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Via Email: Rules Committee Secretary@ao.uscourts.gov

Rebecca A. Womeldorf, Secretary
Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, N.E.
Washington, D.C. 20544

Re: Amending Federal Rule of Evidence 702

Dear Ms. Womeldorf:

The U.S. Chamber Institute for Legal Reform appreciates the opportunity to submit this Comment to the Advisory Committee on Evidence Rules and its Rule 702 Subcommittee. We support the Advisory Committee's efforts to explore possible amendments to Federal Rule of Evidence 702. The use of sound science and reliable expert testimony is essential to a wide range of stakeholders, both in the civil and criminal justice systems.

Over two decades have passed since the U.S. Supreme Court deputized trial courts as gatekeepers over the reliability of expert testimony and, through the *Daubert* trilogy, provided guidance to judges on how to perform that critical function. Two decades have also elapsed since the Advisory Committee substantively addressed, through amending the text of Rule 702 and the Committee Notes that accompany it, the Rule's proper application.

Meanwhile, mass tort litigation has exploded. In recent years, multidistrict litigation (MDL) cases have constituted roughly one-half of the entire federal civil docket (excluding most prisoner and social security cases).[1] In fact, since Rule 702's 2000 amendment, the number of pending cases in MDLs has increased 650%.[2] About 90% of cases in MDLs are product liability

[1] MDL cases were nearly 52% and 47% of the entire federal civil docket (excluding most prisoner and social security cases) in 2018 and 2019, respectively, including 134,462 cases in 194 MDLs in 2019. *See* Lawyers for Civil Justice, Resources, Rules4.MDLs.com (providing MDL infographics and statistics).

[2] At the close of FY 2000, there were almost 40,000 cases pending in MDLs. *See* Judicial Panel on Multidistrict Litigation, Statistical Analysis of Multidistrict Litigation (FY 2000). There are now some 262,228 actions pending in 181 MDLs. *See* Judicial Panel on Multidistrict Litigation, MDL Statistics Report - Distribution of Pending MDL Dockets by Actions Pending (Aug. 17, 2020). Even excluding 142,527 earplug product liability cases in an MDL established in April 2019, the number of pending cases in MDLs has more than tripled since 2000. *See*

(cont'd)

claims. A ruling on the admissibility of expert testimony addressing causation in one of these litigations may mean the difference between ending thousands of claims that are contrary to the prevailing scientific consensus or allowing the suits to advance to trial, placing substantial pressure on defendants to settle and potentially remove safe and beneficial products from the market.

The amount of class action litigation in federal courts since 2000 has also grown significantly.[3] Class action litigation is often reliant on expert testimony offering dubious theories to create a common injury where there is none. The Class Action Fairness Act of 2005, which expanded federal court jurisdiction over multi-state class actions, increases the importance of applying consistent expert testimony standards in these high-stakes cases that may involve thousands or even millions of members.

These significant civil developments are in addition to developments in the criminal justice system, where unreliable expert testimony influences proceedings with life and liberty at stake, and both warrant the Advisory Committee's careful consideration.

The Admission of Expert Evidence Should Not Vary by Jurisdiction

According to the 2000 Notes to Rule 702, questions of the admissibility of expert evidence should be decided by a preponderance of the available evidence.[4] The Committee drew this standard from Rule 104(a) as well as United States Supreme Court precedent.[5] Nonetheless, various courts misunderstand or misinterpret this standard, instead invoking other fragments from the Notes and case law to hold that the standard for expert evidence should have a "liberal thrust" favoring admission of evidence.[6]

The Eighth Circuit, for example, misreads Rule 702 to favor the admission of opinion evidence wherever possible.[7] As a result, the court has consistently held—adhering to a pre-2000 Amendment perspective—that an expert's opinion should be excluded "only if it is so fundamentally unsupported that it can offer no assistance to the jury," not when the proffering

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Judicial Panel on Multidistrict Litigation, Statistical Analysis of Multidistrict Litigation (FY 2019) (indicating 156,511 and 134,462 pending cases in MDLs at the close of FY 2018 and FY 2019, respectively).

[3] *See* Emery G. Lee III & Thomas E. Willging, The Impact of the Class Action Fairness Act of 2005 on the Federal Courts: Fourth Interim Report to the Judicial Conference Advisory Committee on Civil Rules 1 (Fed. Jud. Ctr. Apr. 2008) (finding a 72% increase in class action activity when comparing the period of July through December 2001 to January through June 2007, including a "dramatic increase" in class action filings after CAFA's effective date, primarily alleging consumer protection, contracts, and torts-property damage claims.

[4] Fed. R. Evid. 702, Committee Note on Rules—2000 Amendment.

[5] *See Bourjaily v. United States,* 483 U.S. 171, 175-76 (1987).

[6] *See Daubert v. Merrell Dow Pharm. Co.,* 509 U.S. 579, 588 (1993).

[7] *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); *see also* Thomas D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony,* 95 Notre Dame L. Rev. 2039, 2046-49 (2020) (detailing Eighth Circuit opinions deviating from Rule 702 standard).

party fails to establish by a preponderance of available evidence that Rule 702's requirements are met.[8]

This incorrect approach means that, in complex tort cases, courts admit expert evidence that cannot meet the rigors of the scientific method. For example, in *Berg v. Johnson & Johnson,*[9] the case that touched off the nationwide talcum powder litigation, the plaintiff sued Johnson & Johnson, alleging that its talc products had caused her ovarian cancer. Before moving for summary judgment, Johnson & Johnson challenged the admissibility of the testimony of Ms. Berg's experts, including an epidemiologist who had conducted a prior study of ovarian cancer, but whose methodology was clearly problematic. Among other flaws, the epidemiologist had not ruled out any alternative causes of ovarian cancer, his testimony conflicted with the existing peer-reviewed literature, his data was "'cherry-picked' … solely for purposes of litigation," and his conclusions conflicted with his non-litigation research.[10] Despite conceding the existence of these problems, the trial court relied on the Eighth Circuit's misunderstanding of Rule 702's requirements to admit the expert's testimony.[11] Following this decision, plaintiffs across the country filed nearly identical talc lawsuits against Johnson & Johnson and other talc defendants.

Far from resting on available scientific evidence, these lawsuits flew in the face of established scientific consensus. Most recently, in January 2020, 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."[12] Nevertheless, the federal court overseeing thousands of talc cases ruled in April 2020 that plaintiffs' experts could testify that minute traces of asbestos in talc could cause cancer.[13] Shortly thereafter, Johnson & Johnson announced it was discontinuing North American sales of its talcum-based baby powder.[14] A leading supplier of talc to Johnson & Johnson and others filed for bankruptcy in 2019.[15]

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

[9] 940 F. Supp. 2d 983 (D. S.D. 2013).

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

[11] *Id*.

[12] 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).

[13] *In re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices and Prods. Litig*., MDL No. 2738 (D. N.J. Apr. 27, 2020).

[14] *See* Amanda Bronstad, Expert Ruling Was 'Tipping Point' for J&J's Talc Withdrawal, Lawyers Say, Law.com, May 22, 2020.

[15] Jeff Feeley, *et al*., Imerys Talc Units File Bankruptcy as Cancer-Suit Risk Soars, Bloomberg.com, Feb. 13, 2019.

Similarly, the Ninth Circuit has departed from Rule 702's meaning.[16] Much of this occurred in a series of cases in which various panels allowed the admission of questionable expert evidence, citing the "interests of justice" over those of accuracy.[17]

These cases guided the trial court involved in the starkest example of intuitive "justice" over accuracy: the Roundup litigation. The Roundup cases began with a statement by the International Agency for Research on Cancer (IARC) that glyphosate— a broad-spectrum herbicide used as an ingredient in weed killers—had the potential to be carcinogenic.[18] Unlike other international agencies, the IARC's job is to make preliminary findings with a large degree of speculative freedom, in the hopes of identifying possible threats very early in the process that might require further research.[19] In other words, the finding that spurred mass litigation over the dangers posed by Roundup was based on a tentative finding by an agency tasked with speculating about possible dangers. Nonetheless, that preliminary finding spurred an entire MDL full of lawsuits.

Those lawsuits would be subject to dismissal without admissible expert testimony to back up the IARC's preliminary statement. As a result, the trial court found itself evaluating the testimony of an epidemiologist who testified that a causal relationship existed between exposure to glyphosate and non-Hodgkin's lymphoma. Despite noting the "valid" critique that the proposed expert had not adjusted her data to account for the use of other pesticides[20]—which it found "calls her objectivity and credibility into question"[21]—the court admitted her testimony because it did "not rise to the level of an 'unreliable nonsense opinion.'"[22] The trial court made no reference to any available evidence about the reliability of the opinion, as required by Rule 104(a). Instead, it conceded that this result was compelled by the Ninth Circuit's permissive approach to gatekeeping,

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[16] *See* Schroeder, *Admission of Expert Testimony,* 95 Notre Dame L. Rev. at 2050 ("Ninth Circuit caselaw appears to interpret *Daubert* as liberalizing the admission of expert testimony, which may explain decisions from that circuit that set it apart from most others.").

[17] *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, finding the "interests of justice favor leaving difficult issues in the hands of the jury"); *Messick v. Novartis Pharms. Corp.,* 747 F.3d 1193, 1198-99 (9th Cir. 2014) (reversing summary judgment, finding the trial court erred in excluding expert testimony as scientifically unreliable); *Alaska Rent-a-Car, Inc. v. Avis Budget Group, Inc.,* 738 F.3d 960, 969 (9th Cir. 2013) (reversing exclusion of expert, stating "[b]asically, the judge is supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable").

[18] *In re Roundup Prods. Liab. Litig.,* 390 F. Supp. 3d 1102, 1114 (N.D. Cal. 2018).

[19] *Id*.

[20] *Id.* at 1140.

[21] *Id*. at 1109.

[22] *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) (admitting testimony but noting that plaintiffs' experts "barely inched over the line").

which results in more "deference to experts in close cases than might be appropriate in other circuits."[23]

Like the talc litigation, the science admitted in the Roundup courtroom did not match the clear scientific consensus in the real world. For example, in January 2020, EPA publicly reiterated 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 glyphosate is not likely to be carcinogenic to humans."[24] Similarly, in June of 2020, a California federal district court 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."[25]

These cases show that misunderstanding the Rule 702 standard has real-world effects, driving products off shelves, putting companies into bankruptcy, and transforming tentative agency findings into nationwide litigation.

Expert Gatekeeping Should Not Be More Permissive for Class Certification

Another area of specific concern is the class certification hearing. A plain-text reading of the law indicates that class certification should be governed by the same standard as other hearings before a court, meaning any evidence submitted should be *admissible* evidence, subject to the Federal Rules of Evidence, including Rule 702.[26] Federal Rule of Evidence 1101 carves out exceptions for Rule 104(a) questions, grand jury proceedings, and a list of "miscellaneous" proceedings: "extradition or rendition; issuing an arrest warrant, criminal summons, or search warrant; a preliminary examination in a criminal case; sentencing; granting or revoking probation or supervised release; and considering whether to release on bail or otherwise."[27] The Rule does not mention class certification hearings.

Nonetheless, the Eighth Circuit has decided that, because of the "preliminary nature" of class certification hearings, these hearings do not require expert evidence to be admissible in court in order to be considered; instead the evidence submitted is subjected to a more relaxed "tailored *aubert* analysis."[28] Similarly, the Ninth Circuit has held that evidence submitted in support of class certification need not meet the admissibility requirements of Rule 702.[29]

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

[24] U.S. Envt'l Prot. Agency, Glyphosate Interim Registration Review Decision, Case No. 0178, at 10 (Jan. 2020).

[25] *See Nat'l Ass'n of Wheat Growers v. Becerra*, No. 2:17-cv-2401, 2020 WL 3412732, at *8 (E.D. Cal. Jun. 22, 2020), *appeal filed* (9th Cir. Sept. 11, 2020).

[26] *See* Fed. R. Evid. 1101 (rules of evidence apply to all proceedings before district court).

[27] Fed. R. Evid. 1101(d).

[28] *Cox v. Zurn Pex, Inc.,* 644 F.3d 604, 613-14 (8th Cir. 2011).

[29] *Sali v. Corona Reg'l Med. Ctr.,* 909 F.3d 996, 1104-06 (9th Cir. 2018), *cert. denied*, 139 S. Ct. 1651 (2019).

These rulings contradict the text of Rule 702 and ignore clear direction from the Supreme Court.[30] The rulings also ignore the reality of class actions. Both the Eighth and Ninth Circuits justify their deviations by pointing to the "preliminary nature" of the class certification hearing.[31] The truth is that class certification is often the single most important hearing in the life of a class action.[32] In fact, the decision is important enough to justify its own rule allowing interlocutory review.[33]

The end result is that trial courts in these jurisdictions certify class actions based on evidence that would not be admissible at summary judgment or an actual trial, including expert evidence that has not passed the scrutiny required by Rule 702.

For example, the Northern District of California certified a class of cereal purchasers alleging that health representations on certain cereal boxes were misleading.[34] The court did so despite conceding that the defendants had raised "a number of valid critiques about the expert's survey methodology," because the Ninth Circuit had held—in a case predating Rule 702—that "challenges to survey methodology go to the weight given the survey, not its admissibility."[35] This was not a single error; the court repeatedly conceded that the defendant had raised valid questions about the reliability of the expert's testimony, but said that the Ninth Circuit's holdings required it to ignore these concerns.[36] It did not make any inquiry into the evidence supporting those challenges, as would have been required under Rule 104(a). The end result was that the court certified a class, despite the fact that doing so required relying on faulty expert testimony.[37]

Similarly, the Western District of Missouri admitted opinion testimony supporting certification even though it conceded that the "corridor damage theory" the expert offered in support of certification likely lacked adequate support in the industry, and that the expert's calculations might not be reliable.[38] Such an unsupported opinion would not have passed the

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[30] *Wal-Mart Stores, Inc. v. Dukes,* 564 U.S. 338, 354 (2011) ("The District Court concluded that *Daubert* did not apply to expert testimony at the certification stage of class-action proceedings. We doubt that is so …") (internal citation omitted).

[31] *Zurn Pex,* 644 F.3d at 613; *Sali*, 889 F.3d at 631.

[32] *See Marcus v. BMW of N. Am., LLC,* 687 F.3d 583, 591 n.2 (3d Cir. 2012) ("As a practical matter, the certification decision is typically a game-changer, often the whole ballgame, for plaintiffs and plaintiffs' counsel."); *Prado-Steiman v. Bush,* 221 F.3d 1266, 1274 (11th Cir. 2000) (granting certification may "raise [] the cost and stakes of the litigation so substantially that a rational defendant would feel irresistible pressure to settle").

[33] *See* Fed. R. Civ. P. 23(f).

[34] *Hadley v. Kellogg Sales Co.,* 324 F. Supp. 3d 1084, 1090 (N.D. Cal. 2019).

[35] *Id.* at 1107 (citing *Wendt v. Host Int'l, Inc.,* 125 F.3d 806, 814 (9th Cir. 1997), which predates the 2000 Amendments to Rule 702).

[36] *Id.* at 1108-10.

[37] *Id.* at 1121.

[38] *Barfield v. Sho-Me Power Elec. Coop.,* No. 11-cv-04521-NLL, 2013 WL 12145824, at *3 (W.D. Mo. July 8, 2013).

inquiry into supporting evidence required by Rule 104(a). The trial court went on to rely on this opinion testimony when it certified a class later that month.[39]

Other federal appellate courts do not cast aside Rule 702 when deciding whether to certify class actions. The Third, Fifth, and Seventh Circuits have required trial courts to decide admissibility questions at the class certification stage, at least in cases in which expert testimony is central to certification.[40] This is the proper approach.

Proposed Amendment and Note

A change is needed to clarify the requirements of Rule 702 and to achieve more uniformity in its application across both civil and criminal cases. The necessary clarification may be accomplished by a minor amendment to the text of 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:

In addition, the Notes to any amendment should make clear that:

> Consistent with Rule 1101, the preponderance standard applies to *all* proceedings governed by the Rules of Evidence, including class certification hearings.

These modifications do not change the substance of Rule 702. 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."[41] As discussed throughout this Comment, most rulings admitting questionable evidence rely on misapplied legal standards or intuitions about "weight" and "admissibility," not on an inquiry into whether available evidence supports the ruling. Promoting this language from the Notes to the Rule itself should prevent courts from misunderstanding how to apply the preponderance standard to Rule 702. The amendment would encourage both sides to brief the issues in terms of the preponderance of available evidence and stimulate courts to make findings on each factor of Rule 702, which should aid any appellate review. In addition, coupled with the proposed note text, the amendment should make clear that the preponderance standard governing Rule 702 does not change in class certification proceedings, regardless of how "preliminary" the court considers the hearing. Finally, promoting the language to the text of the Rule should trigger courts to rely on the Rule itself, instead of common-law admissibility standards concocted before the Rule was established.

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[39] *Barfield v. Sho-Me Power Elec. Coop.,* No. 11-cv-04521-NLL, 2013 WL 3872181, at *4 (W.D. Mo. July 25, 2013).

[40] *See, e.g., In re Blood Reagents Antitrust Litig*., 783 F.3d 183, 187 (3d Cir. 2015); *Messner v. Northshore Univ. Health Sys*., 669 F.3d 802, 812 (7th Cir. 2012); *Unger v. Amedisys. Inc*., 401 F.3d 316, 325 (5th Cir. 2005). Unpublished decisions from the Sixth and Eleventh Circuits also support this approach. *See In re Carpenter Co*., No. 14-cv-0302, 2014 WL 12809636, at *3 (6th Cir. 2014); *Sher v. Raytheon Co*., 419 F. App'x 887, 890 (11th Cir. 2011).

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

Conclusion

ILR appreciates the opportunity to share these views. As North Carolina federal District Court Judge Thomas Schroeder recently remarked, "[d]ecisionmaking on the admissibility of expert testimony would be better served if trial judges acknowledged the Rule 104(a) standard and articulated how the expert's opinion fared under each element of Rule 702."[42] We encourage the Committee to adopt amendments to address this problem including the approach we have outlined here and those submitted by other commenters.[43]

[42] Schroeder, *Admission of Expert Testimony,* 95 Notre Dame L. Rev. at 2062.

[43] *See* International Association of Defense Counsel, In Support of Amending Rule 702 and Its Comments to Achieve More Robust and Consistent Gatekeeping (July 31, 2020); 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); 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); Coalition for Litigation Justice, Inc., In Support of Amending Federal Rule of Evidence 702 and Stronger Gatekeeping in Federal Courts (July 29, 2020); Thomas J. Sheehan, *et al*., Amending Federal Rule of Evidence 702 (June 9, 2020); *see also* Lee Mickus, Gatekeeping Reorientation: Amend Rule 702 to Correct Judicial Misunderstanding About Expert Evidence, Wash. Legal Found. Critical Legal Issues Working Paper Series, No. 217 (May 2020).