the proffered opinion be "connected to existing data" by something more than "the *ipse dixit* of the ex-

pert." *Joiner*, 522 U.S. at 146-147; *see also* Fed. R. Evid. 702 advisory committee note (2000) ("The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'").

Indeed, the district court's approach closely tracked this Court's analysis in *Joiner*. *Joiner* involved an allegation that exposure to polychlorinated biphenyls (PCBs) caused the plaintiff to develop cancer. The plaintiff's experts relied on a "weight of the evidence" approach to support their conclusions that PCBs were a contributing cause of the plaintiff's condition. 522 U.S. at 152-153 & n.4 (Stevens, J., concurring in part and dissenting in part). Like the district court here, this Court considered the sources cited by Joiner's experts and rejected each one as insufficient to support a reliable scientific conclusion. Certain studies in mice were "so dissimilar to the facts presented" that they could not be relied upon. *Id.* at 144-145. One epidemiological study did not conclude that PCB exposure caused cancer and thus "did not support the experts' conclusion." *Id.* at 145. Another study was "not statistically significant" and "did not suggest a link" between PCB exposure and lung cancer deaths. *Id.* And two others noted statistically-significant increases in lung cancer deaths, but involved subjects who either were not exposed to PCBs at all or were exposed to other potential carcinogens as well. *Id.* at 145-146. Based on those findings, this Court reversed the Eleventh Circuit's holding that the district court had impermissibly "dr[awn] different conclusions from the research than did each of the experts." *Id.* at 141. This Court concluded instead that the district court had discretion to reject an opinion based on studies that "were not sufficient, *whether individually or in combination*, to support [the experts'] conclusions." *Id.* at 146-147 (emphasis added).

The district court below proceeded in exactly the same way. It identified several logical flaws and gaps in the scientific data that undermined the conclusions that Dr. Smith sought to draw. *See supra* pp. 8-12. In one instance, for example, the court concluded that Dr. Smith had given an epidemiological study an interpretation for purposes of his litigation testimony that differed from the interpretation reflected in his own published peer-reviewed work (App. 52a)—an issue that this Court has specifically directed district courts to consider. *See Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 152 (1999) (court must ensure that the testifying expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). In another instance, the court found that, by relying on data that "concededly lacks statistical significance," Dr. Smith "deviat[ed] from sound practice of the scientific method." App. 53a.

The court of appeals did not meaningfully disagree with the district court's criticisms; on the contrary, it acknowledged them as "sensible." App. 22a. Instead, it faulted the district court for considering Dr. Smith's various arguments "atomistically." *Id.* But this Court's analysis in *Joiner* was "atomistic[]" as well, if that term refers to considering the weaknesses of each proffered body of evidence or line of reasoning and concluding that they do not support the expert's conclusion either "individually or in combination." 522 U.S. at 146-147. Rule 702 itself provides that expert testimony is inadmissible unless it is "based upon sufficient facts or data" and "the product of reliable principles and methods" that have been "applied … reliably"—thus *requiring* a gatekeeping court to inquire into the data and reasoning underlying an expert's testimony. Fed. R. Evid. 702; *see also Kumho Tire*, 526 U.S. at 149 (district

court must determine reliability where testimony's "factual basis, data, principles, methods, or their application are called sufficiently into question").

The court of appeals ruled that, because Dr. Smith applied a "weight of the evidence" approach that depended on the exercise of his "judgment," he could draw a "reliable" conclusion from inconclusive evidence. But the *Joiner* experts also "used a 'weight of the evidence' methodology to assess whether Joiner's exposure to transformer fluids promoted his lung cancer." 522 U.S. at 152 (Stevens, J., concurring in part and dissenting in part). And Dr. Smith did not *explain* how he "weighed" the evidence before him. App. 62a. He did not indicate why the insufficiencies and logical flaws the district court relied upon did not "weigh" decisively against his conclusion. His opinion was based on his unelaborated "judgment." App. 87a. Dr. Smith's methodology, if it can be called one, thus connected the data to his conclusions through nothing more than "the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146; *see also* Krimsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am. J. Pub. Health S129, S129 (2005) (stating that "weight of the evidence" may "refer[] to nothing more than a subjective assessment on the part of a reviewer") (C.A.J.A. 3149). At the very least, the district court's conclusion that this testimony was not sufficiently reliable to "assist the trier of fact" as contemplated by Rule 702 was well within the "broad latitude" accorded to trial judges by this Court's decisions. *Kumho Tire*, 526 U.S. at 142.[7]

[7] The court of appeals' ruling that the district court abused its discretion by considering the evidence underlying Dr. Smith's opinion "atomistically" and declining to give the combination of

The Court should grant certiorari to reaffirm the district court's discretion to consider not only the general methodology purportedly used by the expert, but also the necessary connection between the data relied upon and the proffered conclusion. *Cf. Joiner*, 522 U.S. at 146 ("[C]onclusions and methodology are not entirely distinct from one another."). By placing that inquiry off-limits, the First Circuit decided an important question of federal law in a way that conflicts with the relevant decisions of this Court. S. Ct. R. 10(c).

II. THE COURT OF APPEALS' RULING CONFLICTS WITH DECISIONS IN OTHER CIRCUITS THAT PROPERLY EXCLUDE GENERAL CAUSATION EVIDENCE THAT RESTS ONLY ON HYPOTHESES

The First Circuit's decision also conflicts with the approach that other courts of appeals have taken to expert testimony on general causation. Remaining faithful to *Joiner*, these courts have affirmed the exclusion of expert testimony when the underlying scientific data do not permit a conclusion beyond hypothesis or speculation. The decisions necessarily involve a careful review of the proffered data, after which the court concludes that reliance on the overall weight or totality of the evidence cannot overcome gaps between the scientific evidence and the expert's conclusions.

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evidence greater weight than the sum of its parts has less in common with this Court's opinions than with the decision that this Court reversed in *Joiner*. *See Joiner* v. *General Elec. Co.*, 78 F.3d 524, 532 (11th Cir. 1996) ("Opinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion[.]"), *rev'd*, 522 U.S. 136.

The Eleventh Circuit, for example, reversed the admission of an expert's assertion that a combination of ephedrine and caffeine caused heart attacks or strokes, because the testimony rested on "unsubstantiated analogies" between ephedrine and another drug and "infer[red] conclusions from studies and reports that the papers do not authorize." *McClain* v. *Metabolife Int'l, Inc.*, 401 F.3d 1233, 1240 (11th Cir. 2005). Recognizing that the question of "general causation" was unresolved in the scientific community (*id.* at 1239), the court carefully reviewed the data and reasoning underlying the experts' conclusions. In particular, it rejected the expert's attempt to analogize from another drug to ephedrine, because "even small differences in chemical structure" could produce very different effects and the analogized drug was associated with a different type of stroke from the one at issue. *Id.* at 1246. The court also conducted a "close analysis" of the studies relied upon and found that none actually claimed to "prove causation." *Id.* at 1245-1247. Although the expert purported to apply "the broad principles of pharmacology," the Eleventh Circuit ruled that "such phrases have little value" and "can spring just as quickly from the *ipse dixit* of the expert as some ultimate opinion about causation or toxicity." *Id.* at 1244.

The Sixth Circuit likewise recently reversed the admission of expert testimony that manganese exposure can cause Parkinson's Disease. The court noted that the "causes of Parkinson's Disease range from the obscure to the unknown." *Tamraz* v. *Lincoln Elec. Co.*, 620 F.3d 665, 668 (6th Cir. 2010) (Sutton, J.), *cert. denied*, 131 S. Ct. 2454 (2011). The expert's general causation opinion rested on, among other things, the fact that literature had hypothesized that a combination of toxins and genetics cause Parkinson's Disease and that

manganese was known to cause a different form of parkinsonism, such that "it would be a possible candidate for triggering Parkinson's Disease as well." *Id.* at 670. The Sixth Circuit ruled this opinion unreliable, stating: "That is a plausible hypothesis. It may even be right. But it is no more than a hypothesis, and it thus is not 'knowledge,' nor is it 'based upon sufficient facts or data' or the 'product of reliable principles and methods … applied … reliably to the facts of the case.'" *Id.* (quoting Fed. R. Evid. 702).

The Fifth Circuit employed similar reasoning in affirming the exclusion of expert testimony suggesting a causal link between ethylene oxide exposure and brain cancer. Like the district court here, the Fifth Circuit "examine[d] each of the types of evidence on which [the] experts rel[ied]"—epidemiological studies, animal studies, and cell biology data—and concluded that "none of the scientific data … furnishes a scientifically valid basis for the conclusion [the experts] would draw." *Allen* v. *Pennsylvania Eng'g Corp.*, 102 F.3d 194, 196-198 (5th Cir. 1996). The court expressly addressed "weight of the evidence" reasoning, stating that it was "unpersuaded that the 'weight of the evidence' methodology these experts use is scientifically acceptable for demonstrating a medical link between [plaintiff's] exposure and brain cancer." *Id.* at 198; *see also Moore* v. *Ashland Chem. Inc.*, 151 F.3d 269, 277 (5th Cir. 1998) (en banc) (affirming exclusion where the bases for the expert testimony "were individually and collectively inadequate").

Other courts have likewise held that invocation of the "weight of the evidence" does not compel admission of expert testimony that rests on unreliable or inconclusive data. *See Hollander* v. *Sandoz Pharm. Corp.*, 289 F.3d 1193, 1216 n.21 (10th Cir. 2002) (rejecting

plaintiffs' argument that "even though each individual category of evidence may be insufficient, all of the evidence considered as a whole raises factual questions [concerning causation]" as "inconsistent with *Daubert*"); *Caraker* v. *Sandoz Pharms. Corp.*, 188 F. Supp. 2d. 1026, 1040 (S.D. Ill. 2001) (evidence in the aggregate "amounts to a hollow whole of hollow parts" where "the data points pulled from each 'type' of evidence are too limited, too disparate and too inconsistent"); *see also Magistrini* v. *One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 606-608 (D.N.J. 2002); *Siharath* v. *Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1371 (N.D. Ga. 2001).[8]

Several other courts of appeals have permitted the exclusion of expert testimony where, as here, a careful review of the supporting data revealed significant flaws in the expert's proffered opinions—without any suggestion that those gaps could be overcome by referring to an expert's "judgment" about the "weight of the evidence" or that evaluation of an opinion's basis went beyond the trial courts' proper gatekeeping role. *See, e.g.*,

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[8] State courts of last resort have reached similar conclusions under analogous state law. *See, e.g.*, *Merck & Co.* v. *Garza*, ___ S.W.3d ___, 2011 WL 3796364, at *8 (Tex. Aug. 26, 2011) ("The totality of the evidence cannot prove general causation if it does not meet the standards for scientific reliability …. A plaintiff cannot prove causation by presenting different types of unreliable evidence."); *Estate of George* v. *Vermont League of Cities & Towns*, 993 A.2d 367, 379-380 (Vt. 2010) (affirming exclusion of expert testimony based on "weight of the evidence" methodology where expert "did not specify the precise weight he gave to each study or how he reached his conclusion that the studies, taken together, demonstrated a statistically significant result, when seventy-five percent of the studies, individually, failed to reach that conclusion").

Amorgianos v. *Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267-269 (2d Cir. 2002) (upholding exclusion of expert testimony following district court's "thorough review of the scientific literature on which plaintiffs' experts relied," noting that this Court "recognized in *Joiner* that the district court may carefully review the studies on which proffered experts rely," and finding the logic of plaintiffs' experts "fatally flawed"); *Glastetter* v. *Novartis Pharm. Corp.*, 252 F.3d 986, 990-992 (8th Cir. 2001) (affirming exclusion of expert testimony regarding Parlodel); *see also Rider* v. *Sandoz Pharms. Corp.*, 295 F.3d 1194, 1201-1202 (11th Cir. 2002); *Black* v. *Food Lion, Inc.*, 171 F.3d 308, 313-314 (5th Cir. 1999) (reversing admission of expert testimony on whether a slip and fall in a supermarket could cause fibromyalgia where fibromyalgia has "no known etiology").

Under the approach applied in these circuits, district courts may exclude expert testimony where "any step" in the expert's analysis is unreliable. As the Second Circuit explained, "'[t]he *Daubert* requirement that the expert testify to scientific knowledge—conclusions supported by good grounds for each step in the analysis—means that any step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible*.'" *Amorgianos*, 303 F.3d at 267 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)); *see also McClain*, 401 F.3d at 1245; *Moore*, 151 F.3d at 278 n.10.

Had this case been brought in the Second, Fifth, Sixth, Eighth, Tenth, or Eleventh Circuits, the district court's decision to exclude Dr. Smith's testimony would have been affirmed. The flaws in Dr. Smith's testimony closely resemble the reasons those courts have identified as permissibly informing a district court's decision to exclude expert testimony: equivocal evidence for a

shared cause for APL and other AML subtypes (App. 42a-46a; *Tamraz*, 620 F.3d at 670); lack of support for inferring that, because benzene causes some genetic mutations, it must be able to cause the specific t(15;17) dislocation (App. 47a-49a; *Amorgianos*, 303 F.3d at 269-270; *Rider*, 295 F.3d at 1202); and lack of support for treating benzene as analogous to other topo II inhibitors (App. 49a-51a; *McClain*, 401 F.3d at 1245-1246). Unlike the other circuits, however, the First Circuit required the district court to overlook those flaws and leave their evaluation to the jury.

The First Circuit likened this case to cases involving a "differential diagnosis" methodology (App. 12a), and indeed "[t]he 'weight of the evidence' methodology has much in common with differential diagnosis." Zupanec, *Expert Testimony—"Weight of Evidence" Methodology—Reliability*, 26 Federal Litigator 13 (May 2011). A differential diagnosis is "a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes." *Hall* v. *Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996). It is typically used by clinicians who, faced with a patient presenting particular symptoms, use their best judgment to reach a diagnosis and decide on a course of treatment based on the totality of the evidence before them. *See Tamraz*, 620 F.3d at 674 ("A differential diagnosis seeks to identify the disease causing a patient's symptoms by ruling in all possible diseases and ruling out alternative diseases until (if all goes well) one arrives at the most likely cause."). The related method of "differential etiology" uses the same reasoning in seeking to identify what *caused* a patient's disease.

The circuit decisions addressing differential diagnosis and differential etiology only confirm the need for

this Court's guidance. As commentators have recognized, "[a] sharp split of authority has developed over the admissibility and legal sufficiency of differential etiology testimony on the issues of general and specific causation." Imwinkelried, *The Admissibility and Legal Sufficiency of Testimony About Differential Diagnosis (Etiology)*, 56 Baylor L. Rev. 391, 395 (2004); *see also* Karns, *Establishing the Standard for a Physician's Patient Diagnosis Using Scientific Evidence: Dealing with the Split of Authority Amongst the Circuit Courts of Appeal*, 15 B.Y.U. J. Pub. L. 1 (2000) (reporting "a singular split among the federal circuits that may have to be resolved by the Supreme Court"); *see also Hollander*, 289 F.3d at 1209 (with "regard to differential diagnoses, courts have reached contrasting conclusions as to reliability under *Daubert*").

A majority of circuits holds that, while a differential diagnosis may be admissible as evidence of *specific* causation—*i.e.*, what disease or medical condition a particular plaintiff has or had, or what caused the plaintiff to develop it—the method *presumes* that general causation has been otherwise established. That is, before differential analysis can reliably sort through a range of possible causes, it must already be reliably known that everything in the range *is* in fact an established possible cause.[9] By contrast, a minority of circuits has per-

[9] *See, e.g.*, *McClain*, 401 F.3d at 1252 (differential diagnosis does not prove "the general toxicity of the [substance] and that it can cause the harm a plaintiff suffered"); *see also Hendrix ex rel. G.P.* v. *Evenflo Co.*, 609 F.3d 1183, 1195 (11th Cir. 2010); *Hollander*, 289 F.3d at 1210; *Moore*, 151 F.3d at 275; *Raynor* v. *Merrell Pharms., Inc.*, 104 F.3d 1371, 1374-1376 (D.C. Cir. 1997) (noting that "differential diagnosis" testimony on specific causation "had legitimacy only as follow-up to admissible evidence" on gen-

mitted the admission of differential diagnosis testimony regarding specific causation without independent evidence that the accused agent or substance is even generally capable of causing the plaintiff's disease.[10]

Before the First Circuit's decision in this case, however, no court of appeals had held that a district court abuses its discretion by *refusing* to admit "differential diagnosis"-type testimony directed to *general* causation where the opinion lacks adequate scientific support. By adopting that view, the First Circuit has

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eral causation); *Black*, 171 F.3d at 314 ("The underlying predicates of any cause-and-effect medical testimony [including differential diagnosis] are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur."); *see also Ruggiero* v. *Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (differential diagnosis is generally not a sufficient basis to prove general causation); *Bitler* v. *A.O. Smith Corp.*, 391 F.3d 1114, 1124 (10th Cir. 2004) ("the inference to the best explanation must first be in the range of possible causes; there must be some independent evidence that the cause identified is of the type that could have been the cause"); *Hall*, 947 F. Supp. at 1413 ("[A] fundamental assumption underlying [differential diagnosis] is that the final, suspected 'cause' ... must actually be capable of causing the injury." (internal quotation marks and emphasis omitted)).

[10] *See Heller* v. *Shaw Indus., Inc.*, 167 F.3d 146, 154-156 (3d Cir. 1999) (medical expert need not "cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness"); *Westberry* v. *Gislaved Gummi AB*, 178 F.3d 257, 262-266 (4th Cir. 1999) (affirming admission of differential diagnosis testimony even though there was "no scientific literature on which to rely to 'rule in' talc as a possible basis for [plaintiff's] sinus condition"); *see also* Federal Judicial Center, *Reference Manual on Scientific Evidence* 37 (2d ed. 2000) (noting that the Third Circuit's conclusion in *Heller* "is clearly at odds with what the Fifth Circuit said in *Moore* and *Black*").

essentially treated an expert's assertion of subjective judgment—whether called a "weight of the evidence" conclusion or a "differential diagnosis"—as conclusive on the question of reliability under Rule 702. *Contra Tamraz*, 620 F.3d at 674 ("'[S]imply claiming that an expert used the 'differential diagnosis' method is not some incantation that opens the *Daubert* gate.'" (quoting *Bowers* v. *Norfolk S. Corp.*, 537 F. Supp. 2d 1343, 1360 (M.D. Ga. 2007))).[11]

As one district court explained in excluding "weight of the evidence" testimony:

> "Judgment" does not substitute for scientific method; without a reliable method, result-oriented "judgment" cannot be distinguished from scientifically or methodologically-based judgment. Where, as here, elements of judgment pervade the methodology, it is essential that the expert set forth the method for weighing the evidence upon which his opinion is based. Absent that, this Court's role as gatekeeper to assess the reliability of the methodology applied in this case is nullified.

Magistrini, 180 F. Supp. 2d at 608.[12]

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[11] The First Circuit approved the "weight of the evidence" approach as a "mode of logical reasoning often described as 'inference to the best explanation.'" *See* App. 11a & n.7 (quoting *Bitler*, 391 F.3d at 1124 n.5). But *Bitler* described testimony based on "inference to the best explanation" as a "differential analysis" directed to *specific* causation (akin to a "differential diagnosis"). 391 F.3d at 1124. *Bitler* does not suggest that "inference to the best explanation" testimony is admissible to address *general* causation.

[12] In fact, the only reference cited by Dr. Smith that discusses a "weight of the evidence" approach identifies not one such ap-

Many circuits have quoted with approval Judge Posner's observations that "[l]aw lags science; it does not lead it," and that "the courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen* v. *Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). The paucity and inconclusiveness of existing data is no basis to admit hypotheses, even plausible ones, about what science *might one day* establish. "[C]ourts may only admit the state of science as it is," not "speculation, conjecture, or inference that cannot be supported by sound scientific principles." *Rider*, 295 F.3d at 1202; *see also Daubert*, 509 U.S. at 597 (unproven scientific hypotheses "are of little use" in reaching legal judgments). The First Circuit's ruling that a district court must accept an expert's "judgment" that benzene causes APL, even though none of the evidence cited reaches or even supports such a conclusion, is directly contrary to the rulings of a majority of circuits. This Court should grant certiorari and resolve the disagreement by restoring the district courts' proper gatekeeping role.

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proach but at least four, including one described as a "Seat-of-the-Pants Qualitative Assessment." Krimsky, 95 Am. J. Pub. Health at S132 (C.A.J.A. 3152). This phrase aptly describes Dr. Smith's approach, because he was unable to articulate in any way how he determined what "weight" to accord to particular evidence. App. 62a; *see Magistrini*, 180 F. Supp. 2d at 602 ("In order 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.").

III. THE QUESTION PRESENTED IS OF PRESSING NATIONAL IMPORTANCE

One commentator has already called the decision below "[o]ne of the most significant toxic tort causation cases in recent memory." Green, *Introduction: The Third Restatement of Torts in a Crystal Ball*, 37 Wm. Mitchell L. Rev. 993, 1010 n.53 (2011). Another has called it "the strongest and most explicit judicial endorsement to date of a weight of the evidence methodology for proof of causation." Gold, *The "Reshapement" of the False Negative Asymmetry in Toxic Tort Causation*, 37 Wm. Mitchell L. Rev. 1507, 1576-1577 (2011). These independent assessments make clear the importance of this case.

The decision below will also have ramifications well beyond toxic tort cases, because its reasoning is framed in general terms, broadly accepting (and requiring district courts to accept) the reliability of any expert's unelaborated "judgment" even in the face of unproven hypotheses, the absence of meaningful epidemiological evidence, and significant gaps in data and flaws in reasoning. As the cases cited in Part II illustrate, testimony based only on an expert's "judgment"—whether called "weight of the evidence," "differential diagnosis," "differential etiology," or something else—is proffered in a wide variety of litigation involving scientific, medical, or other expert testimony, from cases involving pharmaceuticals or industrial chemicals to slip-and-fall claims. Proponents of questionable scientific testimony have already invoked the First Circuit's decision in urging that district courts lack the authority to look

carefully at the underlying support for an expert's exercise of judgment.[13]

The First Circuit's approach to Rule 702 would seriously imbalance the incentives for commercial conduct that the tort law imposes—particularly where, as here, the evidence is sought to support a claim of negligence or fault, not simply strict liability. In such a context, 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 148-149 (Breyer, J., concurring).

Moreover, this case presents an unusually good vehicle for review by this Court. As a practical matter, many tort suits rise or fall on the admissibility of expert evidence. *See, e.g.*, Rothstein et al., *A Model of Mass Tort: The PPA Experience*, 54 Drake L. Rev. 621, 625 (2006) ("Expert testimony is a critical part of many complex cases, especially mass tort cases in which the underlying claims involve scientific testimony about the causal relationship between exposure to an allegedly harmful product and a wide range of injuries."). Decisions rejecting *Daubert* challenges are not immediately appealable, and once admitted the expert testimony can "assume a posture of mystic infallibility in the eyes of a jury." *United States* v. *Addison*, 498 F.2d 741, 744

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[13] *See* Opp. to Mot. to Exclude Testimony (Dkt. 88), at 5-6, *First Choice Armor & Equip., Inc.* v. *Toyobo Am., Inc.*, No. 09-cv-11380 (D. Mass. June 17, 2011) (citing the decision below for the proposition that the factual basis of an expert's opinion does not affect admissibility, but rather is an issue for the jury).

(D.C. Cir. 1974); *see also Daubert*, 509 U.S. at 595 ("Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it." (internal quotation marks omitted)). Defendants whose *Daubert* challenges fail thus often opt to settle their cases rather than incur the expense of trial and risk large jury verdicts to preserve their evidentiary issues for appeal. Cheng, *Independent Judicial Research in the Daubert Age*, 56 Duke L.J. 1263, 1265 (2007) ("the scientific admissibility decision can be incredibly influential, if not outcome-determinative"). Here, however, the district court excluded "weight of the evidence" testimony based on a careful examination of the underlying data and reasoning, but the First Circuit countermanded that decision as an abuse of discretion. The case is thus ideally positioned for review.

It has been nearly 15 years since this Court decided *Joiner*. The decision below and the related circuit conflict demonstrate that the Court's guidance is once again needed to ensure that district courts retain the discretion to exclude testimony that, though proffered with the trappings of "science," in the end is nothing more than an "*ipse dixit*" based on speculation and unsupported by reliable scientific knowledge. *Joiner*, 522 U.S. at 146.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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