No. 24-1865, 24-1866, 24-1867, 24-1868

IN THE

UNITED STATES COURT OF APPEALS

FOR THE SEVENTH CIRCUIT

FREDERICK L. RICHTER, ET AL.,

Plaintiffs-Appellants,

V.

SYNGENTA CROP PROTECTION, LLC, ET AL.

Defendants-Appellees.

On Appeal from the U.S. District Court
for the Southern District of Illinois

Nos. 21-md-3004, 21-pq-571, 21-pq-1218, 21-pq-1560, 21-pq-836

Honorable Nancy J. Rosenstengel

AMICI CURIAE BRIEF OF NATIONAL ASSOCIATION OF MANUFACTURERS, CROPLIFE AMERICA, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, IN SUPPORT OF DEFENDANTS AND AFFIRMANCE

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DISCLOSURE STATEMENT PURSUANT TO RULES 26.1 AND 29

Pursuant to Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, counsel for *amici curiae* hereby states that the National Association of Manufacturers, CropLife America, and Pharmaceutical Research and Manufacturers of America are the only parties appearing as *amici* on this brief, have no parent corporations, and have issued no stock.

Pursuant to Rule 29(a)(4)(E) of the Federal Rules of Appellate Procedure, counsel for *amici curiae* hereby states that (1) no party's counsel authored this brief in whole or in part; (2) no party or a party's counsel contributed money that was intended to fund preparing or submitting the brief; and (3) no person — other than the *amici curiae*, their members, or their counsel — contributed money that was intended to fund the preparation or submission of the brief.

Shook, Hardy & Bacon LLP is the only firm appearing for *amici* in this case.

/s/Philip S. Goldberg
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IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici curiae are the National Association of Manufacturers (NAM), CropLife America (CLA), and Pharmaceutical Research and Manufacturers of America (PhRMA). *Amici*, along with their members, are concerned that allowing unreliable expert testimony in cases like this one will lead to the unjust imposition of liability and to undermining the complex and scientifically rigorous federal regulatory process for the review and approval of pesticides and other products that, like pesticides, government agencies regulate to minimize potential risks. It also could spur more scientifically unsound litigation against these manufacturers.

The NAM is the largest manufacturing association in the U.S., representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs nearly 13 million men and women, contributes $2.87 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the U.S.

CLA is the nationwide non-profit trade association representing the major developers, manufacturers, formulators, and distributors of pesticides for agriculture and pest management. CLA's member companies produce, sell, and

distribute most of the pesticide products used by American farmers, professional users, and consumers, including the vast majority of pesticides regulated under the Federal Insecticide Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq*. CLA members have invested billions of dollars to research and test those products for safety to humans and the environment.

PhRMA is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world.[1] Together, PhRMA's members are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

The parties have provided their blanket consent to the filing of *amici* briefs.

INTRODUCTION AND SUMMARY OF ARGUMENT

This appeal presents the Court with the important opportunity to apply Rule 702 as amended last year, and thereby reinforce the need for district courts to ensure that expert testimony results only from sound scientific principles. Last year's reforms had three components. First, Rule 702 was amended to expressly

[1] PhRMA's members are listed at www.phrma.org/about#members.

state that the proponent must prove by a preponderance of the evidence that the testimony meets the admissibility requirements. Second, the amendments clarified that these requirements apply to each opinion offered. And third, the Rules Committee affirmed the district court's gatekeeper function, namely that these determinations are questions of admissibility for judges to decide and that expert evidence not meeting these thresholds is not appropriate for jury consideration.

The district court here provided a textbook example of how judges are to assess expert evidence under this new Rule. The judge embraced her "gatekeeper" role, applied the "more likely than not" standard, and determined whether each "expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Ord. at 8-9, n.8 (citing *Robinson v. Davol, Inc.*, 913 F.3d 690, 696 (7th Cir. 2019) (instructing judges to be "vigorous gatekeeper[s]")). To do so, she took extensive briefings from the parties, held a four-day hearing on the proffered expert testimony, and issued a 97-page ruling setting forth detailed reasons each opinion fell short of the admissibility threshold. Specifically, she found that violations of scientific principles were "evident from the very beginning of the process," Ord. at 58, and the opinion on causation the expert offered "required several methodological contortions and outright violations of [applicable] scientific standards," *id.* at 35. Ultimately, she concluded that the

testimony "presented an ideal example of 'because I said so' expertise that is impermissible under Rule 702." *Id.* at 63. She did not find this to be a close call.

Rulings like this one are particularly important where, as here, the product at issue in the litigation has undergone extensive scientific review as part of the federal government's efforts to manage potential risks associated with its use. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Congress has charged the Environmental Protection Agency (EPA) with regulating the use, sale, and labeling of all pesticides. EPA approves each formulation and use as part of its premarket review and approval process, and revisits that review at least once every fifteen years to determine whether any new literature, studies or data suggests the pesticide poses an unreasonable risk to people or the environment. *See* 7 U.S.C. §§ 136 *et seq.* As part of this process, EPA has studied the paraquat-based herbicides at issue here extensively, including reviewing the studies that formed the basis of the proffered testimony. It has repeatedly and consistently found insufficient evidence that exposure to these pesticides causes Parkinson's disease. Not only does that conclusion support the soundness of the district court's exclusion of contrary "expert evidence," it is important that courts not allow EPA's scientific process and decisions to be undermined by testimony that does not meet the "more likely than not" threshold for reliability.

For these reasons, *amici* respectfully request that the Court uphold the order excluding the testimony of Dr. Martin Wells. The Court should also take this opportunity to affirm the court's gatekeeping role and the standards under the amended Rule 702 for admissibility of expert testimony—namely, the proponent must establish by a preponderance of the evidence that the expert's opinion meets the applicable indicia for reliability. Such a ruling would safeguard the scientific underpinnings of both the courts and the federal regulatory review process.

ARGUMENT

I. THE DISTRICT COURT PROPERLY APPLIED RULE 702 IN DETERMINING THAT THE PROFFERED EXPERT TESTIMONY WAS UNRELIABLE AND, THEREFORE, NOT ADMISSIBLE

The purpose of Rule 702 is to give district courts the tools for admitting only expert evidence that is proven to be "reliable" and will "help" the trier-of-fact make its factual determinations. Fed. R. Evid. 702. To facilitate this goal, the U.S. Supreme Court shifted the focus of the district court's role from allowing evidence based on the scientific community's general acceptance of a methodology to being gatekeepers of science in their courtrooms by assessing the expert's assertions independently to assure they are based on sound scientific principles. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 595, 595 (1995), *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). This responsibility was needed because expert scientific testimony "can be

both powerful and quite misleading." *Daubert*, 509 U.S. at 595. In 2000, the Federal Rules Committee enshrined these principles into Rule 702, explaining in the notes that the courts are to apply a preponderance of the evidence standard when making these determinations. *See* Fed. R. Evid. 702 Advisory Committee Note to 2000 Amendments. Thus, for some twenty-five years, district courts have been charged with ensuring allegations of causation, defect, and other tenets of liability are not supported with scientifically unreliable expert testimony that is more likely to be wrong than right.

The 2023 amendments were adopted to reinforce and clarify this responsibility, as some courts were still citing old case law and applying "more lenient standards than Rule 702 permits." David E. Bernstein, *The Misbegotten Judicial Resistance to the Daubert Revolution*, 89 Notre Dame L. Rev. 27, 30 (2013). The purpose of the amendments, which became effective on December 1, 2023, was to correct these misperceptions. *See* Fed. R. Evid. 702 Advisory Committee Note to 2023 Amendments (hereinafter "2023 Advisory Committee Note"). The Rule clearly places the burden of proof on the proponent of the evidence to demonstrate to the court "that it is more likely than not" that the proffered opinions meet the Rule 702 requirements. Fed. R. Evid. 702(A). In addition, the court must determine whether each expert's opinion "reflects a reliable application of the principles and methods to the facts of the case." *Id*. at

702(A)(d). The Rules Committee explained that it was particularly focused on "overstatements" by experts, as here, who assert conclusions "beyond what can be supported by the underlying science." 2023 Advisory Committee Note.

This Court's sister circuits have taken opportunities like the one here to reinforce these requirements. During the pendency of the 2023 amendments, the Fourth Circuit cited the Rules Committee's work to reinforce the district court's "gatekeeping function" over science in their courtrooms. *See Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283 (4th Cir. 2021) ("the importance of [the] gatekeeping function cannot be overstated"). It instructed the district courts to "make explicit findings . . . as to the challenged preconditions to admissibility." *Id.* The Sixth Circuit recently echoed this ruling, affirming that the gatekeeping function means that Rule 702's indicia of reliability go to admissibility, not weight, of the evidence. *See In re Onglyza (Saxagliptin) and Kombiglyze (Saxagliptin and Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 347-48 (6th Cir. 2024). The Court should similarly take advantage of this case to clarify the role of district courts in this Circuit and the standards they must apply under the amended Rule 702.

As indicated above, the district court properly applied amended Rule 702, which was officially adopted during the pendency of this case. The judge explained her role as a gatekeeper, that the burden of proof resides with the proponent of the evidence to prove the reliability factors by a preponderance of the evidence, and

that the veracity of each of the expert's opinions must meet these standards. Ord. 8-9. The court then assessed the meta-analysis Plaintiff's causation expert conducted of epidemiological studies relating to the link between paraquat and Parkinson's disease. As the court explained, meta-analyses, as a general premise, are prone to bias and manipulation because they rely on the expert to choose which studies to include and exclude, to weigh some studies more than others, and to draw conclusions from the collective analysis that no study drew on its own. Ord. at *57. Because of this challenge, the scientific community has issued guidelines for how meta-analyses should be conducted to avoid overstatements. The foundation of this process is establishing objective criteria "in advance" of undertaking the meta-analysis so the outcome is objective and replicable, and not corrupted by the expert's bias. Diego A. Forero, et al., *Ten Simple Rule for Carrying Out and Writing Meta-Analyses*, PLoS Comput Biol., May 16, 2019.[2]

The district court's ruling clearly demonstrates the judge properly exercised her gatekeeping function. She took briefings from the parties, held a four-day hearing on the expert testimony, and issued a ruling that makes explicit findings on the scientific rigor—or lack thereof—of the expert's methodology. In short, she found the expert violated the foundational rule of meta-analysis: he produced no written methodology or objective criteria for choosing studies and weighing them,

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6521986/.

making the analysis "entirely devoid of a search narrative that would allow other researchers to validate his process." *Id*. at 59. For example, when choosing which studies to include based on participation rates, the court noted the "blatancy" with which the expert treated studies depending on whether they were favorable or unfavorable to Plaintiffs' position. *Id.* at 69. And, although the expert claimed to be investigating only *occupational* exposure to pesticides with paraquat, he eschewed any definition of occupational exposure and, ultimately, relied heavily on a study that included non-occupational exposure. *See id.* at 39.

In response to these deficiencies, the expert offered a rebuttal report that sought to provide some of the standards he purportedly used, but the court explained that it was clear the standards put in that report underwent a "metamorphosis" from the original report. *Id*. at 42. In many instances, they were "transparently reverse-engineered." *Id*. at 74-75. "This type of post hoc methodology is the very antithesis of a systemic review, which relies on predefined eligibility criteria to ensure transparency and scientific objectivity." *Id.* at 60. As the court pointed out, the expert's "failure to clearly predefine his eligibility criteria, his subsequent redefinitions of quality criteria, his varying definitions of quality criteria, and his inconsistent application of quality criteria, which conveniently imposed a more onerous standard on a less favorable study, are just

some examples of his violations of [scientific] standards." *Id*. at *74. As a result, the expert's testimony "does not pass muster under Rule 702." *Id*.

The Court should affirm this ruling. It was the result of a thorough analysis that employed the proper standards and processes for reviewing the reliability of a meta-analysis. Reversing the district court's ruling would result in admitting the exact type of unsupported testimony Rule 702 was amended to exclude.

II. THE COURT SHOULD UPHOLD THE DISTRICT COURT'S RULING SO THAT UNRELIABLE EXPERT TESTIMONY DOES NOT UNDERMINE THE FEDERAL REGULATORY REVIEW PROCESS

A decision overturning the district court's thorough analysis would also allow *unreliable* scientific theories to overtake the rigorous regulatory review that paraquat and other pesticide products undergo as part of the federal review process required by FIFRA. The Supreme Court has explained that science in the courtroom must employ "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. With regard to pesticides, the Supreme Court has also recognized that the need "to control weeds and minimize crop damage caused by insects, disease, and animals has become increasingly more important for American agriculture." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).[3] It was for this reason that, through

[3] The Food and Agricultural Organization of the United Nations estimates that between twenty to forty percent of global crop production is lost to pests annually.

FIFRA, Congress has charged EPA with conducting a thorough scientific review of all proposed uses of pesticides to assure they provide their benefits without posing disproportionate risks to human health or the environment. *See generally* 7 U.S.C. § 136a.

Paraquat is one of the most studied herbicides in the world. It was first registered as a pesticide in the U.S. in 1964 and has completed reregistration by EPA several times. *See* Paraquat Dichloride, Ingredients Used in Pesticide Products, U.S. Envtl. Prot. Agency.[4] As part of this systematic review, the agency has "evaluated hundreds of studies, including published toxicity and epidemiology literature on paraquat exposure and adverse health outcomes, including Parkinson's disease." *Id.* Importantly, EPA has explained that "[a]fter a thorough review of the best available science . . . [it] has not found a clear link between paraquat exposure from labeled uses and adverse health outcomes such as Parkinson's disease and cancer." *Id.*

The process by which EPA reached this determination stands in stark contrast to Plaintiffs' proffered expert evidence. Under FIFRA, all pesticide uses must be thoroughly reviewed, approved and registered with EPA. *See* 7 U.S.C. § 136a; 40 C.F.R. § 152.175. FIFRA requires EPA to conduct rigorous scientific

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New standards to curb the global spread of plant pests and diseases, Food & Agric. Org. of the U.N. (Apr. 3, 2019).

[4] https://www.epa.gov/ingredients-used-pesticide-products/paraquat-dichloride.

analysis of whether a proposed pesticide use will cause "unreasonable adverse impacts" to humans or the environment. *See* 7 U.S.C §§ 136a(a), 136(bb), 136(c). EPA must also assess "the economic, social, and environmental costs and benefits" of using pesticides. 7 U.S.C. §§ 136a(c)(5)(C), 136(bb). And EPA is required to re-review the scientific data at least every fifteen years; this is known as the "registration review" process. *See* 7 U.S.C § 136a(g); 40 C.F.R. Part 155.

To implement Congress's directives, EPA has developed regulatory processes for the introduction of any pesticide to the market, as well as any subsequent expansion of its use to additional crops, that is guided by science. These processes are based on the National Research Council's four-step process for human health risk assessments, which examines both the short- and long-term effects of pesticide exposure on people, including those who apply pesticides ("applicators"). *See* Assessing Human Health Risk from Pesticides, Envtl. Prot. Agency.[5] As part of this process, pesticide manufacturers must provide EPA with proposed "labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use," as well as "the complete formula of the pesticide," so that each product may be thoroughly scrutinized. 7 U.S.C. § 136a(c)(1). To aid EPA's evaluation, "registrants must generate scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and

environmental fate of each pesticide." Data Requirements for Pesticide Registration, Pesticide Registration, Envtl. Prot. Agency.[6]

As part of this process, EPA has developed comprehensive data requirements for pesticides. *See* 40 C.F.R. Part 158. The agency requires registrants to design and conduct studies that will be evaluated as to whether "results were reproducible" and "whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment." 40 C.F.R. § 158.70(a). For example, registrants must adhere to the "good laboratory practice" standards, 40 C.F.R. § 158.70(b), which helps "assure the quality and integrity of data" on pesticide risks. 40 C.F.R. § 160.1(a). Also, for epidemiological studies, EPA has standards for gauging the study's design, exposure assessment, outcome assessment, confounding control, statistical analyses, and bias risks. *See* Guidance on Use of Weight of Evidence When Evaluating the Human Carcinogenic Potential of Pesticides, EPA Office of Pesticide Programs (June 2023).[7]

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[5] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.

[6] https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration.

[7] _https://www.epa.gov/system/files/documents/2023-06/2023%20CARC%20WoE%20Guidance.pdf.

Registrants must supply such scientific data supporting statements made about virtually every aspect of the product, including data regarding the product's chemistry and production, performance, toxicology in humans and domestic animals, hazards to non-target organisms (*e.g.*, birds, mammals, fish, terrestrial and aquatic invertebrates), and residue toxicity and chemistry. *See* 40 C.F.R. § 158.130. With respect to human health risks, EPA requires data "derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity [*i.e.*, genetic mutations in cells] and pesticide metabolism." 40 C.F.R. § 158.130(d). These data show potential adverse effects of a pesticide from different levels and types of exposure over different periods of time. *See* Understanding the Science behind EPA's Pesticide Decisions, U.S. Envtl. Prot. Agency[8] (explaining EPA's "human health risk assessment process" that identifies potential hazards and assesses dose responses and exposure levels to accurately characterize the nature and extent of risks). EPA's assessments also include analysis of toxicity "through exposure of humans to pesticide residues remaining after application," including upon reentering treated areas. 40 C.F.R. § 158.130(e).

EPA also has the authority "to establish or modify data needs for individual pesticide chemicals." 40 C.F.R. § 158.30(a). This authority includes designing and conducting government-funded studies of pesticides for which FIFRA mandates

[8] https://www.epa.gov/pesticide-registration/understanding-science-behind-epas-

review by a scientific advisory panel and adoption of peer review procedures. *See* 7 U.S.C. § 136w(d), (e). The agency may also consider data developed in foreign countries or generated for purposes other than satisfying FIFRA's data requirements, provided that data meets the scientific rigor required under FIFRA. *See* 40 C.F.R. § 158.80.

Based on all of this data and analysis, EPA determines not only whether, but under which conditions or restrictions, a pesticide may be used to control pests and maximize crop yield while minimizing risks to human health and the environment.[9] Those conditions or restrictions are then included in the product's label, which EPA specifically approves as part of the registration (or registration review) process. *See* 7 U.S.C. § 136a(c)(1)(C). Thus, EPA does not simply give a pesticide product a thumbs-up or thumbs-down, but specifically determines the precise conditions for or restrictions on use, which often include limitations of application methods, requirements that applicators use particular personal protective equipment, and directions regarding the spray and other equipment to be used for each application. And, again, EPA revisits this assessment at least every fifteen years to determine "whether any new data or information on the pesticide . . . warrant conducting a new risk assessment or a new risk/benefit

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pesticide-decisions.

[9] *About Pesticide Registration*, Envtl. Prot. Agency, at https://www.epa.gov/pesticide-registration/about-pesticide-registration.

assessment," 40 C.F.R. § 155.53(a), which in turn may result in the imposition of additional or changed conditions for or restrictions on use

EPA has reviewed paraquat several times, including a registration review beginning in 2011.[10] In August 2021, after a notice-and-comment process, EPA published its Final Interim Registration Review Decision[11] for paraquat, which reflected EPA's updated assessment of paraquat's risks and benefits, and imposed additional mitigation measures and label requirements.[12]

As the district court recognized, this EPA review was "a systematic review of the available literature to assess the potential relationship between paraquat and Parkinson's disease." Ord. at 31. The agency did so only "out of an abundance of caution" because a "connection has been hypothesized," not because Parkinson's disease represents an expected result of paraquat use. EPA's Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat, Docket No. EPA-HQ-OPP-2011-0855 (Jan. 30, 2024), at 14. EPA, following "standard practice for assessing risks in

[10] For pesticides like paraquat that were registered before 2007, the statutory deadline for completing the initial registration review was October 1, 2022. 7 U.S.C. § 136a(g)(1)(A)(iii)(I). The Consolidated Appropriations Act, 2023 extended that deadline until October 1, 2026. Pub. L.No. 117-328, § 711(a) (2022).

[11] Final Interim Registration Review Decision, Envtl. Prot. Agency, at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0307.

registration review," evaluated "the entire available database" of toxicity studies for paraquat in addition to other available literature and data that included hundreds of epidemiological, animal, and *in vitro* studies. *Id.* at 28-29, 33-34.

The agency also took the extra step of issuing several documents to explain to the public the scope and qualitative assessments involved in this scientific study. *See* Memorandum Regarding Paraquat: Response to Comments on the Draft Human Health Risk Assessment, Office of Chemical Safety and Pollution Prev., Envtl. Prot. Agency (Sept. 24, 2020), at 2-3[13] (detailing EPA's qualitative review of available studies and literature, which involved more than 7,100 publications); Memorandum Regarding Paraquat Dichloride: Systematic Review of the Literature to Evaluate the Relationship between Paraquat Dichloride Exposure and Parkinson's Disease, Office of Chemical Safety and Pollution Prev., Envtl. Prot. Agency (June 26, 2019), at 4[14] (explaining development of database in which "studies were separated into three lines of evidence – human, animal, and *in vitro* – and evaluated for quality, substance, and environmental relevance").

Based on this scientific record, the agency has repeatedly determined that the "evidence is insufficient to link paraquat exposure from pesticidal use of EPA

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[12] EPA's regulations allow it to issue an "interim registration review decision" before completing a registration review. *See* 40 C.F.R. § 155.56. That is what EPA has done for paraquat.

[13] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0216.

registered products to [Parkinson's disease] in humans." EPA's Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat, *supra*, at 33-34. While EPA is in the process of updating aspects of this interim registration review decision in response to litigation filed in the Ninth Circuit challenging it, EPA has repeatedly and consistently found that the available science does not show a connection between Parkinson's Disease and paraquat use. *See* EPA Document in Support of the Paraquat Interim Registration Review Decision; Notice of Availability, 89 Fed. Reg. 6521-01 (Feb. 1, 2024) (noting EPA intends to issue final supplemental document(s) assessing human health and other issues by Jan. 17, 2025).

To be sure, courts have sometimes allowed juries to assess and reach different conclusions about pesticides and other chemical products than federal or state regulators. But district courts should carefully scrutinize supposed "expert testimony" that flies in the face of the scientific conclusions reached through EPA's rigorous regulatory review process—just as the court below did here, when it barred the presentation of evidence that failed to meet the preponderance of evidence standard for reliability. The scientific standards in the courtroom should, at the very least, be comparable to those employed outside the courtroom by EPA.

[14] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0125.

The district court rightly kept that in mind when assessing the expert testimony at issue here and in concluding that it was insufficiently reliable to present to a jury.

III. IMPOSING LIABILITY BASED ON UNRELIABLE EXPERT EVIDENCE CAN LEAD TO THE WIDESPREAD USE OF PRODUCTS THAT PROVIDE FEWER BENEFITS, ARE LESS SAFE, AND COULD CAUSE MORE HARM

From a practical perspective, a judicial finding that a product can cause a particular disease or harm (or is otherwise defective)—and subsequent imposition of liability—is not just a compensatory decision; it instructs the manufacturer to change the product to address the "flaw." Redesigning a safe and effective product based on testimony that has not been shown by a preponderance of evidence to be reliable could lead to products that are less safe. The new design could make the product less valuable—here, by limiting use of or access to a product that has been found to prevent crop loss due to persistent pests and increase yields of a variety of U.S. crops—or could increase risks in ways not considered in the litigation. These adverse outcomes would be exacerbated if liability based on unsound science led to the withdrawal of beneficial products from the market altogether. These reasons are why manufacturers, farmers, and the public rely on government regulators to balance the risks and benefits of pesticides through the use of sound science.

The impact of this case, therefore, is much broader than the parties here. Other federal agencies beyond EPA, including the Food and Drug Administration (FDA) and the National Highway Transportation Safety Administration, undertake

similar science-based assessments of products that have potential risks, even when they are used as instructed, when they find that the social, health, or economic benefits of their use outweigh those risks.

For example, pharmaceutical medicines are subject to considerable scientific analysis and review by the FDA in determining whether they are safe and effective. *See* 21 U.S.C. § 355 *et seq*. (requirements for new drug applications). The same is true for vehicles, which are regulated pursuant to Federal Motor Vehicle Safety Standards (FMVSS). *See* 49 C.F.R. Part 571. Often, the designs and warnings of these products need to balance competing risks, as solving one potential outcome can make a product riskier elsewhere. These scientific decisions should not be undone through "expert" testimony that is focused on creating civil liability and fails to take these other risks into consideration, and does not reliably assess the risks that it does review.

It is critical that courts fulfill their gate-keeping role under Rule 702 because designating someone as an "expert" provides the witness with a cloak of authority. *See Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1063-64 (9th Cir. 2002) (referring to "the aura of authority experts often exude, which can lead juries to give more weight to their testimony"). Jurors can falsely assume the expert's testimony is credible, particularly when the expert devises a plausible-enough-sounding theory for finding a source of compensation for people who are sick or suffered an injury.

Studies have shown that juries often fill the voids in the experts' testimony with sympathy and hindsight bias, regardless of the effectiveness of cross-examination or the veracity of opposing expert evidence. *See* David P. Sklar, *Changing the Medical Malpractice System to Align with What We Know About Patient Safety and Quality Improvement*, 92 Acad. Med. 891, 891 (2017) (explaining juries may seek to "find someone to blame" to compensate a sympathetic plaintiff); *see also* Michael A. Haskel, *A Proposal for Addressing the Effects of Hindsight and Positive Outcome Biases in Medical Malpractice Cases*, 42 Tort & Ins. Prac. L.J. 895, 905 (2007). But, it has long been a maxim of basic science that "[p]lausibility is not a substitute for evidence, however great may be the emotional wish to believe." E. Bright Wilson, Jr., An Introduction to Scientific Research 26 (1952).

This Court should affirm the ruling below to assure that district courts in the Seventh Circuit follow amended Rule 702 and issue expert evidence decisions based only on sound scientific principles. Because experts are permitted to reach conclusions on the ultimate issue in a case, their conclusions must flow from a well-articulated methodology. Here, the district court rightly found, after a thorough Rule 702 review, that this was not the case with the proposed paraquat "expert" and his proffered meta-analysis on causation.

CONCLUSION

For these reasons, the Court should affirm the Order below.

Respectfully submitted,

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Dated: October 2, 2024

CERTIFICATE OF COMPLIANCE

I certify that this *amici curiae* brief complies with the length limits permitted by Seventh Circuit Rule 29. The brief contains 4,739 words, excluding the portions exempted by Fed. R. App. P. 32(f), and is prepared in a format, type face, and type style that complies with Fed. R. App. P. 32(a)(4)-(6).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally-spaced typeface using Microsoft Word in Times New Roman 14-point font.

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Dated: October 2, 2024

CERTIFICATE OF SERVICE

I certify that on this 2nd day of October, 2024, I caused to be electronically filed the foregoing *amici curiae* brief with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit via the Court's CM/ECF system. All parties are registered CM/ECF users, have consented to receive electronic service, and will be served by the CM/ECF system.

Respectfully submitted,

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