#### IN THE

#### Supreme Court of the United States

ACCENTURE, LLP,

Petitioner,

v

WELLOGIX, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

AMICUS BRIEF FOR THE AMERICAN CHEMISTRY COUNCIL, THE AMERICAN COATINGS ASSOCIATION, THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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#### INTRODUCTION AND INTEREST OF AMICI

Amici curiae the American Chemistry Council, the American Coatings Association, the National Association of Manufacturers, and the Pharmaceutical Research and Manufacturers of America respectfully submit this brief in support of the Petitioner. Amici urge the Court to grant certiorari because the ruling below (1) disregards the Court's direction that a trial court must serve as a gatekeeper to prevent the admission of factually unfounded expert testimony and (2) illustrates a sharp division that has emerged in federal circuit courts of appeal since the Court's last ruling on the admissibility of expert testimony more than a dozen years ago.<sup>1</sup>

The error committed in this case arises from the confusion spawned at the intersection of two fundamental tenets of judicial practice. It is of course firmly established that "it is the exclusive province of the jury, to decide what facts are proved by competent evidence." Lessee of Ewing v. Burnett, 36 U.S. 41, 50-51 (1837). However, in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), the Court recognized that this general principle needed to be tempered by the reality that "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises

<sup>&</sup>lt;sup>1</sup> 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). Letters expressing such consent have been filed with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no person other than the *amici curiae* or their counsel made any monetary contribution intended to fund the preparation or submission of this brief.

more control over experts than over lay witnesses." *Id.* at 595.

A trial court's responsibility to protect juries from "powerful and misleading" expert testimony requires a more active judicial role in scrutinizing factual predicates than is appropriate for lay testimony. Fact witnesses may testify as to ambiguous and uncertain facts, and jurors are trusted to weigh the credibility and significance of those facts based upon their lay experience and judgment. However, in screening unreliable and irrelevant expert testimony, Daubert and its progeny require an expert witness to "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). Thus, if a set of facts is insufficient to be relied upon by an expert outside a courtroom, a trial court is required under *Daubert* to exclude expert testimony based upon such facts.

The Fifth Circuit's failure to properly scrutinize the factual underpinnings of the Respondent's software expert in the present case is but one manifestation of a splintering of the *Daubert* gate that is weakening the Court's protection against factually unfounded expert testimony. The following associations accordingly urge the Court to grant *certiorari* and restore the *Daubert* gate to its original condition:

The American Chemistry Council represents the leading companies engaged in the business of chemistry, a \$770 billion enterprise that serves as 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 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.

The Pharmaceutical Research and Manufacturers of America is a voluntary nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.

#### ARGUMENT

In the decision below, the Fifth Circuit concluded that the district court did not err in admitting expert testimony that the Petitioner had destroyed all of the Respondent's business value through an alleged theft of a confidential software package, notwithstanding that this opinion testimony had no factual support. The Fifth Circuit also upheld the admission of critical testimony on liability that was centrally premised on two incorrect factual predicates: (1) that information was confidential despite being available on the Respondent's public website and (2) that there was a source code match even though the expert inexplicably compared the wrong software package. Pet. App. 21a. In excusing the trial court's abdication of its gatekeeping responsibility to screen out this factually unfounded testimony, the Fifth Circuit reasoned that Petitioner "had the chance to highlight and dispute these errors through vigorous cross-examination and the presentation of contrary evidence." Id. (alteration and internal quotation marks omitted).

The Fifth Circuit's ruling contravenes this Court's unambiguous rulings, illustrates a sharp division among federal circuit courts, and presents an issue of incredible importance regarding the trial court's gatekeeping responsibility that extends well beyond the present case. The Court should grant the petition for certiorari review.

#### I. THE DECISION BELOW CONTRAVENES THIS COURT'S DECISIONS REQUIRING THE EXCLUSION OF FACTUALLY UN-FOUNDED EXPERT TESTIMONY.

The Fifth Circuit's refusal to scrutinize the factual underpinnings of Respondent's software expert's opinion stands in sharp conflict with this Court's rulings on expert admissibility. In *Daubert*, the Court focused the expert admissibility determination on the requirements for expert testimony set forth in Federal Rules of Evidence 702 and 703. 509 U.S. at 587, 595. As the Court explained, these admissibility rules establish a clear demarcation between a trial court's role in reviewing fact and expert testimony, reflecting the greater latitude extended to expert witnesses to offer opinion testimony beyond their first hand knowledge:

Unlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. See Rules 702 and 703. Presumably, this relaxation of the usual requirement of firsthand knowledge—a rule which represents "a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information," Advisory Committee's Notes on Fed. Rule Evid. 602, 28 U.S.C. App., p. 755 (citation omitted)—is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

*Id.* at 592.

Federal Rules 702 and 703 set forth the evidentiary strictures on this "assumption" of a "reliable basis" for expert testimony. Rule 702 provides, *inter alia*, that an expert may only offer opinion testimony if "the testimony is based on sufficient facts or data." Rule 703, in turn, identifies the kinds of facts or data that will be deemed sufficient, explaining that "[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." *See also Daubert*, 509 U.S. at 595 (expert testimony admissible only if based on facts or data "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject") (quoting former version of Rule 703).

Even before *Daubert*, courts properly recognized the trial court's central role under the federal rules in insuring that expert testimony is based on reliable facts. In Head v. Lithonia Corp., 881 F.2d 941, 943 (10th Cir. 1989), the court explained that Rule 703's "limitation that the facts and data be of a type reasonably relied upon by experts in the field' provides a mechanism by which the court can evaluate the trustworthiness of the underlying data on which an expert relies." In reversing a district court opinion admitting factually unfounded expert testimony, the Tenth Circuit explained that the trial court must "make a preliminary determination pursuant to Rule 104(a) whether the particular underlying data is of a kind that is reasonably relied upon by experts in the particular field in reaching conclusions." Id. at 944. Likewise, in *United States v. Various Slot Machines on* Guam, 658 F.2d 697 (9th Cir. 1981), the Ninth Circuit explained that "[t]o hold that Rule 703 prevents a court from granting summary judgment against a party who relies solely on an expert's opinion that has no more basis in or out of the record than . . . theoretical speculations would seriously undermine the policies of Rule 56." *Id.* at 700 (quoting *Merit Motors, Inc. v. Chrysler Corp.*, 569 F.2d 666, 673 (D.C. Cir. 1977)).

In *Daubert*, the Court delineated the role of the court and the jury in evaluating the factual predicate for expert testimony. "[T]he rules of evidence," the Court explained, "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 598. The Court instructed that "[p]roposed [expert] testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known," and explained that "the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Id.* at 590. Only expert testimony that meets these requirements may be submitted to the jury to be weighed along with other admissible evidence.

Lower courts, however, misapplied two statements from the Court's opinion. First, the Court stated that "[t]he focus" of the admissibility determination "must be solely on principles and methodology, not the conclusions that they generate." *Id.* at 595. Properly understood, an expert's "principles and methodology" include the identification and selection of a proper factual basis for an expert conclusion. This statement, accordingly, is consistent with *Daubert*'s requirement that expert testimony must have an adequate foundation. However, many lower courts created an artificial divide between an expert's factual foundation and methodology, with only the latter subject to

judicial scrutiny. Second, the Court reaffirmed the principle that "[v]igorous well-settled examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596. This statement, by its plain language, limits a jury to consideration of "admissible evidence." It does not authorize lower courts to abdicate their gatekeeping responsibility to determine whether expert testimony is admissible in the first instance. Again, however, many lower courts improperly seized on this language as somehow lessening the *Daubert* standard.

The Court followed *Daubert* with two opinions in which it sought to clarify this lower court confusion. In General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997), the Court addressed the improper conclusions some courts had reached from Daubert's focus on expert methodology, explaining that "conclusions and methodology are not entirely distinct from one another." The Court explained that "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." Id. And reaffirming the central importance of a gatekeeper's analysis of the foundational bases for expert opinion testimony, the Court held 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." Id. at 146-47.

In *Kumho Tire*, the Court reemphasized the need for judicial scrutiny of the factual foundation of expert testimony, explaining that "where [an expert's] testimony's *factual basis*, *data*, principles, methods, or

their application are called sufficiently into question,. .. the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline." Kumho Tire Co., 526 U.S. at 149 (emphasis added) (quoting *Daubert*, 509 U.S. The Court affirmed the district court's at 592). exclusion of expert testimony based, in part, upon the Court's assessment of the faulty factual assumptions that informed the expert's opinions. See id. at 154 (noting that expert opinion as to alleged defect in the defendant's tire was predicated on fact that the tire was not abused "despite some evidence of the presence of the very signs [of abuse] for which he looked (and two punctures)"); id. at 155 (pointing to expert's statement that the remaining tread depth on the tire "was 3/32 inch, though the opposing expert's (apparently undisputed) measurements indicate that the tread depth taken at various positions around the tire actually ranged from .5/32 of an inch to 4/32 of an inch") (citation omitted).

In Weisgram v. Marley Co., 528 U.S. 440, 455 (2000), the Court explained that *Daubert* imposed "exacting standards of reliability" for expert testimony. Having provided direction on expert admissibility in four cases over seven years, the Court then left the issue in the hands of the lower courts.

In the past fourteen years, however, a number of lower courts have drifted far afield of the Court's teachings. Like the Fifth Circuit below, these courts have abdicated their gatekeeping responsibility through improper reliance on "vigorous cross-examination" as a cure for factually unfounded expert testimony. The time has come for the Court to steer the lower courts back to their proper *Daubert* course. The Petition should be granted.

# II. THE CIRCUIT COURTS ARE SHARPLY DIVIDED OVER THE TRIAL COURT'S GATEKEEPING RESPONSIBILITY WHEN CONFRONTED WITH EXPERT TESTIMONY PREMISED ON UNRELIABLE FACTS.

The Fifth Circuit's ruling below illustrates a sharp divide that has emerged in the circuit courts since the Court's last ruling on expert admissibility. While some circuits properly recognize that the factual foundation of an expert's testimony must be considered as part of the *Daubert* admissibility analysis, other circuits have adopted the misguided rule that analysis of the factual underpinnings of expert testimony is reserved for the jury. By ignoring the central importance of a reliable factual basis to an expert's methodology, this latter group of circuit courts has punched a gaping hole in *Daubert* that demands this Court's attention.

Cases from the Second, Third, and Sixth Circuits have faithfully applied this Court's rulings in analyzing the factual foundation of expert testimony. As these circuits have explained, the "suggestion that the reasonableness of an expert's reliance on facts or data to form his opinion is somehow an inappropriate inquiry under Rule 702 results from an unduly myopic interpretation of Rule 702 and ignores the mandate of Daubert that the district court must act as a gatekeeper." ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 294 (3d Cir. 2012), cert. denied, 133 S. Ct. 2025 These cases recognize that, "[i]n deciding whether a step in an expert's analysis is unreliable, the district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). Accordingly, trial courts acting as gatekeepers in these circuits "may, indeed must, look beyond the conclusions of the experts to determine whether the expert testimony rests on a reliable foundation." *Kalamazoo River Study Group v. Rockwell Int'l Corp.*, 171 F.3d 1065, 1072 (6th Cir. 1999) (alterations omitted)

For these courts, "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony." Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 255 (2d Cir. 2005). Thus, litigants are assured that "expert testimony based on assumptions lacking factual foundation in the record [will be] properly excluded." Meadows v. Anchor Longwall & Rebuild, Inc., 306 F. App'x 781, 790 (3d Cir. 2009); see also Davison ex rel. Davison v. Cole Sewell Corp., 231 F. App'x 444, 450 (6th Cir. 2007) (affirming exclusion of expert testimony because it "was not supported by an adequate factual foundation, but rather was based solely upon conjecture and speculation"); Elcock v. Kmart, 233 F.3d 734, 754 (3d Cir. 2000) ("expert's testimony . . . must be accompanied by a sufficient factual foundation before it can be submitted to the jury").

2. Decisions from other circuit courts stand on the opposite side of this divide. These courts maintain that "[t]he soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." *Milward* 

v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 22 (1st Cir. 2011). District courts are instructed that "[t]he reliability of data and assumptions used in applying a methodology is tested by the adversarial process and determined by the jury; the court's role is generally limited to assessing the reliability of the methodology—the framework—of the expert's analysis." Manpower, Inc. v. Ins. Co. of Pennsylvania, 732 F.3d 796, 808 (7th Cir. 2013).

Fatally misconstruing *Daubert*, these courts conclude that "the factual basis of expert testimony goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in crossexamination." Bonner v. ISP Techs., Inc., 259 F.3d 924, 929 (8th Cir. 2001). Indeed, these courts go so far afield as to hold that "[t]he district court usurps the role of the jury, and therefore abuses its discretion, if it unduly scrutinizes the quality of the experts data and conclusions rather than the reliability of the methodology the expert employed." Manpower, Inc., 732 F.3d at 806 (emphasis added). Accordingly, litigants are deprived of any meaningful judicial protection from factually unfounded expert testimony.

In the decision below, the Fifth Circuit appears to have moved away from the proper understanding of *Daubert* in force in many circuit courts towards the mistaken view that holds sway elsewhere. Absent correction by the Court of the Fifth Circuit's misstep, the sharp divide among circuit courts on the proper treatment of the factual foundations of expert testimony will continue to grow and will further entrench the unequal treatment of litigants in the nation's courts.

## III. THE DISCREPANT TREATMENT OF THE FACTUAL UNDERPINNINGS OF EXPERT TESTIMONY IS SUBJECTING LITIGANTS TO UNEQUAL JUSTICE IN ALL MANNER OF CIVIL LITIGATION.

A trial court's failure to scrutinize the factual underpinnings of expert testimony can be all but determinative. See Pet. at 12-13. The threat posed by this relaxation of the *Daubert* admissibility standard extends far beyond software or financial experts. Indeed, all manner of expert opinions depend on the expert's proper reliance only on the kinds of facts or data upon which "experts in the particular field would reasonably rely." Rule 703. The issue raised in this case accordingly is of extraordinary importance to litigants in a wide variety of legal disputes, and the discrepant treatment of expert testimony in different courts is subjecting broad categories of litigants to different legal protections under the federal rules based upon the mere happenstance of the circuit in which their case is brought.

## A. Daubert Scrutiny of the Factual Foundations of General Causation Expert Opinions.

The Court's first two rulings on the admissibility of expert testimony, *Daubert* and *Joiner*, each addressed expert opinions regarding general causation in personal injury litigation, *i.e.*, whether an exposure is generally capable of causing the injury in question, and general causation expert testimony has remained one of the most active areas of *Daubert* jurisprudence over the past 20 years.

In *Joiner*, the Court was unambiguous in directing lower courts to examine the data underlying general

causation opinions. The Court specifically examined each piece of scientific data proffered by the plaintiff's general causation expert in support of his opinion that PCBs cause lung cancer, and the Court affirmed the exclusion of the expert's testimony based upon its conclusion that none of this data provided a reliable foundation for his opinion. In particular, the Court held that the expert could not rely on animal studies involving massive doses of directly injected PCBs or on human epidemiology studies that did not find statistically significant associations or that involved different chemical exposures or disease endpoints. 522 U.S. at 144-46. As the Court explained, "[t]he studies were so dissimilar to the facts presented in this litigation that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them." *Id.* at 144-45.

Following *Joiner*, many circuit courts have properly examined the factual predicates of general causation opinions in pharmaceutical products liability and toxic tort litigation. For example, in Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194 (11th Cir. 2002), the court excluded general causation expert testimony that improperly relied on animal studies, case reports, chemical analogies and regulatory findings. Likewise, in Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989 (8th Cir. 2001), the court rejected general causation experts "reli[ance] on various types of scientific data—published case reports; medical treatises; human rechallenge/ dechallenge data; animal studies; internal [company] documents; and the FDA's [regulatory findings regarding the drug]" explaining that "this data does not demonstrate to an acceptable degree of medical certainty" that the drug at issue caused strokes.<sup>2</sup>

In *Milward*, however, the First Circuit rejected this authority and held that the district court had "overstepped the authorized bounds of its role as gatekeeper" when it analyzed the factual foundations of an expert's general causation opinion that benzene exposure can cause Acute Promyelocitic Leukemia. 639 F.3d at 22. Although the First Circuit did not dispute the district court's conclusion that none of the lines of evidence underlying the expert's opinion supported a reliable inference of causation, id. at 23, the First Circuit concluded that the district court was required to defer to the expert's inchoate balancing of the "weight of the evidence." *Id.* But the First Circuit conceded that "no scientific methodology exists" for this approach, which—along with the command that the trial court not consider the reliability of the specific evidence being weighed—deprives Daubert of any meaning. Id. at 18-19.

## B. Daubert Scrutiny of the Factual Foundation of Specific Causation Expert Opinions.

Judicial scrutiny of the factual underpinnings of causation testimony is equally important when experts opine on specific causation, that is, whether an exposure in fact caused a particular plaintiff's injury. Specific causation experts apply a methodology called differential diagnosis, in which the expert first "rules

<sup>&</sup>lt;sup>2</sup> See also, e.g., Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 670 (6th Cir. 2010) (studies associating manganese exposure to manganism held not to provide sufficient facts or data to support expert's opinion that manganese exposure could cause Parkinson's Disease).

in" all scientifically plausible causes of the plaintiff's injury and then rules out the least plausible causes of injury until the most likely cause remains. See, e.g., Glastetter, 252 F.3d at 989. While differential diagnosis is generally recognized as a reliable methodology, courts that faithfully apply *Daubert* understand that "an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient." Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1253 (11th Cir. 2010). Indeed, the experiential nature of the differential diagnosis methodology makes it essential that district courts scrutinize the factual foundations of a differential diagnosis opinion to insure that it is founded on the type of evidence that a physician normally would look to outside the courtroom.

Courts accordingly have held that "performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence makes it much less likely that a differential diagnosis is reliable." Best v. Lowe's Home Ctrs., Inc., 563 F.3d 171, 179 (6th Cir. 2009) (internal quotation marks omitted). Where medical experts fail to base differential diagnoses on such evidence, their specific causation opinions have been See Cooper v. Smith & Nephew, Inc., excluded. 259 F.3d 194, 203 (4th Cir. 2001) (excluding specific causation opinion of expert who "failed to conduct a physical examination of [the plaintiff] and did not speak with any of [the plaintiff's] treating physicians"); In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 763 (3d Cir. 1994) (excluding specific causation opinion of expert who "did not examine the plaintiffs or review their medical records [but] simply relied on

their answers to a questionnaire he had given them"); *Conde v. Velsicol Chem. Corp.*, 24 F. 3d 809, 813 (6th Cir. 1994) (excluding specific causation testimony where "numerous tissue, bone, and blood samples taken from the [plaintiffs] revealed no evidence of detectible amounts of chlordane accumulated in their bodies") (internal quotation marks omitted).

This proper *Daubert* scrutiny is thwarted, however, in circuits that preclude judicial review of the factual bases of an expert's opinion. In Walker v. Soo Line Railroad Co., 208 F.3d 581 (7th Cir. 2000), a plaintiff presented a psychologist's expert testimony that a workplace accident had impaired the plaintiff's mental abilities. The psychologist's opinion depended on his understanding of the plaintiff's educational history prior to the accident, which in turn was based on information supplied to the psychologist by the plaintiff's girlfriend. Id. at 586. The district court determined that this educational history was inaccurate and—following the psychologist's acknowledgement that such inaccuracy would affect his opinion—excluded the expert's testimony. *Id.* The Seventh Circuit reversed. In accord with its general misunderstanding of *Daubert*, the court held that "[i]n situations in which a medical expert has relied upon a patient's self-reported history and that history is found to be inaccurate, district courts usually should allow those inaccuracies in that history to be explored through cross-examination." *Id*.

#### C. Daubert Scrutiny of the Factual Foundation of Fate and Transport Expert Opinions in Environmental Litigation.

Environmental litigation provides another example of the importance of judicial scrutiny of the factual foundations of expert testimony. Environmental litigation often turns on questions regarding the source, geographic scope and magnitude of alleged air, soil, or groundwater contamination. To answer these questions, litigants turn to experts who rely on complicated models to portray the fate and transport of contaminants. While the models used by these experts are often generally accepted, the results can vary widely depending on what data is selected as inputs to the models. If the underlying data is faulty, the model output is meaningless (*i.e.*, garbage in, garbage out).

In Renaud v. Martin Marietta Corp., 972 F.2d 304 (10th Cir. 1992), the Tenth Circuit properly applied this understanding to a case brought against a missile manufacturer for injuries allegedly arising from the defendant's contamination of drinking water. support their claims, plaintiffs submitted testimony of expert witnesses who proffered a fate and transport model that purported to track eleven years of discharges from the defendant's plant to the plaintiffs' water supplies. However, as the court noted, this "11-year postulation by plaintiffs was extrapolated back by their experts from a single water sample." Id. at 307. The Tenth Circuit held that the district court "had an independent duty here to decide whether the single data point supported the admissibility of the conclusions plaintiffs' experts sought to draw therefrom" and concluded that the district court properly exercised its gatekeeping responsibility "in excluding as unsound the plaintiffs' experts' conclusions as to causation based on the single data point the record contained." *Id.* at 308.

Likewise, in *Kalamazoo River Study Group*, the Sixth Circuit affirmed the exclusion of an expert's testimony that a release of PCBs in a ditch on the

defendant's property could be causally linked to contamination of a nearby river. 171 F.3d at 1070-73. The expert based his opinion that contamination in the ditch had spread to the river on an unfounded factual assertion that there was sufficient waterflow to carry the PCBs from the ditch into a nearby lake. *Id.* at 1072. The district court excluded the expert's opinion, noting also a 1700-foot gap between the ditch and the lake in which no PCBs had been detected. *Id.* at 1703. In appealing the district court's exclusion of this testimony, plaintiffs argued that the district court had "overstepped its discretionary bounds . . . by resolving credibility judgments in favor of [defendant's] experts." Id. at 1702. The Sixth Circuit disagreed, finding that the district court had properly "focused on the factual underpinnings of [plaintiff's expert's] conclusions." *Id*.

A similar fact pattern, however, resulted in a different outcome in *United States v. Dico, Inc.*, 266 F.3d 864 (8th Cir. 2001). As in *Kalamazoo River*, the plaintiff's expert in *Dico* opined that contamination on the defendant's property had spread along a "continuous line" to reach groundwater. *Id.* at 871. The defendant sought to exclude this testimony because the expert's conclusion that the contamination had left a trail of dense non-aqueous phase liquid was unsupported by the factual record. *Id.* The panel rejected this argument, holding that "the sufficiency of factual basis of expert testimony goes to credibility, not admissibility." *Id.* (citing *Hose v. Chicago N.W. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995)).

## D. Daubert Scrutiny of the Factual Foundation of Dose Reconstruction Expert Opinions.

Judicial review of the factual basis of expert testimony is also centrally important in the emerging field of dose reconstruction testimony. Courts throughout the country properly have concluded that "[s]cientific knowledge of the harmful level of exposure to a chemical plus knowledge that the plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden in a toxic tort case." *Mitchell v*. Gencorp Inc., 165 F.3d 778, 781 (10th Cir. 1999).<sup>3</sup> In response, plaintiffs in toxic tort cases increasingly rely on experts in the "relatively new field of exposure science," who seek to proffer opinions on the dose and duration of historical exposures. See Paul J. Lioy, Exposure Science: A View of the Past and Milestones for the Future, 118(8) Environmental Health Perspectives 1081, 1081 (Aug. 2010).

As with environmental fate and transport experts, the opinions of these "dose reconstruction" experts rely heavily on the factual assumptions underlying the exposure calculations. Thus, as explained in Joseph V. Rodricks, *Reference Guide on Exposure Science, in* Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 503, 539 (3d ed. 2011), "experts presenting testimony regarding exposure reconstruction must be queried heavily on the sources of data used in their application of exposure methods." Where those

<sup>&</sup>lt;sup>3</sup> See also, e.g., Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 677 (6th Cir. 2011); Buzzerd v. Flagship Carwash of Port St. Lucie, Inc., 397 F. App'x 797, 800 (3d Cir. 2010); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241 (11th Cir. 2005); Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1107-08 (8th Cir. 1996).

sources of data do not provide a reliable factual foundation, the expert's testimony should be excluded. For example, in *Amorgianos*, the Second Circuit properly excluded the historical exposure opinions of an industrial hygienist who "inexplicably" did not consider data in his calculations that he conceded a "proper exposure assessment" would take into consideration. 303 F.3d at 268; *see also Mitchell*, 165 F.3d at 781 (excluding opinion of industrial hygienist as to plaintiff's level of exposures based solely on review of material safety data sheets and pictures showing some chemical spillage in the plaintiff's workplace).

A different result occurred in Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426 (7th Cir. 2013), however, where the Seventh Circuit's rule shielding experts from *Daubert* scrutiny of the factual bases of their opinions led to the admission of similarly unfounded dose reconstruction testimony. Schultz was decided by the Seventh Circuit in a unique procedural posture, because the district court had dismissed plaintiff's claim based on the exclusion of plaintiff's medical causation expert and, accordingly, had not addressed a Daubert challenge to plaintiff's dose reconstruction expert. In reversing the district court's ruling, however, the Seventh Circuit relied on the dose reconstruction expert's testimony as providing necessary foundation for the causation expert's opinion. See 721 F.3d at 428-29. On remand, the defendant reasserted its *Daubert* challenge to the dose reconstruction expert, arguing that the expert's testimony was based on inaccurate factual assumptions regarding "work place protection (i.e., respirators), plant size and volume, duration of exposure, numbers of hours painting each day, air exchange rate, and air speed and inter zonal air flow." Shultz v. Glidden Co., No. 08-C-919, 2013 WL 4959007, at \*3 (E.D. Wis. Sept. 13, 2013). Following Seventh Circuit precedent, the district court gave short shrift to this argument, explaining that "the accuracy of the actual evidence [underlying the expert's opinion] is to be tested before the jury." *Id*.

## E. Daubert Scrutiny of the Factual Foundation of Design Defect Expert Opinions.

As demonstrated by *Kumho Tire*, a proper *Daubert* scrutiny of the factual underpinnings of an expert's opinion likewise can play a central role in design defect cases. *See* 526 U.S. at 154-55 (excluding testimony regarding alleged defective tire). Again, however, a litigant's ability to get a trial court to review the factual underpinnings of such testimony will vary depending on the court in which the case is brought.

In Meadows, 306 F. App'x at 782-83, a plaintiff was injured when an allegedly defective shut-off valve in a hydraulic lift cylinder pulled loose from its housing and struck plaintiff in the face. Plaintiff's expert conducted an investigation of the accident and opined that the injury was caused by a defect in the valve that left it unable to withstand a spike in pressure in the hydraulic system. Id. at 788. However, the expert based his opinion on pressure tests on a valve assembly that did not match the one that allegedly caused the injury and a gradual increase in pressure that did not replicate the pressure spike that the expert hypothesized to be the cause of the accident. Finding that the expert's testimony was "based on assumptions lacking factual foundation in the record," the Third Circuit held that the expert's testimony was "properly excluded." *Id.* at 790.

In *Davison*, a plaintiff injured upon being struck by a metal bracket that was part of a floor display brought suit against the display manufacturer. 231 F. App'x at 446. Plaintiff's expert based his opinion that the display was defective on photographs of the display, an inspection of a similar display manufactured by the defendant, deposition testimony about a missing screw, and internet research about screws. *Id.* at 449. The Sixth Circuit affirmed the exclusion of the expert's testimony, concluding that that these predicate factual findings "do not form a reliable foundation . . . upon which to state [an] opinion on the condition of the . . . display and on the cause of the alleged accident." Id. at 449. See also Valente v. Textron, Inc., No. 13-1456-cv, 2014 WL 903820 (2d Cir. Mar. 10, 2014) (excluding expert testimony regarding alleged defect in golf cart that was based upon factual assumption not supported by the record evidence).

In contrast, the court in *Marvin Lumber & Ceder Co*. v. PPG Industries, Inc., 401 F.3d 901 (8th Cir. 2005) undertook a more circumscribed Daubert review of an expert opinion regarding an allegedly defective wood preservative. Plaintiff's expert based his opinion on a comparison of wood samples treated with the defendant's preservative to samples treated with a different preservative. *Id.* at 916. The expert relied, however, on data that "was collected by an employee of [the plaintiff's] legal department who was aware of the purpose of the studies." *Id.* While the use of such questionable data hardly reflects the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field," Kumho Tire, 526 U.S. at 152, the Eighth Circuit refused to address the defendant's *Daubert* challenge, concluding that it was directed "primarily to the factual basis for [the expert's] analysis, not to its evidentiary reliability."

Marvin Lumber, 401 F.3d at 916. Again following the incorrect legal proposition likewise in place elsewhere, the court mistakenly asserted that "even post-Daubert, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Id.* (internal quotation marks omitted).

#### CONCLUSION

For the foregoing reasons, *amici curiae* herein urge the Court to grant the petition for writ of certiorari.

Respectfully submitted,

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