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 FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AMERICAN CHEMISTRY COUNCIL, AMERICAN COATINGS ASSOCIATION, AMERICAN INSURANCE ASSOCIATION, AMERICAN PETROLEUM INSTITUTE, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE* [1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest busi-

[1] The parties consented to the filing of this brief after receiving 10 days' notice of *amici curiae*'s intention to file, pursuant to Supreme Court Rule 37.2(a). No counsel for a party authored this brief in whole or in part, and no person other than *amici curiae* or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

ness federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, and from every region of the country.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. The business of chemistry is a $720 billion enterprise and a key element of the nation's economy.

The American Coatings Association is a voluntary, nonprofit trade association representing some 300 manufacturers of paints, coatings, adhesives, sealants and caulks, raw materials suppliers to the industry, and product distributors.

The American Insurance Association is a leading national trade association representing over 300 major property and casualty insurance companies across the United States.

The American Petroleum Institute is a national non-profit trade association that represents over 480 members engaged in all aspects of the petroleum and natural gas industry.

The National Association of Manufacturers is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states.

Each of the *amici* closely monitors legal issues that impact the nation's business community and their respective membership. To that end, each of the *amici* has regularly participated in cases before this Court at both the certiorari and merits stages.

This case is especially important to the *amici* because the protections that this Court established

against scientifically unreliable expert evidence in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997), have provided an essential check on skyrocketing legal liabilities based on unfounded allegations in tort and other expert-based litigation. As Justice Breyer explained in *Joiner*, "modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances," and the gatekeeping role bestowed on district courts in *Daubert* is needed to 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).

Unfortunately, in the years since *Daubert* and *Joiner*, those cases have come under often withering attacks by plaintiffs' counsel, their experts, and like-minded academicians, who dispute the very premise of trial courts acting as gatekeepers against junk science. In reversing the district court's discretionary exercise of its gatekeeping function and ordering the admission of expert testimony based upon inchoate science and *ipse dixit* assertions about the "weight of the evidence," the First Circuit sided with arguments put forth by these critics and significantly degraded the *Daubert* standard. The First Circuit's reasoning would return the law to the pre-*Daubert* era in which experts were not held to the scientific method, and, in so doing, it would subject defendants to liability based on speculative hypotheses rather than scientific knowledge.

As the Eleventh Circuit has elsewhere cogently noted:

> The *Daubert* trilogy, in shifting the focus to the kind of empirically supported, rationally explained reasoning required by science, has greatly improved the quality of the evidence upon which juries base their verdicts. Although making determinations of reliability may present the court with a difficult task of ruling on matters that are outside its field of expertise, this is less objectionable than dumping a barrage of scientific evidence on a jury, who would be less equipped than a judge to make reliability and relevancy determinations.

Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1197 (11th Cir. 2002).

INTRODUCTION AND SUMMARY OF ARGUMENT

The question posed in this case is whether a district court abuses its gatekeeping discretion under *Daubert* in concluding that an expert cannot testify based on his *ipse dixit* opinion as to the weight of the scientific evidence when that expert provides no testable methodology for his claimed balancing of different pieces of scientific evidence, each of which individually are also not derived by the scientific method.

In *Daubert* and *Joiner*, the Court set forth clear standards for the admissibility of scientific expert testimony: Expert testimony must be based upon reliable scientific methodology, in which hypotheses are subject to the essential crucible of testing and validation before crossing over to the realm of scien-

tific knowledge. Experts may not rely on evidence that is not derived by the scientific method, and disparate pieces of scientifically unreliable evidence cannot be transformed into a scientifically reliable whole based upon an expert witness' claimed weighing of the evidence. Nor may experts opine based upon hypotheses of what future science may show. Courts must decide legal disputes based upon the state of science as it is, not as it might someday be. Over the past 18 years, these basic admissibility requirements have protected the judicial system from expert opinions premised upon an expert's say so rather than the dictates of sound science. These requirements have provided a necessary counterweight against an aggressive and well-financed plaintiffs' bar that has threatened every segment of the business community with massive liabilities premised on often shaky science.

In the years since *Daubert* and *Joiner*, there has been an active campaign of critical commentary disputing the premises of the Court's opinions, fueled by the very plaintiffs' counsel and expert witnesses whose unreliable testimony gave rise to the Court's rulings. Illustrative of this criticism are the "Coronado Conferences," discussed below, the first of which in 2003 brought together a collection of plaintiff experts and like-minded academicians to excoriate the supposed errors in the *Daubert* requirements. In its opinion below, the First Circuit sided with these critics, two of whose Coronado arguments played a central role in the First Circuit's opinion. Thus, in contravention to *Joiner*, but as advocated by (1) one of the Coronado commentaries upon which plaintiffs' causation expert principally relied and (2) plaintiffs' "scientific methodology" expert, who had sharply criticized *Joiner* in a separate Coronado paper, the

First Circuit reversed the district court's exclusion of expert causation testimony premised on a purported "weight of the evidence" methodology. Likewise, in contravention to *Daubert*, but in keeping with the Coronado criticisms, the First Circuit lowered the bar for admissibility of plaintiffs' expert's testimony because of the purported difficulties of securing the scientific evidence that would be necessary to validate plaintiffs' causal hypothesis.

The First Circuit opinion is directly contrary to the Court's holdings in *Daubert* and *Joiner*. Moreover, the First Circuit opinion highlights a split in the circuit courts over the nature of scientific evidence that must be proffered to lift an expert opinion above *ipse dixit*. *Amici* urge the Court to grant certiorari to resolve this dispute and reaffirm the vital protections against unreliable expert testimony set forth in its earlier rulings.

ARGUMENT

I. THE DECISION BELOW THREATENS THE CONTINUED VITALITY OF THE COURT'S RULINGS IN *DAUBERT* AND *JOINER*.

A. *Daubert* and *Joiner* Establish Necessary Safeguards for Litigants Faced with Scientifically Unsound Tort Claims.

In *Daubert*, the Supreme Court held that scientific testimony is not admissible unless it satisfies the dual requirements of scientific reliability and relevance. The Supreme Court explained that "in order to qualify as 'scientific knowledge,' an inference must be derived by the scientific method." *Daubert*, 509 U.S.

at 590. The Court defined the scientific method as follows: "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Id.* at 593;[2] *see also id.* at 590 (quoting the American Association for the Advancement of Science *amicus* for the proposition that science "represents a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement").[3]

Daubert also explains that while admissible expert testimony must be based on the scientific method, "there are important differences between the quest for truth in a courtroom and the quest for truth in the laboratory." *Id.* at 596-97. "Scientific conclusions are subject to perpetual revision. Law on the other hand, must resolve disputes finally and quickly." *Id.* at 597. Accordingly, expert testimony must be judged based on the current state of scientific knowledge, not on the possibility that additional knowledge may

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[2] The Supreme Court cited two philosophical texts on the nature of scientific evidence. *See id.* (citing C. Hempel, The Philosophy of Natural Science 49 (1966) ("[T]he statements constituting a scientific explanation must be capable of an empirical test"); K. Popper, Conjectures and Refutations: The Growth of Scientific Knowledge 37 (5th ed. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability")).

[3] The four factors discussed in *Daubert* as considerations in the admissibility determination provide different methods by which an expert's opinion can be analyzed for adherence to the scientific method. *See id.*, at 593-94. Two of the factors, testing and error rates, are integral parts of the scientific method itself. The other two factors, peer review and general acceptance, can provide independent support that an expert opinion was properly derived by the scientific method.

emerge in the future. The Court recognized that the requirement of existing scientific data "on occasion will prevent the jury from learning of authentic insights and innovations" but held that this "is the balance struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for particularized resolution of legal disputes." *Id.*; *see also* Joe G. Hollingsworth & Eric G. Lasker, *The Case Against Differential Diagnosis: Daubert, Medical Causation Testimony, and the Scientific Method*, 37 J. Health L. 85, 87 (2004).

Four years after *Daubert*, in a case that is markedly similar to the case below, this Court provided further guidance on how judges should exercise their gatekeeping responsibilities. In *Joiner*, the district court excluded plaintiffs' experts' opinions that PCBs could cause lung cancer after carefully reviewing and rejecting as scientifically unreliable each of the individual pieces of evidence upon which the experts relied. The Eleventh Circuit reversed, holding that the district court abused its discretion in failing to credit the experts' testimony that the weight of these individually unreliable pieces of evidence provided a scientifically reliable whole. The Eleventh Circuit explained that:

> 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, one reliable enough to be submitted to a jury along with the tests and criticisms cross-examination and contrary evidence would supply.

Joiner v. General Elec. Co., 78 F.3d 524, 532 (11th Cir. 1996), *rev'd*, 522 U.S. 136 (1997).

By an 8-1 majority, this Court reversed the Eleventh Circuit and reinstated the district court's exclusion of plaintiffs' experts' testimony. Expressly affirming the district court's approach, the Court tested each of the individual pieces of scientific evidence relied on by plaintiffs' experts for scientific reliability and relevance and found them lacking. *See Joiner*, 522 U.S. at 145-46. The Court then rejected the Eleventh Circuit's "weight of the evidence" argument, holding that "it was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, *whether individually or in combination*, to support their conclusions that Joiner's exposure to PCB's contributed to his cancer." *Id.* at 146-47 (emphasis added); *see also id.* at 153 (Stevens, J., dissenting) (stating that he would affirm the Eleventh Circuit's holding that "a 'weight of the evidence' methodology was scientifically acceptable").

Quantitative research conducted after *Daubert* and *Joiner* indicates that the Court's new admissibility standards for expert testimony had an immediate salutary effect, both in increasing judicial scrutiny of expert testimony based on shaky science and in encouraging attorneys to pay more careful attention to the expert testimony they proffered in their cases. *See* Lloyd Dixon & Brian Gill, *Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision*, 8 Psychol. Pub. Pol'y & L. 251 (2002) (identifying trends in judicial rulings indicating increased judicial attention to reliability and relevance of expert testimony and increased attorney attention to proffering expert testimony that would meet the *Daubert* standards); Carol Krafka, *et al.*, *Judge and Attorney Experiences, Practices, and Concerns Regarding Expert Testimony*

in Federal Civil Trials, 8 Psychol. Pub. Pol'y & L. 309, 330 (2002) (concluding based on surveys of judges and attorneys that *Daubert* and *Joiner* "have influenced the practices of federal judges and attorneys with respect to expert testimony in civil cases. Clarification of admissibility standards appears to have encouraged both groups to take a more active role in scrutinizing proffered testimony.").

More recent research has also demonstrated *Daubert*'s importance in protecting jurors from "powerful and quite misleading" expert testimony based on shaky science. *Daubert*, 509 U.S. at 595. Investigators have found that prospective jurors are more likely to view scientific evidence as reliable if it is presented in a trial setting rather than a non-trial setting, suggesting that "jurors assume that judges review scientific evidence before it is presented to them, and that any evidence used in a trial must be above some threshold of quality." *See* N.J. Schweitzer & Michael J. Saks, *The Gatekeeper Effect: The Impact of Judges' Admissibility Decisions on the Persuasiveness of Expert Testimony*, 15 Psychol. Pub. Pol'y & L. 1, 12 (2009). This phenomenon highlights the vital role of a trial court's proper exercise of its gatekeeping responsibility: "If a judge's decision to admit evidence endows that evidence with additional weight, and if that phenomena is exacerbated by the *Daubert* ethos, then the burden on judges to make the correct gatekeeping decision is that much greater." *Id.* at 13.

B. The First Circuit Opinion, if Not Reversed, Will Mark a Major Retreat from the *Daubert* and *Joiner* Safeguards.

The First Circuit's opinion reflects a different view of *Daubert* advocated by certain portions of the plain-

tiffs' bar, which have been pursuing aggessive strategies aimed at weakening or rolling back the expert admissibility standards set out by the Court. *Amici* have fought long and hard against such strategies, and they believe that review and reversal of the First Circuit's opinion is essential to keep this concerted effort to subvert *Daubert* in check.

A particularly notable example of the strategy of the plaintiffs' bar occurred in 2003 when, with financing from a plaintiffs' fund established as part of the settlement of the silicone breast implant litigation, a group of plaintiffs' experts convened a two-day symposium on "Scientific Evidence and Public Policy" in Coronado, California. *See* Editorial, *Scientific Evidence and Public Policy*, 95 Am. J. Public Health S5 (2005). The symposium was organized to "discuss the use and misuse of science in public policy" and "to examine why polluters and manufacturers of dangerous products have been so successful in influencing our systems of justice and regulation." *See id.* at S6; *see also* DefendingScience.org: Coronado Conference Papers, http://www.defendingscience.org/coronado_conference_papers/Coronado-Conference-Papers.cfm. The papers presented at the symposium were published in a special issue of the American Journal of Public Health.

The Coronado Conference was heavily weighted towards the interests of the plaintiffs' bar. Of the 22 articles published in the special issue, fully half were authored or co-authored by individuals who are identified on Westlaw as plaintiffs' experts in civil litigation. Conversely, none of the authors are identified as having served as a defense expert witness.

The attacks on *Daubert* and *Joiner* in the Coronado Conference papers were scathing. For example, one

paper argued that "the confusions, misconceptions, and attempts to fuse contradictory philosophies" in *Daubert* "is a cautionary tale of what happens when lay people try to opine on technical matters of another discipline, in this case jurists holding forth on the philosophy of science."[4] Another paper argued that "*Daubert* rests on serious misconceptions about the nature of science, the goals of legal fact-finding, and the role of the judiciary."[5] A third described the Court's *Daubert* ruling as "muddled" and castigated the Court's opinion in *Joiner*, saying "the Court sounded like nothing so much as a conclave of medieval logicians."[6] And the papers repeatedly attributed to the Court some nefarious scheme to improperly stack the deck in favor of defendants: "The *Daubert* litigation thus gave the Supreme Court an opportunity to stem the increasing flow of resource-intensive toxic tort lawsuits through a politically invisible interpretation of the words 'scientific and knowledge' in the obscure Federal Rules of Civil Procedure."[7] "[T]he application of *Daubert* in jury trials tips the scale of justice strongly in favor of defendants."[8] "[T]he very fact of science being on

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[4] David Ozonoff, *Epistemology in the Courtroom: A Little "Knowledge" Is a Dangerous Thing*, 95 Am. J. Public Health S13, S13 (2005).

[5] Sheila Jasanoff, *Law's Knowledge: Science for Justice in Legal Settings*, 95 Am. J. Public Health S49, S49 (2005).

[6] Susan Haack, *Trial and Error: The Supreme Court's Philosophy of Science*, 95 Am. J. Public Health S66, S68 (2005).

[7] Thomas McGarity, *Daubert and the Proper Role of the Courts in Health, Safety, and Environmental Regulation*, 95 Am. J. Public Health S92, S94 (2005).

[8] Ronald L. Melnick, *A Daubert Motion: A Legal Strategy to Exclude Essential Scientific Evidence in Toxic Tort Litigation*, 95 Am. J. Public Health S30, S32 (2005).

trial via *Daubert* tips the scales further against the public interest and toward corporate interests."[9] *Daubert* "works overall against the public interest in such cases, and has become part of the arsenal of the radical right."[10]

Of particular significance here is that the seeds planted in the Coronado Conference bore fruit in the First Circuit's erroneous opinion below, both directly and doctrinally. The direct links between the Coronado Conference and the First Circuit opinion are unambiguous. In defending the plaintiffs' expert's "weight of the evidence" methodology, the First Circuit expressly relied on: (1) a Coronado Conference paper by Sheldon Krimsky (upon which plaintiffs' causation expert also had relied), which criticized *Daubert* for adopting a "corpuscular approach to expert testimony,"[11] *see* App. 10a n.5, 11a, and (2) plaintiffs' "methodology expert," Dr. Cranor, who had contributed his own paper at the Coronado Conference in which he argued that "[t]he Court's opinion in *Joiner* risks misleading lower courts, inviting similar mistaken rejections of particular evidence or having a chilling effect on efforts to review science in the same way that scientists do."[12] App. 11a.

Doctrinally, the Coronado papers, in their repeated attacks on *Daubert* and *Joiner*, advocated a number

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[9] George P. Lakoff, *A Cognitive Scientist Looks at Daubert*, 95 Am. J. Public Health S114, S117 (2005).

[10] *Id.* at S120.

[11] Sheldon Krimsky, *The Weight of Scientific Evidence in Policy and Law*, 95 Am. J. Public Health S129, S134 (2005).

[12] Carl Cranor, *Scientific Inferences in the Laboratory and the Law*, 95 Am. J. Public Health S121, S123 (2005).

of contrary rules of admissibility for expert testimony that were incorporated into the First Circuit's opinion. These doctrinal errors are detailed below.

C. The First Circuit's Opinion is Contrary to the Court's Holdings in *Daubert* and *Joiner*.

The First Circuit's opinion is premised on doctrinal holdings that are contrary to the Court's clear instructions in *Daubert* and *Joiner*.

The First Circuit's primary holding is that "the district court erred in reasoning that because no one line of evidence supported a reliable inference of causation, an inference of causation based on the totality of the evidence was unreliable." App. 22a-23a. In so holding, the First Circuit acknowledged that "no body of evidence" cited by the plaintiffs' expert "was itself treated as justifying an inference of causation" of acute promyelocytic leukemia ("APL") and benzene, and that the science behind each of the different lines of evidence was still unsettled. App. 23a; *see also* App. 18a-20a. The First Circuit likewise did not dispute the district court's finding that none of the epidemiologic studies provided direct support for the expert's opinion. App. 24a n.7. The First Circuit held, however, that the district court's focus on the individual pieces of evidence was an abuse of discretion because plaintiffs' expert did not rely on any one piece of evidence but rather on his purported "weight of the evidence" approach. App. 22a, 24a n.7.

The First Circuit explained that plaintiffs' expert's "'weight of the evidence' approach to making causal determinations involves a mode of logical reasoning often described as 'inference to the best explanation,'

in which the conclusion is not guaranteed by the premises." App. 11a. The First Circuit continued:

> Unlike a logical inference made by deduction where one proposition can be logically inferred from other known propositions, and unlike induction where a general conclusion can be inferred from a range of known particulars, inference to the best explanation – or 'abductive inferences' – are drawn from a particular process of eliminating all other possible conclusions to arrive at the most likely one that best explains the available data.

App. 11a n.7 (citation omitted). This methodology, though, does not describe the derivation of scientific knowledge; it describes the process of generating hypotheses. As the First Circuit itself recognized, "[n]o scientific methodology exists for this process." App. 12a.[13]

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[13] The First Circuit attempted to bolster this methodology by liking it to differential diagnosis, App. 12a, but while a differential diagnosis, properly applied, can provide a reliable basis for a "specific causation" opinion "ruling out" potential causes for a disease, it does not provide a reliable basis for a general causation opinion "ruling in" a substance as a potential cause of disease in the first place. *See, e.g.*, *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010) (explaining the confusion in some *Daubert* case law between the medical concept of "differential diagnosis" and the legal concept of "differential etiology"). The First Circuit's reliance on "inference to the bext explanation" in this context is likewise misguided. *See Bitler v. A.O. SmithCorp.*, 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")

The First Circuit's reliance on this "weight of the evidence" approach disregards *Daubert*'s admonition that expert testimony must be derived by the scientific method, *i.e.*, "based on generating hypotheses and testing them to see if they can be falsified." *Daubert*, 509 U.S. at 594. While a trial court can – as the district court did below – review individual lines of scientific evidence to determine whether they meet this admissibility threshold, there is no way for a court to so evaluate the "weight of the evidence" approach followed by the Milwards' expert. As the First Circuit acknowledged, this purported "weighing" of scientific evidence cannot be tested, it cannot be falsified, and it cannot be validated against known or potential rates of error. App. 11a-12a. Ultimately, then, the court is left with nothing but the expert's *ipse dixit* assurances that he has weighed the evidence in a scientifically appropriate manner.

In *Joiner*, this Court made clear that such reasoning is not enough. In reversing an Eleventh Circuit opinion very much like the First Circuit opinion here, the Court first examined each line of evidence proffered by the plaintiffs' causation expert to determine whether that evidence supported the expert's opinion under the scientific method and held that each line of evidence was deficient. *Joiner*, 522 U.S. at 144-45. The Court then rejected plaintiffs' argument that the Court must nonetheless defer to the expert's conclusion based on an undefined weighing of this same evidence, explaining that "conclusions and methodology are not entirely distinct from one another." *Id.* at 146. As the Court explained, "nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit evidence that is connected to existing data only by the *ipse dixit* of an expert." Accordingly, the "weight of the evidence" approach advocated by

Mr. Joiner's experts – the same methodology properly rejected by the district court in this case – was only able to garner a single vote on the Court. *See id.* at 153-154 (Stevens, J., dissenting). Remarkably, the First Circuit does not even note the *Joiner* majority's holding in its opinion.

The First Circuit also appeared to be guided in its ruling by the flawed belief that the admissibility bar should be lowered if an expert's failure to proffer sound scientific support for his opinion is due to a lack of existing scientific evidence. App. 25a-26a (arguing that plaintiffs' expert's methodology in citing epidemiological studies that failed to show any statistically significant increased risk of disease was reliable because "the rarity of APL and difficulties of data collection in the United States make it very difficult to perform an epidemiological study of the causes of APL that would yield statistically significant results").[14] Again, in so holding, the First Circuit sided with the Coronado Conference critics of *Daubert* rather than the instructions of this Court. *Compare Daubert*, 509 U.S. at 597 (acknowledging that "a gatekeeping role for the judge … inevitably on occasion will prevent the jury from learning of authentic insights and innovations" but that that "is the balance struck by Rules of Evidence … for the particularized resolution of legal disputes") *with* Cranor (2005), at S121 (arguing that "very little is

[14] *See also* App. 65a-66a, 68a (plaintiffs' expert's testimony that "with some of the new breakthroughs in biology, we'll be able to" look for his hypothesized link between benzene and t(15;17) translocation); App. 49a (plaintiffs' expert's testimony that his hypothesis that "any chemical agent that inhibits [topo II] is capable of producing AML" is "something for science to follow up on").

known about most substances registered for use in commerce" and that "scientists must utilize the evidence available, which may not be the best, yet when combined it may be sufficient to support causal inferences").

Again, under the scientific method, an expert witness cannot reliably opine based upon the assumption that missing evidence, if it existed, would support a causal hypothesis. Rather, "proposed testimony must be supported by appropriate validation – *i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590

II. THE CIRCUITS ARE DIVIDED ON THE PROPER APPLICATION OF *DAUBERT* AND *JOINER* TO EXPERT TESTIMONY NOT DERIVED BY THE SCIENTIFIC METHOD.

As Petitioners note, the First Circuit's opinion – by requiring the admission of expert testimony not derived by the scientific method – stands in clear conflict with the Second, Fifth, Sixth, Eighth, Tenth, and Eleventh Circuits, each of which properly have excluded such expert testimony. *See* Merits Petition, at 21-26. But while the First Circuit opinion may present the starkest illustration of a circuit court's failure to properly follow *Daubert* and *Joiner*, it does not stand alone.

For example, in *Westberry v. Ginslaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999), the plaintiff alleged that workplace exposure to talc caused a severe sinus infection leading to surgery in which the plaintiff's frontal sinuses were obliterated. Defendant moved to exclude the plaintiff's causation expert's testimony, noting that there were "no peer-reviewed studies, no

animal studies, and no laboratory data to support a conclusion that inhalation of talc caused [plaintiffs'] disease" and that the expert did not "have studies showing that talc, at any threshold level, causes sinus disease." *Id.* at 262. The Fourth Circuit did not dispute this showing. *See id.* at 264 ("[defendant] is correct that [plaintiff's expert] had no scientific literature on which to rely to 'rule in' talc as a possible cause for [plaintiff's] sinus condition"). Nonetheless, the Fourth Circuit held that the expert testimony was admissible, concluding that the expert could reliably "rule in" talc as a cause of the plaintiff's condition based upon a differential diagnosis and a temporal relationship between the alleged exposure and the onset or worsening of symptoms. *Id.* at 262. In so holding, the Fourth Circuit confused clinical hypothesis with the type of scientific methodology required under *Daubert*. As one court explained,

> Doctors in their day-to-day practices stumble upon coincidental occurrences and random events and often follow human nature, which is to confuse association and causation. They are programmed by human nature and the rigors and necessities of their clinical practices to conclude that temporal association equals causation, or at least that it provides an adequate proxy in a chaotic and sometimes inconclusive world of medicine. This shortcut aids doctors in their clinical practices because their most important objective day-to-day is to help their patients and "first do no harm," as their Hippocratic oath requires. Consequently, they make a leap of faith … [This type of] clinical impression is not the sort of scientific methodology that *Daubert* demands.

Siharath v. Sandoz Pharm. Corp., 131 F. Supp. 2d 1347, 1372 (N.D. Ga. 2001), *aff'd*, *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002); *see also Tamraz*, 620 F.3d at 673; Hollingsworth & Lasker, at 98.

Similarly, in *Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 154 (3rd Cir. 1999), the Third Circuit held that an expert could opine as to general causation based upon a differential diagnosis and temporal proximity between the alleged toxic exposure and disease, notwithstanding the expert's inability to point to any research supporting his causal hypothesis.[15] In seeking to justify this opinion, the Third Circuit reasoned that to hold otherwise "would doom from the outset all cases in which the state of research on the specific ailment or on the alleged causal agent was at its early stages." *Id.* at 155. But, as this Court explained in *Daubert*, the need to proffer expert testimony "based on what is known" is "the balance that is struck by [the federal] rules." *Daubert*, 509 U.S. at 590, 597. As Judge Posner has correctly explained, "law lags science, it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996).

And in *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (9th Cir. 1998), *cert. denied*, 526 U.S. 1099 (1999), the Ninth Circuit reversed a district court's exclusion of expert testimony that a medical product, Zyderm, caused plaintiff's lupus, despite the undisputed fact that plaintiff's expert could proffer no

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[15] The Court ultimately affirmed exclusion of the expert's testimony, however, because he failed to demonstrate a temporal relationship between the exposure and the alleged symptoms. *Id.* at 157-58.

human or animal studies showing such a causal link. The Ninth Circuit held that the district court should have admitted the expert's testimony based upon studies showing that Zyderm could induce the production of autoimmune antibodies that had been linked to *other types* of autoimmune diseases. *Id.*, at 1228. But the Ninth Circuit offered no explanation, let alone a reliable scientific methodology, by which the expert could leap from studies involving other diseases to a causal opinion regarding lupus. *See Tamraz*, 620 F.3d at 670 (rejecting causation opinion based, *inter alia*, on reasoning that "manganese is know to cause manganism, so it would be a reasonable candidate for triggering [another type of parkinsonism] Parkinson's Disease, as well"). The First Circuit made this same error here. App. 14a (citing expert's reliance on evidence that benzene can cause other sub types of AML).

* * * *

The clarity of the Court's *Daubert* and *Joiner* rulings are of immense and ongoing importance. To note just one measure, there have been over 440 reported federal circuit court opinions since 1993 that have referred to *Daubert* or *Joiner* in the opinion syllabus or Westlaw digest, with 21 new federal circuit court opinions already in 2011. The protections afforded in *Daubert* and *Joiner* against scientifically unreliable and irrelevant expert testimony extend to virtually every sector of our economy and are applied on virtually a daily basis in trial courts across the country. Unless reversed, the First Circuit's opinion risks significant erosion of those protections.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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