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

REPLY BRIEF FOR PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement contained in the petition for certiorari remains accurate, with the following exceptions:

The parent corporation of CRC Industries, Inc. was incorrectly listed as Berwind Industries, LLC. The correct corporate name is Berwind Industries LLC.

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

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Respondents do not deny that, under the decision below, a district court *must* admit expert testimony on general causation that rests only on an unexplained "judgment" through a "weighing" of evidence and *must* overlook identified gaps between the data and the proffered opinions. That holding cannot be reconciled with *General Electric Co.* v. *Joiner*, 522 U.S. 136 (1997), or decisions of six other circuits, most of which Respondents do not address.

Other than restating Dr. Smith's qualifications and testimony (Opp. 3-23), Respondents mainly defend the First Circuit's decision as an application of a "broad standard" that "trial courts should not exclude expert testimony that 'falls within the range where experts might reasonably differ.'" Opp. 29 (misquoting *Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 153 (1999)); *see*

also Opp. i, 1, 23-24, 28. That approach has no basis in the text of Federal Rule of Evidence 702, which directs trial courts to assess whether the testimony consists of scientific "knowledge" (not speculation or hypotheses) and results from "reliable" analysis "based upon sufficient facts or data." Respondents make no effort to reconcile the First Circuit's approach with this Court's precedents, which emphasize that "Rule 702 grants *the district judge* discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case." *Kumho Tire*, 526 U.S. at 158 (emphasis added).

Finally, this case's interlocutory posture is not a reason to deny review, any more than it was in *Joiner* or *Kumho Tire*. As confirmed by scholarly commentary and the Federal Judicial Center manual that Respondents cite, the question presented here is important and arises regularly in litigation throughout the country. It warrants consideration by this Court.

ARGUMENT

I. THE CIRCUITS ARE DIVIDED AS TO WHETHER A DISTRICT COURT MUST ADMIT "WEIGHT OF THE EVIDENCE" TESTIMONY THAT IT CONCLUDES REFLECTS ONLY HYPOTHESES, NOT SCIENTIFIC KNOWLEDGE

Respondents first argue (Opp. 25-27) that the question presented has not split the circuits. As the petition demonstrates, however, the Second, Fifth, Sixth, Eighth, Tenth, and Eleventh Circuits would have affirmed the district court's ruling. Pet. 21-30. Many of those circuits have affirmed the exclusion of expert testimony (or reversed its admission) in situations specifically involving the "weight of the evidence" approach or the related concepts of differential etiology and differential diagnosis. Pet. 23-24.

In particular, other circuits recognize that district courts may and should "carefully review the studies on which proffered experts rely," *Amorgianos* v. *National R.R. Passenger Corp.*, 303 F.3d 256, 267-269 (2d Cir. 2002), and ensure that they do not "admit speculation, conjecture, or inference that cannot be supported by sound scientific principles," *Rider* v. *Sandoz Pharms. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002). *See also* Pet. 22-26 (citing cases). When the district court here did exactly that, the First Circuit ruled it an abuse of discretion. Respondents have no meaningful response; they do not even address most of the decisions discussed in the petition or the commentary acknowledging a circuit split with respect to differential etiology. Pet. 26-27. The most recent edition of the Federal Judicial Center's *Reference Manual on Scientific Evidence*—published after the petition was filed—expressly mentions the disagreement. Recognizing the majority view that "trial judges have great discretion under *Daubert* and a court is free to choose an atomistic approach that evaluates the available studies one by one," the manual cites the First Circuit's decision in this case for a minority position: "Some judges have found this practice contrary to that of scientists who look at knowledge incrementally." Federal Judicial Center, *Reference Manual on Scientific Evidence* 23 & n.61 (3d ed. 2011) ("FJC Manual").

Respondents' discussion dodges the central issue, which is not whether there is some "absolute prohibition against use of the 'weight of the evidence' method." Opp. 25. The question here is whether a district court abuses its discretion when it excludes expert testimony on general causation that, in the end, rests completely on the expert's application of unelaborated "judgment" to data that the court, after careful analysis, concludes

cannot support anything more than a working hypothesis. Pet. i. The First Circuit's decision that a district court abuses its discretion under these circumstances cannot be reconciled with the conclusions of other courts. *E.g.*, *Tamraz* v. *Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) (ruling that, in light of underlying data, inference that manganese caused Parkinson's Disease was "no more than a hypothesis, and it thus is not 'knowledge'"), *cert. denied*, 131 S. Ct. 2454 (2011).[1]

The First Circuit's contrary holding rests on a fundamentally different view of a district court's role under Rule 702, forbidding any "atomistic[]" analysis of the evidence on which an expert relies when invoking "the weight of the evidence." Pet. App. 22a. That position deepens a circuit conflict on an important issue warranting this Court's review. Pet. 28-29.

II. THE FIRST CIRCUIT'S DECISION CONFLICTS WITH RULE 702 AND THIS COURT'S DECISIONS

Respondents next argue that the decision below simply applies settled law. Opp. 27-31. Again, however, they offer no convincing response to the petition's demonstration (Pet. 16-21) that the First Circuit's reversal of the district court's exercise of gatekeeping discretion cannot be reconciled with Rule 702 or this Court's decisions. The district court approached its task as required by the Rule and consistently with

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[1] Respondents argue that *Tamraz* involved "a *specific causation* question" (Opp. 27), but the passages referred to discuss general causation—the expert's "theory that manganese exposure may cause Parkinson's Disease *in general*." *Tamraz*, 620 F.3d at 670 (emphasis added). The court addressed different flaws in the specific causation analysis as a separate "final step" after the discussion of general causation. *Id.* at 670-671.

Joiner and *Kumho Tire*: assessing the specific data on which Dr. Smith relied to determine whether his proffered conclusion that benzene was capable of causing acute promyelocytic leukemia (APL) was "based upon sufficient facts and data" and "the product of reliable principles and methods … applied … reliably to the facts of the case." Fed. R. Evid. 702. It concluded that, while Dr. Smith's testimony reflected plausible "hypotheses" (Pet. App. 53), it should not be presented to the jury because there was "'simply too great an analytical gap between the data and the opinion proffered.'" Pet. App. 37a (quoting *Joiner*, 522 U.S. at 146).

In rejecting that conclusion as an abuse of discretion, the First Circuit did not suggest that the district court's criticisms of Dr. Smith's analysis were ill-founded. On the contrary, it called them "sensible." Pet. App. 22a. The court ruled instead that close scrutiny of the data underlying an expert's "weight of the evidence" conclusion was simply off-limits. In the First Circuit's view, the district court was powerless to do more than determine that Dr. Smith had "taken into account all of the evidence" and reached a conclusion; no more was needed to demonstrate "a scientifically sound and methodologically reliable foundation, as is required by *Daubert*." Pet. App. 17a. As Petitioners have demonstrated, that approach to abuse-of-discretion review in this context cannot be reconciled either with Rule 702 or *Joiner*. Pet. 15-21.

Respondents do not address the text of Rule 702, particularly its requirement that expert testimony be "based upon sufficient facts or data." Instead, they defend the First Circuit's ruling by asserting that a district court must allow expert testimony to reach the jury unless "no reasonable expert would agree" with it. Opp. 31. This Court has never endorsed such a rule; on

the contrary, it has stated that a "technique which has been able to attract only minimal support within the community"—a level of support that would presumably satisfy Respondents' rule—"may properly be viewed with skepticism." *Daubert* v. *Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993). "Law lags science; it does not lead it," and "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). Hypotheses, even if reasonable, are not "scientific … knowledge." Fed. R. Evid. 702.

Respondents cite a sentence in *Kumho Tire* describing how the district court in that case decided to *exclude* expert testimony that "fell outside the range where experts might reasonably differ." 526 U.S. at 153.[2] But this Court framed the inquiry differently, stressing that district judges have broad discretion to assess the "reliability" of expert testimony "in light of the particular facts and circumstances of the particular case." *Id.* at 158. The Court observed that the expert's "repeated reliance on the 'subjective[ness]' of his mode of analysis" could properly have "augmented" the district court's reliability concerns. *Id.* at 155. That observation applies equally here, and it stands in stark contrast to the First Circuit's uncritical reliance on the subjective exercise of expert "judgment" to require admission of the "weight of the evidence" testimony proffered in this case. Pet. 20. Indeed, Respondent's argument would appear to require admission of almost *any* "weight of the evidence" testimony, since that approach is necessarily subjective and—as the First Cir-

[2] Respondents misquote *Kumho Tire* as though it stated a positive test *requiring* admission of testimony that "falls within" such a range. Opp. 1, 29.

cuit recognized—always permits disagreement among reasonable scientists. Pet. App. 12a.

Respondents assert that "weight of the evidence" testimony may still be excluded if an expert has "failed to review critical data." Opp. 31. But Rule 702 requires more than that an expert simply "review" data. The opinion must be "based upon" facts or data that are "sufficient" and rest on "reliable" principles and methods that the expert has "applied … reliably to the facts of the case." Fed. R. Evid. 702. Bare assertions that Dr. Smith "evaluat[ed] all available evidence" (Opp. 4), "review[ed] and analyz[ed]" data (Opp. 31), or "t[ook] into account" evidence (Pet. App. 17a) do not show that his opinion is "connected to the existing data" by anything more than "the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

Beyond asserting that reasonable experts could propound conflicting hypotheses regarding general causation in this case, Respondents do not address the numerous flaws in Dr. Smith's reasoning identified by the district court. Pet. 8-12; Pet. App. 42a-53a. They instead insist that Petitioners' experts agreed with certain propositions that were part of Dr. Smith's analysis. Opp. 1, 20-22, 29-30. But an expert's reliance on *some* accepted propositions does not necessarily make the ultimate inferences or opinion reliable. APL's classification as a type of acute myeloid leukemia (AML) (Opp. 12) does not mean that all AMLs share a common *cause*. In fact, APL differs by being the only AML subtype associated with the t(15;17) genetic translocation, as Dr. Smith admitted. Pet. App. 43a.[3] Nor does ben-

[3] Respondents mischaracterize the testimony of Petitioner's expert Dr. Pyatt by saying that he admitted that the evidence,

zene's ability to damage DNA (Opp. 21, 29) demonstrate that it causes the kind of damage associated with APL—particularly given the finding (in a study co-authored by Dr. Smith) that benzene causes "selective" mutations at specific locations, not random mutations everywhere. Pet. 10; Pet. App. 48a. Likewise, the fact that *some* "topo II" inhibitors are associated with APL (Opp. 22, 29-30) does not mean that *all* are; on the contrary, research shows that any topo II inhibition by benzene is "*affirmatively different* from that effected by other classes of topo II inhibitors" (Pet. App. 50a (emphasis added)). And Respondents have no response to the ruling that Dr. Smith "made unduly favorable assumptions in reinterpreting the [epidemiological] studies" and made "faulty calculations" with regard to two of them. Pet. App. 52a.

Respondents do not explain why it was an abuse of discretion for the district court to conclude that such flaws made Dr. Smith's analysis inadmissible. Respondents cannot overcome them by asserting the exercise of scientific "judgment." Opp. 6. Dr. Smith's "judgment" was concededly "subjective" (Pet. App. 71a) and unaccompanied by any explanation of *how* he "weighed" the evidence (Pet. App. 62a). Respondents' insistence that the "'weight of the evidence' methodology … enjoys unanimous acceptance from the relevant scientific community" (Opp. 30) is thus beside the point. The issue is whether the district court was entitled to consider the reliability of that approach *as it was applied here.* This

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"taken together with the conclusion that all subtypes of AML have a common origin, provides evidence that benzene exposure is capable of causing APL." Opp. 21. In fact, Dr. Pyatt was asked to *assume* that all AML subtypes have a common origin. C.A.J.A. 1208.

Court has said yes (*Joiner*, 522 U.S. at 143-146); the First Circuit said no (Pet. App. 22a-23a, 26a-27a).[4]

Respondents also imply that "weight of the evidence" reasoning is reliable because agencies crafting precautionary regulations sometimes employ a similar approach. Opp. 5. But just as "there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory," *Daubert*, 509 U.S. at 596-597, regulators have greater leeway than courts or juries to take action based on hypotheses. *E.g.*, *Rider*, 295 F.3d at 1201 ("A regulatory agency such as the FDA may choose to err on the side of caution. Courts, however, are required … to engage in objective review of the evidence to determine whether it has sufficient scientific basis to be considered reliable."); *see also* DRI *Amicus* Br. 11; FJC Manual 649, 651 (describing the "weight of evidence" approach in regulatory risk assessment, which has "different goals" from a toxic tort case); FDA, *Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use*, 67 Fed. Reg. 72,555, 72,556 (Dec. 6, 2002) ("To mandate a warning, or take similar regulatory action, FDA need not show, nor do we allege, actual causation."). The First Circuit's importation of this regulatory approach into Rule 702's very different context only heightens the need for this Court's review.

Respondents' arguments thus confirm that the decision below departs radically from the text of Rule 702

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[4] Respondents' invocation of the Hill factors—the subject of the *Restatement* comment they cite (Opp. 30)—is off-point, because those factors would apply only if statistically significant evidence showed an association between benzene and APL, which is concededly not the case. Pet. 12-13; DRI *Amicus* Br. 8-10.

and from this Court's cases addressing district courts' gatekeeping function under the Rule. Indeed, Respondents' own philosophy expert, Dr. Cranor, has hailed the First Circuit's decision as an "encouraging … change in the law" because it "rejected" what Dr. Cranor called "a number of misleading or mistaken doctrines"—including this Court's endorsement in *Joiner* of "a study-by-study assessment of scientific data as to whether each piece individually and reliably supported an expert's inference of causation." Cranor, *Milward v. Acuity Specialty Products: How the First Circuit Opened Courthouse Doors for Wronged Parties to Present Wider Range of Scientific Evidence* (July 25, 2011).[5] The First Circuit's divergence from Rule 702 and this Court's precedents warrants review.

III. THIS CASE IS A SUITABLE VEHICLE

Respondents do not deny that the First Circuit's decision is "[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); *see also* Gold, *The "Reshapement" of the False Negative Asymmetry in Toxic Tort Causation*, 37 Wm. Mitchell L. Rev. 1507, 1580 (2011) (arguing that this case holds the "promise of reshaping toxic tort causation law"). Repeated references in the FJC Manual (at 20 n.51, 24 n.61, 565 n.48, 578 n.85) underscore the decision's importance. Other plaintiffs and their lawyers have already sought to extend the First Circuit's approach to other circuits. *E.g.*, Brief of *Amicus Curiae* Arkansas

[5] Available at http://www.progressivereform.org/CPRBlogcfm?idBlog=616EE094-D602-ED68-85FD84E7EB0A212E.

Trial Lawyers Association in Support of Appellant for Reversal, *Kuhn* v. *Wyeth, Inc.*, No. 11-1809, 2011 WL 3892676, at *12 (8th Cir. Aug. 1, 2011); Brief for Appellant, *Boutin* v. *Westchester Fire Ins. Co.*, No. 11-30062, 2011 WL 1747677, at *35 (5th Cir. May 2, 2011).

Respondents nonetheless argue that the Court should defer review because the First Circuit's decision on this critical evidentiary point is interlocutory. Opp. 31-33. But this Court has granted certiorari in situations indistinguishable from this one—most notably in *Joiner* and *Kumho Tire*—and should do so here because "the opinion of the court below has decided an important issue, otherwise worthy of review, and [this Court's] intervention may serve to hasten or finally resolve the litigation." Gressman *et al.*, Supreme Court Practice § 4.18, at 282 (9th ed. 2007) (citing cases).

Indeed, as the petition explains (Pet. 32-33), the procedural posture of this case makes it an unusually *good* vehicle for review. Cases in which a court of appeals affirms the exclusion of expert testimony do not present the question here in sharp relief, because of the wide discretion accorded to trial courts. Cases in which a district court *admits* expert testimony may never reach this Court, because the evidentiary decision by itself is not immediately appealable and—as Respondents do not deny—places enormous pressure on defendants to settle even dubious cases. Pet. 32-33; U.S. Chamber of Commerce *Amicus* Br. 10; PLAC *Amicus* Br. 25-26.[6] It is only when, as here, a district court ex-

[6] This is one reason why there is no comparison between this case and *Virginia Military Institute* v. *United States*, 508 U.S. 946 (1993) (denying certiorari). There, the only issue to be resolved on remand from the court of appeals was determination of an appro-

cludes expert testimony but the court of appeals reverses and forces its admission that the question presented—whether a district court *must* admit expert testimony that rests only on subjective "judgment" regarding the "weight of the evidence"—can arise. That question is recurring, important, and squarely presented.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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priate remedy, so the likelihood of Virginia settling the case before final judgment was remote. In addition, *VMI* involved sensitive constitutional questions subject to established doctrines of avoidance. *See, e.g.*, *Ashwander* v. *TVA*, 297 U.S. 288, 346-348 (1936) (Brandeis, J., concurring).