COMMENT TO THE

ADVISORY COMMITTEE ON EVIDENCE RULES AND ITS RULE 702 SUBCOMMITTEE

IN SUPPORT OF AMENDING RULE 702 AND ITS COMMENTS TO ACHIEVE MORE ROBUST AND CONSISTENT GATEKEEPING

July 31, 2020

The International Association of Defense Counsel ("IADC") respectfully submits this Comment in support of amending Federal Rule of Evidence 702 and its comments to achieve more robust and consistent judicial gatekeeping.

The IADC is an invitation-only, peer-reviewed membership organization of approximately 2,500 of the world's leading corporate and insurance defense lawyers and insurance executives. The IADC has been serving its members for a century. Its core purpose is to enhance the development of skills and professionalism of its members to benefit the civil justice system, the legal profession, and society in general. IADC members handle cases in all federal jurisdictions and have been involved in many precedent-setting decisions and appeals.

Rule 702 is a rule more often misunderstood by some courts than followed over the last twenty years.[1] As the Advisory Committee notes to the 2000 Amendments to the Rule state clearly, "the admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."[2]

Too many courts misunderstand this clearly-articulated standard. In fact, at least two appellate circuits—the Eighth and the Ninth Circuits—have expressly adopted standards for admissibility that defy the Advisory Committee's 2000 Comment. In addition, numerous trial courts throughout the nation frequently admit flimsy expert evidence, usually by reasoning that challenges to an expert's methods are challenges to the weight the evidence should receive rather than its admissibility. The Standing Committee is aware of this specific problem, lamenting that "crafting an amendment that essentially tells federal courts to 'apply the rule' may be challenging."[3]

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[1] *See, e.g.*, Victor E. Schwartz & Cary Silverman, *The Draining of* Daubert *And The Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 127 (2006).

[2] Advisory Committee Notes on Rule 702—2000 Amendment (citing *Bourjaily v. United States,* 483 U.S. 171 (1987)).

[3] Agenda Book for June 12, 2018, Standing Committee Meeting, at 433.

I. The Eighth Circuit Refuses Only "Fundamentally Unsupported" Expert Testimony

The Eighth Circuit has interpreted Rule 702 to admit evidence wherever possible rather than as a tool to exclude evidence that will not help the trier of fact.[4] As a result, the court has held that an expert's opinion should be excluded "only if it is so fundamentally unsupported that it can offer no assistance to the jury."[5] These standards originate in opinions that predate not only the 2000 Amendments to Rule 702, but the Supreme Court's announcement of new standards for admitting expert testimony in *Daubert.*[6]

To give an idea of the pernicious effects this legacy standard for admitting expert testimony has imposed, one need only look at the case that served as the origin point for mass litigation over talcum powder: a trial in the District of South Dakota in *Berg v. Johnson & Johnson.*[7] In *Berg,* the plaintiff sued Johnson & Johnson, alleging that its talc products had caused her ovarian cancer.

In preparing to move for summary judgment, Johnson & Johnson challenged the testimony of the various experts Ms. Berg had indicated she would employ, including an epidemiologist who had conducted a prior study of ovarian cancer, but whose methodology was severely flawed. Among other problems, the epidemiologist did not rule out alternative causes of ovarian cancer,[8] his testimony conflicted with the existing scientific literature,[9] his data was "'cherry-picked' … solely for purposes of litigation,"[10] and his conclusions conflicted with his non-litigation research and with each other internally.[11]

Despite conceding the existence of these problems, the trial court admitted the expert's testimony, relying heavily on the highly permissive standard the Eighth Circuit had articulated.[12]

Post-*Berg*, plaintiffs across the country filed nearly identical talc lawsuits against Johnson & Johnson and other defendants. Those copycat suits have produced dramatically different results.[13] At one extreme, a twenty-two plaintiff case in the City of St. Louis produced a $4.69 billion verdict, reduced to $2.12 billion by the Missouri Court of Appeals.[14] There have been several multi-million dollar verdicts in various jurisdictions, including California.[15] Despite these

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[4] *See, e.g., Sappington v. Skyjack, Inc.,* 512 F.3d 440, 448 (8th Cir. 2008); *Lauzon v. Senco Prods., Inc.,* 270 F.3d 681, 686 (8th Cir. 2001); *Arcoren v. United States,* 929 F.2d 1235, 1239 (8th Cir.), *cert. denied*, 502 U.S. 913 (1991).

[5] *Wood v. Minn. Mining & Mfg. Co.,* 112 F.3d 306, 309 (8th Cir. 1997).

[6] *Daubert v. Merrell Dow Pharms., Inc.*509 U.S. 579 (1993).

[7] 940 F. Supp. 2d 983 (D.S.D. 2013).

[8] *Id.* at 991.

[9] *Id.*

[10] *Id*.

[11] *Id.* at 992.

[12] *Id.* at 991-92.

[13] *See* Nicole Prefontaine, *Talcum Powder & Expert Power: Admissibility Standards of Scientific Testimony*, 59 Jurimetrics J. 341 (2019).

[14] *See Ingham v. Johnson & Johnson*, 2020 WL 3422114 (Mo. Ct. App. June 23, 2020). J&J has said it will appeal to the Missouri Supreme Court.

[15] *See* William L. Anderson & Kieran Tuckley, *How Much Is Enough? A Judicial Roadmap to Low Dose Causation Testimony in Asbestos & Tort Litigation,* 42 Am. J. Trial Advoc. 39 (2018).

verdicts, New Jersey courts have dismissed similar cases,[16] and Johnson & Johnson has won others at trial.[17]

In May 2020, Johnson & Johnson announced it was discontinuing North American sales of its talcum-based baby powder.[18] Among other reasons, the company attributed the decision to declining demand caused by misinformation from a "constant barrage of litigation advertising."[19]

In contrast to the inconsistent rulings in the courts, the scientific consensus supports Johnson & Johnson. For example, in January, the *Journal of the American Medical Association* published the results of an original investigation in which it announced that, after examining four cohort populations involving more than 250,000 women, "there was not a statistically significant association between use of [talcum] powder in the genital area and ovarian cancer."[20]

II. The Ninth Circuit Admits Everything Short of "Unreliable Nonsense"

The Ninth Circuit has interpreted Rule 702 past the bounds of its text, impacting cases such as the litigation involving the popular herbicide Roundup™.[21] That litigation has taken a finding by the International Agency for Research on Cancer (a watchdog group tasked with identifying novel potential carcinogens for further study) that the active ingredient in Roundup™ (glyphosate) has the potential to cause cancer, and expanded it into a wholesale challenge to the sale of glyphosate in the United States.

The scientific consensus remains that glyphosate does not pose cancer risks at human-level doses.[22] Nonetheless, in the years preceding the Roundup™ litigation, the Ninth Circuit had decided a series of cases in which various panels of the appellate court had—in a series of admitted "close calls"—allowed the admission of "shaky" expert evidence to the jury, citing the "interests of justice" over those of accuracy.[23]

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[16] *See* Prefontaine, *supra* note 13, at 341.

[17] *See, e.g.*, Tina Bellon, *Jury Clears J&J of Liability in New Jersey Talc Cancer Case*, 41 No. 1 Westlaw J. Asbestos 5 (2018); Tina Bellon, *New Jersey Jury Finds J&J Not Liable in Talc Cancer Trial; Company Settles Three Other Cases*, 41 No. 13 Westlaw J. Asbestos 2 (2019); Nate Raymond, *Johnson & Johnson Wins California Lawsuit Claiming Asbestos in Talc Caused Cancer*, 28 No. 11 Westlaw J. Prod. Liab. 5 (2017); Nate Raymond, *Johnson & Johnson Wins Trial in Talc Product Liability Lawsuits*, 28 No. 2 Westlaw J. Prod. Liab. 4 (2017).

[18] *See* Tiffany Hsu & Roni Caryn Rabin, *Johnson & Johnson to End Talc-Based Baby Powder Sales in North America,* N.Y. Times, May 19, 2020, *at* https://www.nytimes.com/2020/05/19/business/johnson-baby-powder-sales-stopped.html.

[19] Amanda Bronstad, *Expert Ruling Was 'Tipping Point' for J&J's Talc Withdrawal, Lawyers Say*, Law.com, May 22, 2020, *at* https://www.law.com/2020/05/22/expert-ruling-was-tipping-point-for-jjs-talc-withdrawal-lawyers-say/?cmp=share_twitter.

[20] Katie M. O'Brien, *et al*., *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*, 323 JAMA 49, 49-59 (2020).

[21] *See In re Roundup Prods. Liab. Litig*., 390 F. Supp. 3d 1102, 1108 (N.D. Cal. 2018).

[22] *See Nat'l Ass'n of Wheat Growers v. Becerra*, 2020 WL 3412732, at *2 (E.D. Cal. June 22, 2020) (stating that, in contrast to IARC, "several other organizations, including the EPA, other agencies within the World Health Organization, and government regulators from multiple countries, have concluded that there is insufficient or no evidence that glyphosate causes cancer.").

[23] *See Wendell v. GlaxoSmithKline LLC,* 858 F.3d 1227, 1237-38 (9th Cir. 2017), *cert. denied sub nom. Teva Pharms. USA, Inc. v. Wendell*, 138 S. Ct. 1283 (2018) (reversing exclusion of expert evidence as abuse of discretion; "interests of justice favor leaving difficult issues in the hands of the jury," even when they involve "shaky" expert evidence);

In the Roundup™ litigation, the trial court admitted the testimony of an epidemiologist who testified that there was a specific relationship between exposure to glyphosate and non-Hodgkin's lymphoma, despite the admittedly "valid" critique that she did not adequately adjust her data to account for use of other pesticides,[24] and an outright admission that "this portion of her presentation calls her objectivity and credibility into question."[25]

The court ultimately admitted her testimony because—quoting the Ninth Circuit—it did "not rise to the level of an 'unreliable nonsense opinion.'"[26] The trial court conceded that the Ninth Circuit's permissive standard "has resulted in slightly more room for deference to experts in close cases than might be appropriate in other circuits," which is "a difference that could matter in close cases."[27]

That difference has mattered a great deal. There have been three trials in cases alleging that plaintiffs developed Non-Hodgkin's lymphoma from exposure to Roundup™, one in San Francisco federal court and two in Bay Area state courts.[28] The trials resulted in plaintiff verdicts totaling $2.4 billion before post-trial reductions and received national media attention because of their enormity.[29] The cases are on appeal and there are reports that Bayer may be working toward a resolution of the litigation at a cost of up to $9.6 billion for the current claims alone. The *Wall Street Journal* called the potential settlement "a shakedown for the history books,"[30] after describing "the entire Roundup litigation" as "a stickup."[31]

Like the talc litigation, the science in the courtroom in Roundup™ does not match the scientific consensus in the real world.

For example, EPA publicly reiterated in January 2020 that the agency had "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that

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Messick v. Novartis Pharms. Corp., 747 F.3d 1193, 1198-99 (9th Cir. 2014) (reversing summary judgment; trial court erred in excluding expert testimony as scientifically unreliable, not recognizing that "[m]edicine partakes of art as well as science"); *Alaska Rent-a-Car, Inc. v. Avis Budget Group, Inc.,* 738 F.3d 960, 969 (9th Cir.), *cert. denied*, 571 U.S. 1024 (2013) (reversing exclusion of expert: "Basically, the judge is supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable.").

[24] *In re Roundup Prods. Liab. Litig.,* 390 F. Supp. 3d 1102, 1140 (N.D. Cal. 2018).

[25] *Id*. at 1109.

[26] *Id.* at 1113 (quoting *Alaska Rent-a-Car, Inc.,* 738 F.3d at 969); *see also In re Roundup Prods. Liab. Litig*., 358 F. Supp. 3d 956, 957 (N.D. Cal. 2019) (stating that plaintiffs' experts "barely inched over the line.").

[27] *In re Roundup Prods. Liab. Litig.,* 390 F. Supp. 3d at 1113.

[28] *See* Editorial, *The Roundup Settlement*, Wall St. J., June 29, 2020, at A14, *at* https://www.wsj.com/articles/the-roundup-settlement-11593212426.

[29] Sara Randazzo & Jacob Bunge, *Inside the Mass-Tort Machine That Powers Thousands of Roundup Lawsuits*, Wall St. J., Nov. 25, 2019, *at* https://www.wsj.com/articles/inside-the-mass-tort-machine-that-powers-thousands-of-roundup-lawsuits-11574700480; *see also Johnson v. Monsanto Co*., 2020 WL 4047332 (Cal. Ct. App. July 20, 2020).

[30] *See* Editorial, *The Roundup Settlement*, *supra* note 28.

[31] Editorial, *The Roundup Stickup,* Wall St. J., Dec. 25, 2019, *at* https://www.wsj.com/articles/the-roundup-stickup-11577299381. Bayer's CEO told Fox Business, "I would say that the country's in dire need of tort reform." *Werner Baumann, CEO of Bayer, is Interviewed on Fox Business*, CQ-Rollcall Pol. Transcriptions, 2020 WLNR 17711970 (June 25, 2020).

glyphosate is not likely to be carcinogenic to humans."[32] EPA's position is consistent with other international authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.[33]

In June of 2020, a California federal district court permanently enjoined the state from requiring a "Proposition 65" cancer warning on glyphosate-based herbicides because "the great weight of evidence indicates that glyphosate is not known to cause cancer."[34]

III. Other Courts Do the Same, Even Without Explicit Appellate Guidance

Other courts also misunderstand the rule's requirement that the plaintiff bears the burden of establishing admissibility. As a result, we see cases where courts push off valid questions about methodology—which is supposed to determine reliability—as questions of weight of the evidence. This allows the courts to avoid difficult decisions about whether scientific evidence is appropriate. But those decisions will be equally—if not more—difficult for juries to make, especially with the knowledge that the appointed gatekeeper found the evidence appropriate for them to hear. As several commentators have noted, courts conflate the concepts of sufficiency and weight in ways that keep scientifically dubious cases alive.[35]

- In *Zollicofer v. Gold Standard Baking, Inc.,*[36] the defendants challenged the admissibility of a rebuttal declaration by an economist purporting to show that certain policies were discriminatory in effect. The trial court admitted his testimony over objections about his failure to vet the data used, because questions of proper vetting of data went to the "weight" of testimony, not its admissibility.[37]
- In *Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tenn. v. Momenta Pharmaceuticals, Inc.,*[38] the defendants challenged the admissibility of a report from an economist because it was unreliable given the expert's failure to perform the usually required statistical analysis. The trial court admitted the testimony anyway, holding that the use of statistical analysis (a methodological question) went to "weight," not admissibility.[39]

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[32] U.S. Envtl. Prot. Agency, Glyphosate Interim Registration Review Decision, Case No. 0178, at 10 (Jan. 2020), *at* https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

[33] Letter from Michael L. Goodis, P.E., Dir., Registration Div., Office of Pesticide Programs, EPA to Glyphosate Registrants (Aug. 7, 2019), *at* https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.

[34] *See Nat'l Ass'n of Wheat Growers*, 2020 WL 3412732, at *8.

[35] *See, e.g.,* David L. Faigman, *et al., Gatekeeping Science: Using the Structure of Scientific Research to Distinguish Between Admissibility and Weight in Expert Testimony,* 110 Nw. U. L. Rev. 859, 862 (2016) (noting persistent confusion between admissibility and weight in federal courts).

[36] 2020 WL 1527903 (N.D. Ill. Mar. 31, 2020).

[37] *Id.* at *15.

[38] 333 F.R.D. 390, 400 (M.D. Tenn. 2019).

[39] *Id.* at 402.

- In *In re National Prescription Opiate Litigation,*[40] the court denied the defendant's Rule 702 challenge to an expert who had "failed to adequately consider econometrics concepts such as nonstationarity and endogeneity in her analysis."[41] The court held that "the significance of endogeneity goes to the weight, not the admissibility" of the testimony.[42]
- In *Taylor v. Trapeze Management, LLC,*[43] the court rejected a challenge to a proposed marketing research expert, holding that challenges to survey design and population went to weight, not admissibility.

Each of these opinions represents a judge's misunderstanding that a jury is the best arbiter of the methodology for difficult questions. Rule 702 should be clear that it is the court's responsibility to decide question such as the appropriate method of vetting data or the proper role of nonstationarity and endogeneity in econometrics research, to use examples from the cases mentioned above.

Leaving these questions to the jury is not just abdicating the judge's gatekeeping role, it is privileging persuasiveness—which can depend on a number of non-rational factors such as narrative framing, cognitive bias, and outright prejudice—over accuracy. These decisions do not meet the requirements of Rule 702. They also conflict with the purpose of the federal rules, which are meant to "ascertain[] the truth and secur[e] a just determination."[44]

IV. Proposed Amendment

Reform does not require revolutionary changes to the Federal Rules of Evidence. Rule 702 already requires a preponderance of proof standard. Currently, the 2000 Committee Notes state that, consistent with Rule 104(a) "the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."[45]

Not all rulings admitting experts based on a preponderance of the available evidence will be free from criticism. However, each of the various holdings listed above—which defer questions of methodology to the jury or knowingly admit faulty findings—lacked any mention of this standard, or any finding which would meet it.[46]

Therefore, we propose the following amendment to Rule 702:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if, after findings consistent with Rule 104, the court determines:".

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[40] 2019 WL 3934597, *10 (N.D. Ohio Aug. 20, 2019).

[41] *Id.* at *10.

[42] *Id.*

[43] 2019 WL 1977514, *3 (S.D. Fla. Feb. 28, 2019).

[44] *See* Fed. R. Evid. 102 ("These rules should be construed so as to administer every proceeding fairly, eliminate unjustifiable expense and delay, and promote the development of evidence law, to the end of ascertaining the truth and securing a just determination.").

[45] Fed. R. Evid. 702, Committee Notes on Rules – 2000 Amendment.

[46] *See Zollicofer,* 2020 WL 1527903, at *15 (no mention of preponderance standard); *Hosp. Auth. of Nashville,* 333 F.R.D. at 402; *In re Nat'l Prescription Opiate Litig.,* 2019 WL 3934597, at *10; *Taylor,* 2019 WL 1977514, at *3.

Adding language to Rule 702 specifically referencing this standard, instead of leaving it in the Notes, should prevent courts from continuing to misunderstand the preponderance standard. It should also encourage both sides to brief the issues in terms of the preponderance of available evidence and encourage courts to make findings on each factor.

V. Conclusion

The IADC appreciates the opportunity to share its views. We are particularly concerned about mass tort litigations in which the science in the courtroom seems increasingly divorced from the mainstream scientific consensus outside the courtroom. The rule of law and credibility of the civil justice system will suffer along with the nation's competitiveness if outcomes in the courts appear arbitrary. We encourage the Committee to adopt amendments to address this problem including the approach we have outlined here and those submitted by other commenters.[47]

[47] *See* Lawyers for Civil Justice, Comment to the Advisory Committee on Evidence Rules and its Rule 702 Subcommittee, Clearing Up the Confusion: The Need for a Rule 702 Amendment to Address the Problems of Insufficient Basis and Overstatement (Sept. 6, 2019); Lawyers for Civil Justice, Comment to the Advisory Committee on Evidence Rules and its Subcommittee on Rule 702, In Support of Amending Rule 702 to Address the Problem of Insufficient Basis for Expert Testimony (Oct. 10, 2018); Federation of Defense & Corporate Counsel, Comment on Potential Amendment to Federal Rule of Evidence 702 (June 30, 2020); Letter from 50 General Counsel re Amending Federal Rule of Evidence 702 to Clarify Courts' "Gatekeeping" Obligation (Mar. 2, 2020).