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

June 9, 2020

Re: Amending Federal Rule of Evidence 702 - A Review of Gatekeeping Practices in Multidistrict Litigation

Dear Ms. Womeldorf:

The Advisory Committee on Evidence Rules is considering an amendment to Federal Rule of Evidence 702 and a Committee Note to clarify that problems with the basis of an expert's opinion or the application of an expert's methodology are threshold issues of admissibility.[1] This letter addresses confusion among some federal courts as to the proper application of Rule 702 in the context of high-stakes Multidistrict Litigation cases ("MDLs"). As attorneys who frequently deal with Rule 702-related issues in mass tort MDLs, we believe this perspective may be helpful to the Advisory Committee.

Our review of twenty-seven recent decisions from MDLs in the pharmaceutical, medical device, and chemical exposure fields demonstrates the need for Advisory Committee action on Rule 702. Courts in these cases frequently dismiss problems with an expert's factual basis or applied methodology as relating to the weight of the evidence rather than its admissibility. Further, differences in the application of Rule 702 have split MDL courts on substantive legal questions. To prevent clogging the federal system with meritless claims based on unreliable opinion testimony and undermining

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[1] *See* Daniel Capra, *Memorandum to Rule 702 Subcommittee re: Rule 702(b) and (d) – Weight and Admissibility Questions*, at 1 (Oct. 1, 2018) (Agenda Book, Advisory Committee on Evidence Rules (Oct. 19, 2018, meeting) at 171); *see also* David E. Bernstein & Eric G. Lasker, *Defending* Daubert*: It's Time to Amend Federal Rule of Evidence 702*, 57 WM. & MARY L. REV. 1, 30, 33 (2015).

the goal of uniformity that justifies use of the MDL process, we urge the Advisory Committee to draft an amendment to Rule 702 and a Committee Note expressly stating that an expert's factual basis and application of methodology are matters of admissibility, rather than weight.

I. THE MDL PERSPECTIVE ON RULE 702.

We elected to focus on MDLs for several reasons. The first is the sheer impact of MDL decisions. Rulings in MDLs affect hundreds, and sometimes thousands, of individual cases. As of the end of Fiscal Year 2019, more than 130,000 individual actions were pending in MDL matters.[2] Excluding prisoner and social security cases, MDLs make up a majority of the pending civil docket in federal courts.[3] MDLs are a pervasive means of litigation in federal court.

Given the number of individual cases, the monetary stakes of MDL rulings can be staggering. In large MDLs, total recoveries can measure in the billions of dollars.[4] Defendants threatened with potential MDL liability risk adverse publicity and reputational harm, fear among consumers, and reticence from physicians worried about their own liability. These concerns can lead to the unavailability of products that may

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[2] *See* United States Judicial Panel on Multidistrict Litigation, *Statistical Analysis of Multidistrict Litigation Under 28 U.S.C. § 1407 Fiscal Year 2019*, at 5 (2020), https://www.jpml.uscourts.gov/sites/jpml/files/JPML_Statistical_Analysis_of_Multidistrict_Litigation-FY-2019_0.pdf.

[3] Bloch Judicial Institute, Duke Law School, *Guidelines and Best Practices for Large and Mass-Tort MDLs*, at vi (2d ed. Sept. 2018).

[4] *See* Elizabeth Chamblee Burch, *Judging Multidistrict Litigation*, 90 N.Y.U. L. REV. 71, 73 n.1 (2015).

be important to public health.[5] Other MDL defendants face bankruptcy.[6] Nearly all experience tremendous pressure to settle: "An MDL judge holds the power, with a single decision, to dramatically recast the risk of liability in tens, hundreds, or even thousands of cases at a time," leaving "the painful choice of bearing the risk and expense of trial or succumbing to the pressures to settle."[7] These institutional incentives are amplified by the absence of a practical method for appellate review of district court decisions.[8]

Because of the importance of MDL decisions, Rule 702 issues are more likely to be comprehensively and capably presented and argued by both sides. Similarly, courts are more likely to focus on these matters and provide thorough analyses. If courts are failing to properly apply Rule 702 in MDLs, they are likely failing to do so elsewhere. In this regard, MDL decisions can have a domino effect. Because of their importance, MDL decisions on Rule 702 are frequently cited in both MDL and non-MDL cases

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[5] *See* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 319, 348, 364 (1992) (noting that the drug Bendectin was pulled from the market following the assertion of MDL claims despite an eventual "scientific consensus that if Bendectin has any teratogenic effects they are virtually undetectable").

[6] *See* Michael Higgins, Mass Tort Makeover? ABA J. Nov. 1998, at 52, 54.

[7] Andrew S. Pollis, *The Need for Non-Discretionary Interlocutory Appellate Review in Multidistrict Litigation*, 79 FORDHAM L. REV. 1643, 1670 (2011) (internal quotation marks omitted); *see In re Gen. Motors LLC Ignition Switch Litig.*, 2019 WL 6827277, at *14 (S.D.N.Y. Dec. 12, 2019) (noting that "the vast majority of MDL cases are, in fact, resolved by settlement . . . due, at least in part, to the sheer magnitude of the risk, in terms of dollar value, of trials").

[8] *See* U.S. Chamber, Institute for Legal Reform, *MDL Imbalance: Why Defendants Need Timely Access to Interlocutory Review* 1 (April 2019) ("Defendants faced with unfavorable dispositive motion rulings that they know will not be addressed by an appellate court for years often feel pressured to settle the hundreds or thousands of claims in an MDL proceeding, rather than incur massive additional litigation expenses and roll the dice on costly trials.").

across jurisdictions.[9] Accordingly, an incorrect application of Rule 702 is more likely to be propagated through MDL decisions.

For many of the same reasons, we concentrated on the portions of MDL decisions that consider the reliability of "general causation" opinions in drug, medical device, and chemical exposure tort cases.[10] General causation decisions typically affect more cases and have more overall impact than specific causation decisions. Experts providing such testimony often rely on similar methodologies, analyses of the Bradford Hill or other causal criteria,[11] in formulating their opinions. Accordingly, the general causation analysis—as its name suggests—is more generalizable between cases of this sort, providing fertile ground for comparison among MDL courts.

We considered twenty-seven most recent decisions from seventeen MDLs to assess how courts in those cases are applying Rule 702. They meet the following criteria: (1) MDL mass tort cases; (2) from the last eight years;[12] (3) concerning

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[9] For example, *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164 (S.D.N.Y. 2009), has been cited in 173 subsequent cases, including district court decisions in every regional circuit.

[10] The general causation question is whether a product is capable of causing a medical problem, as opposed to the specific causation question of whether a product caused the problem in a particular plaintiff. *See, e.g., Goebel v. Denver & Rio Grande W.R.R. Co.*, 346 F.3d 987, 990 (10th Cir. 2003).

[11] These nine criteria for assessing whether a causal relationship exists were first described in a famed epidemiological lecture. *See* Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE 205 (1965).

[12] We did not include cases that reconsider or review rulings that were initially made more than eight years ago. *See, e.g., In re Denture Cream Prods. Liab. Litig.*, 2015 WL 392021 (S.D. Fla. Jan. 28, 2015), *aff'd, Jones v. SmithKline Beecham*, 652 F. App'x 848 (11th Cir. 2016) (conducting updated analysis of general causation testimony following *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345 (S.D. Fla. 2011)). Similarly. we did not separately analyze cases that merely adopt prior reasoning. *See, e.g., In re Actos*

pharmaceuticals, medical devices, or chemical exposure; and (4) regarding the admissibility of general causation expert opinion testimony.[13]

(Pioglitazone) Prods. Liab. Litig., 2014 WL 108923, at *6 (W.D. La. Jan. 8, 2014) ("[T]his Court adopts and incorporates rulings as to general causation found in [two prior decisions] to address Defendants' 'core arguments' as to general causation.").

[13] The decisions we have considered are: *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291 (N.D. Fla. 2018); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, 2013 WL 6796461 (W.D. La. Dec. 19, 2013); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, 2014 WL 60324 (W.D. La. Jan. 7, 2014); *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 2017 WL 6397721 (D. Minn. Dec. 13, 2017); *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 2019 WL 4394812 (D. Minn. July 31, 2019); *In re Celexa & Lexapro Prods. Liab. Litig.*, 927 F. Supp. 2d 758 (E.D. Mo. 2013); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 889 F. Supp. 2d 1272 (N.D. Ala. 2012); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 2013 WL 1558690 (D.N.J. Apr. 10, 2013); *In re Johnson & Johnson Talcum Powder Prods. Marketing, Sales Practices & Prods. Litig.*, No. 3:16-MD-2738(FLW) (D.N.J. Apr. 27, 2020); *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.*, 145 F. Supp. 3d 573 (D.S.C. 2015); *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.*, 174 F. Supp. 3d 911 (D.S.C. 2016); *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.*, 892 F.3d 624 (4th Cir. 2018); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016); *In re Mirena IUD Prods. Liab. Litig.*, 713 F. App'x 11 (2d Cir. 2017); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018); *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 2014 WL 5313871 (C.D. Cal. Sept. 30, 2014); *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 662 F. App'x 528 (9th Cir. 2016); *In re Prempro Prods. Liab. Litig.*, 2012 WL 13033298 (E.D. Ark. Apr. 11, 2012); *In re Prempro Prods. Liab. Litig.*, 2012 WL 13033302 (E.D. Ark. Apr. 19, 2012); *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102 (N.D. Cal. 2018); *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 2019 WL 3997122 (E.D. La. Aug. 23, 2019); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2017 WL 1833173 (N.D. Ill. May 8, 2017); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2018 WL 4030585 (N.D. Ill. Aug. 23, 2018); *In re Viagra (Sildenafil Citrate) & Cialis (Tadlafil) Prods. Liab. Litig.*, 424 F. Supp. 3d 781 (N.D. Cal. Jan. 13. 2020); *In re Zoloft*

II. MDL DECISIONS FREQUENTLY HOLD THAT RELIABILITY ISSUES RELATE TO WEIGHT RATHER THAN ADMISSIBILITY.

Our review of these important MDL decisions revealed some troubling trends. Many courts mischaracterize the Rule 702 standard, indicating insufficient guidance from the Rule and uncertainty about the Rule's meaning. Even in cases that correctly state the standard, some courts fail to apply it as intended. Although many MDL decisions properly considered whether a proffered expert had a sufficient factual basis for his or her opinion and whether the expert reliably applied his or her methodology, we also found numerous instances in which courts failed to conduct these inquiries.

A. Overview and Background.

Judges are not scientists. Faced with competing accounts of confidence intervals, p-values, or confounding variables, judges may be all too tempted to simply throw up their hands and send the matter to a jury. Indeed, there is no shortage of cases repeating the refrain that any underlying problems with a proposed expert's testimony are fodder for cross-examination at trial and can be weighed by the trier of fact. This impulse to shift responsibility is understandable, but misguided. If federal judges have trouble sorting good science from bad, why would lay juries fare better? As Justice Breyer has written, "neither the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the 'gatekeeper' duties that the Federal Rules of Evidence impose."[14]

One core purpose of the Federal Rules of Evidence is to provide clear guidance to federal judges. The drafters of the 2000 amendment to Rule 702 explained that the proponent of expert testimony "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence" under Rule

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(Sertraline Hydrochloride) Prods. Liab. Litig., 2015 WL 7776911 (E.D. Pa. Dec. 2, 2015); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449 (E.D. Pa. 2014); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017).

[14] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 148 (1997) (Breyer, J., concurring).

104(a).[15] They believed "[t]he amendment makes clear that the sufficiency of the basis of an expert's testimony is to be decided under Rule 702."[16] And they noted that "[t]he amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case."[17]

Despite this ostensible clarity, several Circuits have held that courts cannot review the factual basis of an expert's testimony.[18] Others have concluded that the misapplication of an expert's methodology is an issue for the jury.[19] The Advisory Committee has taken note of these decisions, in which "courts appear to have not read the Rule as it is intended."[20] As described in an influential article by David Bernstein and Eric Lasker, "[m]any courts continue to resist the judiciary's proper gatekeeping

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[15] Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Bourjaily v. United States*, 483 U.S. 171 (1987)). The Supreme Court mandated this standard in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 & n.10 (1993).

[16] Fed. R. Evid. 702 advisory committee's note to 2000 amendment.

[17] *Id.* (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)).

[18] *See, e.g., Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013) ("The 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, or, where appropriate, on summary judgment." (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000))); *Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11, 22 (1st Cir. 2011) (same).

[19] *See, e.g., City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1048 (9th Cir. 2014) ("[O]nly a faulty methodology or theory, as opposed to imperfect execution of laboratory techniques, is a valid basis to exclude expert testimony."); *United States v. Shea*, 211 F.3d 658, 668 (1st Cir. 2000) ("[A]ny flaws in [an expert]'s application of an otherwise reliable methodology went to weight and credibility and not to admissibility.").

[20] *See* Capra, *supra* note 1, at 1 (citing Bernstein, *supra* note 1).

role, either by ignoring Rule 702's mandate altogether or by aggressively reinterpreting the Rule's provisions."[21]

Such misunderstanding regarding the meaning and application of Rule 702 is disconcerting. Excluding unreliable expert testimony "is particularly important considering the aura of authority experts often exude, which can lead juries to give more weight to their testimony."[22] If courts do not fulfill their gatekeeping role, "expert testimony may be assigned talismanic significance in the eyes of lay jurors."[23] This is, of course, the danger that Rule 702 seeks to address: "for the very reason that an expert is needed (because lay jurors need assistance) the jury may well be unable to figure out whether the expert is providing real information or junk."[24]

B. MDL Decisions Frequently Misstate the Rule 702 Standard.

Uncertainty among some federal courts regarding Rule 702's meaning leads to problems in its application in the MDL context. In some cases, MDL courts hold directly and in broad terms that required findings under Rule 702 relate to weight rather than admissibility. Such rulings clearly indicate a fundamental misunderstanding of the Rule.

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[21] Bernstein & Lasker, *supra* note 1, at 48. Other scholars have reached the same conclusion. *See, e.g.*, Brandon L. Garret & M. Chris Fabricant, *The Myth of the Reliability Test*, 86 FORDHAM L. REV. 1559, 1564 (2018) (noting the "reliability language" of Rule 702 "has largely been ignored by state and federal judges" and that "[m]ore forceful language might make the importance of assessing reliability more salient to judges, perhaps with more detailed accompanying guidance in Advisory Committee notes").

[22] *Elsayed Mukhtar v. Cal. State Univ., Hayward*, 299 F.3d 1053, 1063-64 (9th Cir. 2002), *amended*, 319 F.3d 1073 (9th Cir. 2003).

[23] *United States v. Frazier*, 387 F.3d 1244, 1263 (11th Cir. 2004).

[24] Daniel J. Capra, *Memorandum to Advisory Committee on Evidence Rules re: Possible Amendment to Rule 702*, at 11 (Oct. 1, 2019) (Agenda Book, Advisory Committee on Evidence Rules (Oct. 25, 2019, meeting) at 131).

In the *Nexium* MDL, for example, the district court announced that under Rule 702, "the factual basis of an expert opinion 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 cross-examination."[25] In the *Bair Hugger* case, the court stated that "generally, the credibility of an expert's basis goes to weight."[26] And in the *Prempro* MDL, the court read Rule 702 to provide that "in most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility."[27]

Similarly, in the *Testosterone Replacement Therapy* MDL, the court understood Rule 702 as indicating 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 jury."[28] The *Talcum Powder* MDL also relied on this quotation, and held that disputes regarding study results and trends "cannot be resolved in the context of this *Daubert* motion" because its review "is only confined to whether [an expert's] methodologies in interpreting the studies are reliable."[29] In the same decision, the court stated that "disagreement with the methods used by an expert is a question that goes more to the weight of the evidence than to reliability for *Daubert* purposes" and that the court's role is "simply to evaluate whether the methodology

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[25] *In re Nexium*, 2014 WL 5313871, at *1 (quoting *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1017 n.14 (9th Cir. 2004)).
[26] *In re Bair Hugger Forced Air Warming Devices*, 2017 WL 6397721, at *3.
[27] *In re Prempro*, 2012 WL 13033298, at *3 (quoting *Hemmings v. Tidyman's Inc.*, 285 F.3d 1174, 1188 (9th Cir. 2002)).
[28] *In re Testosterone Replacement Therapy*, 2017 WL 1833173, at *5 (quoting *Smith*, 215 F.3d at 718).
[29] *In re Johnson & Johnson Talcum Powder*, No. 3:16-MD-2738(FLW), Slip Op. at 79 (quoting *Smith*, 215 F.3d at 718); 126.

used by the expert is reliable, *i.e.*, whether, when correctly employed, that methodology leads to testimony helpful to the trier of fact."[30]

In the *Chantix* decision, the court also stated 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 jury"[31] and emphasized that "the factual basis of an expert opinion is assessed by the jury."[32] Importantly, the Chantix MDL followed an FDA-required black box warning regarding potential risks identified through adverse event reports (uncontrolled and often unverified reports from the public and health professionals). After the district court denied defendant's motion to exclude general causation experts, the litigation settled for approximately $300 million.[33] Subsequently, results from a randomized controlled trial (the gold standard for determining scientific causation) did not show a significantly increased risk of the alleged side effects with the drug and the FDA removed the black box warning from the Chantix label.[34]

MDL decisions also often rely on Circuit Court opinions that demonstrate similar confusion regarding the scope of Rule 702 and thus include analogous, incorrect statements when discussing general standards. For example, the *Roundup* decision cited repeatedly to *City of Pomona v. SQM North America Corp.*;[35] the *Abilify* decision

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[30] *Id.* at 46 (quoting *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 962545, at *13 (E.D. Pa. June 28, 2000), and *Walker v. Gordon*, 46 F. App'x 691, 695 (3d Cir. 2002)).
[31] *In re Chantix*, 889 F. Supp. 2d at 1286 (quoting *Tucker v. SmithKline Beecham Corp.*, 701 F. Supp. 2d 1040, 1055 (S.D. Ind. 2010), in turn quoting *Smith*, 215 F.3d at 718).
[32] *Id.* at 1297 (citing *Larson v. Kempker*, 414 F.3d 936, 941 (8th Cir. 2005)).
[33] *See* Jeff Lingwall et al., *The Imitation Game: Structural Asymmetry in Multidistrict Litigation*, 87 MISS. L.J. 131, 158 n.160 (2018).
[34] Jeffrey Chasnow & Geoffrey Levitt, *Off-Label Communications: The Prodigal Returns*, 73 FOOD & DRUG L.J. 257, 269 (2018); Natalie Grover, *FDA Drops Black Box Warning on Pfizer's Anti-Smoking Drug*, REUTERS (Dec. 16, 2016).
[35] *In re Roundup*, 390 F. Supp. 3d at 1113, 1141, 1142 (citing *City of Pomona*, 750 F.3d at 1043-49, 1044).

relied on *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*;[36] and both the *Taxotere* and *Fosamax* cases rested on *Milward v. Acuity Specialty Products Group, Inc.*[37] All three of these Circuit Court rulings were brought to the attention of the Rule 702 Subcommittee by Committee Reporter Daniel Capra as likely misunderstanding the required analysis under the current iteration of Rule 702.[38]

Further, a significant proportion of MDL decisions rely—whether directly or indirectly—on case law that predates the 2000 amendment to Rule 702, or even the *Daubert* decision.[39] Reliance on these older cases is inconsistent with the Rules Enabling Act[40] and suggests that amending the Rule to reinforce the impact of the 2000 amendment is warranted. As the court in the *Viagra and Cialis* MDL recently noted, although issues concerning expert testimony are often referred to as *Daubert* matters,

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[36] *In re Abilify*, 299 F. Supp. 3d at 1305 (quoting *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003)).

[37] *In re Taxotere*, 2019 WL 3997122, at *6 n.34 (citing *Milward*, 639 F.3d at 17-22); *In re Fosamax*, 2013 WL 1558690, at *4, *6 (citing *Milward*, 639 F.3d at 15).

[38] Capra, *supra* note 1, at 5-7 (discussing *Milward*) 12-13 (discussing *City of Pomona*), and 15-16 (discussing *Quiet Tech.*).

[39] *See In re Lipitor*, 892 F.3d at 632 (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)); *In re Zoloft*, 858 F.3d at 792-93 (quoting *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000)); *In re Testosterone Replacement Therapy*, 2017 WL 1833173, at *12 (quoting *Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 597 (9th Cir. 1996)); *In re Abilify*, 299 F. Supp. 3d at 1318 (quoting *Bazemore v. Friday*, 478 U.S. 385, 400 (1986)); *In re Lipitor*, 174 F. Supp. 3d at 920 (quoting *Westberry*, 178 F.3d at 261); *In re Lipitor*, 145 F. Supp. 3d at 920 (quoting *Westberry*, 178 F.3d at 261); *In re Zoloft*, 2015 WL 7776911, at *3 (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 745, and *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 784 (3d Cir. 1996)).

[40] *See* 28 U.S.C. § 2072(b) ("All laws in conflict with" duly enacted Rules of Evidence "shall be of no further force or effect after such rules have taken effect").

"the governing rule is set out in Rule 702" which "was amended in 2000, seven years after *Daubert* was decided . . . and the amended rule superseded any other law."[41]

C. MDL Decisions Frequently Fail to Apply the Rule 702 Standard as Intended.

In addition to misconstruing Rule 702, many MDL courts dismiss numerous arguments challenging the reliability of expert testimony as going to weight rather than admissibility. For example, in the *Prempro* MDL, the district court accepted that defendants raised "several interesting questions regarding the experts' findings."[42] It asked:

> Why does it appear that one expert lifted her report from another expert? Why does one of Plaintiffs' experts criticize observational studies as potentially misleading but rely on them in the expert report? Why does one of Plaintiffs' experts say it is not appropriate to differentiate receptor status, but other experts say it is appropriate? Why were studies cited in the expert reports that did not support the expert's position?[43]

Nevertheless, the court dispatched these concerns collectively, holding without significant analysis that "all of these points go to credibility, not admissibility."[44] Similarly, the court declined to consider the argument that experts had disregarded differences in drug formulations by noting that the experts "attempted to explain why the differences in formulation were irrelevant" and thus the "jury can determine whether they believe" the proffered reasoning.[45] This deference to "attempted" explanations is plainly not an independent analysis of reliability required by Rule 702, indicating uncertainty about the scope of gatekeeping mandated by the Rule. The

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[41] *In re Viagra & Cialis*, 424 F. Supp. 3d at 788-89.
[42] *In re Prempro*, 2012 WL 13033298, at *4.
[43] *Id.*
[44] *Id.*
[45] *Id.* at *3.

defendants eventually settled thousands of claims in this MDL, probably for more than $1 billion.[46]

A decision in the *Taxotere* MDL likewise demonstrates misapprehension of Rule 702 and the Rule's requirements to independently assess reliability of the proffered opinion. There, the court simply accepted the expert's "personal judgment in deciding what articles to review and include in her analysis."[47] In assessing an expert's consideration of the Bradford Hill criteria, the court held that if "an expert cannot articulate support for a particular factor, this goes to the weight of the expert's opinion, not its admissibility."[48] The court further held that issues with a study's use of overbroad terms to search an FDA database, consideration of studies evaluating medical problems other than the one at issue in the case, and lack of statistically significant results in individual studies were matters that went to weight rather than admissibility.[49]

The *Testosterone Replacement Therapy* MDL provides yet another example. There, the court concluded that Rule 702 did not require an analysis of epidemiological literature underlying the experts' opinions, summarily ruling that larger, more recent studies undercutting plaintiffs' experts' conclusions were "no more authoritative than plaintiffs' argument" and thus "the studies' 'merits and demerits . . . can be explored at trial.'"[50] Although the *Daubert* opinion itself identifies testability and known error rate

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[46] *See* Jordan A. Marzzacco, *A Dose of Reality: The Deadly Truth About Federal Preemption of Generic Drug Manufacturer Liability*, 24 WIDENER L.J. 355, 379 & n.160 (2015).
[47] *In re Taxotere*, 2019 WL 3997122, at *6.
[48] *Id. Cf. In re Zoloft*, 858 F.3d at 796 ("To ensure that the Bradford Hill/weight of the evidence criteria is truly a methodology, rather than a mere conclusion-oriented selection process there must be a scientific method of weighting that is used and explained." (quotation and alteration omitted)).
[49] *In re Taxotere*, 2019 WL 3997122, at *4-5.
[50] *In re Testosterone Replacement Therapy*, 2018 WL 4030585, at *2 (quoting *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013) (alteration in original)).

as factors pertinent to admissibility,[51] the court stated that an "expert's inability to quantify the cardiovascular risk he finds" was "an issue affecting the weight to be accorded to his analysis, not its admissibility."[52] It further ruled that criticisms directed toward an expert's use of a "totality-of-the-evidence methodology" unmoored from any particular discipline "bear on the weight, rather than the admissibility" of opinion testimony.[53] The final defendant in that MDL settled after juries in two cases awarded $140 million and $150 million in punitive damages (both awards were later vacated).[54]

Even in cases in which the court generally conducted an appropriate Rule 702 analysis, we find comments suggesting reluctance to assess reliability. For example, in the *Mirena IUD* MDL, the court "expresse[d] no opinion on the validity of" a study, noting that "because the parties so vehemently disagree on its credibility, it is a suitable topic for cross-examination before a jury."[55] In the *Lipitor* MDL, the court provided a cursory evaluation of various studies, stating that arguments indicating an expert misapplied the Bradford Hill criteria were "a matter for cross-examination, not exclusion."[56] And in the *Zoloft* litigation, the Third Circuit affirmed the exclusion of a particular expert, but cautioned that several problems identified by the district court—including reliance on studies with overlapping populations and drawing conclusions from a study opposite those reached by its authors—were "inquiries . . . more appropriately left to the jury."[57] This reluctance to engage with reliability questions suggests that some courts are not clear about their gatekeeping responsibilities under Rule 702.

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[51] 509 U.S. at 593-94.
[52] *In re Testosterone Replacement Therapy*, 2018 WL 4030585, at *3.
[53] *Id.* at *4.
[54] Alexia Elejalde-Ruiz, *AbbVie Nears Settlement in Thousands of Lawsuits Alleging Harm by Testosterone Drug AndroGel*, CHICAGO TRIBUNE (Sept. 18, 2018).
[55] *In re Mirena*, 169 F. Supp. 3d at 419.
[56] *In re Lipitor*, 174 F. Supp. 3d at 921, 922.
[57] *In re Zoloft*, 858 F.3d at 800.

D. MDL Decisions Frequently Lack Clarity Regarding the Rule 702 Standard.

As Professor Capra has previously noted, it can be difficult to determine whether a court is actually applying an incorrect test when it states that a certain argument goes to weight rather than admissibility.[58] This problem is exacerbated by a lack of clarity in many decisions we considered. District courts must find that the three reliability factors are established by a preponderance of the evidence under Rule 104(a).[59] This analysis should be distinguished from inquiries under Rule 104(b), which merely require evidence "sufficient to support a finding" of the proposition urged.[60] Thus, Rule 104(a) requires a finding that expert testimony is more likely than not based on sufficient facts or data, is the product of reliable principles and methods, and that the expert has reliably applied those principles and methods to the facts of the case.[61] Under Rule 104(b), in contrast, the question would be only whether a reasonable person could make those three findings.[62]

Few courts are clear about these distinctions, which indicates a need to clarify Rule 702. Nearly half of the decisions we reviewed do not reference the preponderance standard at all.[63] In decisions that do so, other language muddies the water. For

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[58] Capra, *supra* note 1, at 2 ("A ruling that some disputes are questions of weight is not necessarily a misapplication of Rule 702/104(a) . . . because even under 104(a) there are disputes that will go to weight and not admissibility.").
[59] *Daubert*, 509 U.S. at 592 n.10; Fed. R. Evid. 702 advisory committee's note to 2000 amendment.
[60] Fed. R. Evid. 104(b).
[61] Fed. R. Evid. 702(b), (c), (d).
[62] *See* Capra, *supra* note 1, at 3.
[63] *In re Lipitor*, 892 F.3d 624; *In re Zoloft*, 858 F.3d 787; *In re Mirena*, 713 F. App'x 11; *In re Nexium*, 662 F. App'x 528; *In re Viagra & Cialis*, 424 F. Supp. 3d 781; *In re Bair Hugger Forced Air Warming Devices*, 2019 WL 4394812; *In re Testosterone Replacement Therapy*, 2018 WL 4030585; *In re Bair Hugger Forced Air Warming Devices*, 2017 WL 6397721; *In re*

example, two decisions in the *Actos* MDL directly cite Rule 104(a) as the controlling standard—a rare occurrence in our sample.[64] But these decisions repeatedly referred to plaintiffs' burden as making a "prima facie" showing of reliability,[65] which is language one would expect in the Rule 104(b) context.[66] Such language indicates that this court did not appreciate the actual requirements of Rule 702.

Despite these interpretational difficulties, the MDL decisions we examined reveal a clear problem. Many MDL courts, whether explicitly or implicitly, have misinterpreted Rule 702 and failed to fulfill their duty to ensure expert testimony has a sufficient basis and is the result of a methodology reliably applied.

III. THE LACK OF UNIFORMITY IN MDL DECISIONS RESULTS IN SUBSTANTIVE DIVISIONS ON CORE ISSUES RELATING TO THE RELIABILITY OF GENERAL CAUSATION OPINIONS.

In the foregoing discussion, we highlight those MDL decisions that have diverged most clearly from the intent of Rule 702. This is not to suggest that all courts share the same misapprehensions regarding the Rule's requirements as to weight and admissibility. In some of the decisions we reviewed, courts appropriately engage with the scientific literature and the methodology underlying a proposed expert's opinion. But differences in MDL courts' application of Rule 702 should give us pause. These differences have led courts to split on important questions.

Zoloft, 2015 WL 7776911; *In re Nexium*, 2014 WL 5313871; *In re Celexa*, 927 F. Supp. 2d 758; *In re Chantix*, 889 F. Supp. 2d 1271.

[64] *In re Actos*, 2014 WL 60324, at *1; *In re Actos*, 2013 WL 6796461, at *2.

[65] *In re Actos*, 2014 WL 60324, at *3, *5, *9; *In re Actos*, 2013 WL 6796461, at *4, *7, *10.

[66] *See United States v. Enright*, 579 F.2d 980, 984-5 (6th Cir. 1978) (describing "the language of 104(b) as a classic restatement of the Prima facie test" and noting that "[a] determination under 104(a) is more demanding than a Prima facie test and calls for the exercise of judicial fact-finding responsibilities by the trial judge").

A. Differing Approaches to Rule 702 Lead to Different Results.

In the *Roundup* MDL, the district court was frank about the problem of divergent approaches to Rule 702. It concluded the scientific "evidence, viewed in its totality, seems too equivocal to support any firm conclusion" on general causation.[67] But it nevertheless admitted opinion testimony supporting plaintiffs' general causation theory.[68] The court stressed that in the Ninth Circuit, Rule 702 has been interpreted to mean that "weaknesses in an unpersuasive expert opinion can be exposed at trial, through cross-examination or testimony by opposing experts," which "has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits."[69]

The *Roundup* court acknowledged that inter-Circuit differences on Rule 702 "could matter in close cases."[70] And the impact of those inter-Circuit differences could be enormous in the *Roundup* MDL. Some observers have estimated a likely settlement amount in the range of $10 billion.[71]

A set of two decisions from the *Bair Hugger* MDL further demonstrates how misunderstanding of Rule 702 can lead to different results. In an initial decision on the admissibility of testimony from several plaintiffs' experts, the district court apparently read Rule 702 as requiring only a superficial appraisal of their factual bases and methodologies.[72] It indicated expert testimony could be excluded only if "so fundamentally unsupported that it can offer no assistance to the jury."[73] And the court

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[67] *In re Roundup*, 390 F. Supp. 3d at 1109.
[68] *Id.*
[69] *Id.* at 1109, 1113.
[70] *Id.* at 1113.
[71] Jef Feeley et al., *Bayer Proposes Paying $8 Billion to Settle Roundup Cancer Claims*, BLOOMBERG (Aug. 9, 2019).
[72] *In re Bair Hugger Forced Air Warming Devices*, 2017 WL 6397721, at *2-6.
[73] *Id.* at *2 (quoting *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 865 (8th Cir. 2004)).

stated that the credibility of an expert's basis, the need to conduct more thorough testing, and bias in conducting a scientific literature review were issues that went to weight rather than admissibility.[74]

After the jury returned a verdict in defendants' favor in a bellwether trial, the court addressed a renewed motion to exclude the same experts.[75] Despite plaintiffs' insistence that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility," the court admirably reconsidered its prior decision.[76] It rejected an expert who did "not have any basis" for his assertions and had "drifted from the factual realities of his test."[77] After conducting a thorough, if belated, evaluation of the scientific literature and case law concerning Rule 702, the court found "too great an analytical gap between the evidence and the expert's conclusions," and excluded the testimony it had previously ruled admissible.[78]

B. Differing Approaches to Rule 702 Lead Courts to Split on Recurring Substantive Issues.

Variations in the application of Rule 702 impact the broader contours of the law, in addition to the outcomes of particular cases. In considering general causation in these matters, we see the same issues arise again and again. Yet courts have not been able to reach a consensus on some common questions. This discord, driven in large measure by some courts' misunderstanding of Rule 702's requirements, engenders uncertainty regarding the resolution of perennial general causation questions.

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[74] *Id.* at *3, *4, *6.
[75] *In re Bair Hugger Forced Air Warming Devices*, 2019 WL 4394812, at *2-3.
[76] *Id.* at *5 (quoting *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001)), *11.
[77] *Id.* at *7, *9.
[78] *Id.* at *20. This result also highlights the importance of hearing live testimony from proffered experts. The court's prior ruling followed only briefing and oral argument. *In re Bair Hugger Forced Air Warming Devices*, 2017 WL 6397721, at *1.

Courts attempting to apply Rule 702 have reached different conclusions as to the reliability of non-statistically significant, "trending" data. Some courts have permitted experts to rely on such data in support of their general causation conclusions.[79] However, other courts have held that the "novel technique of drawing conclusions by examining 'trends' (often statistically non-significant) across selected studies" is "not scientifically sound."[80]

Many of the proposed experts in the cases we reviewed purport to engage in a Bradford Hill causation analysis. Several courts have recognized that although a statistically significant association is not always required to show causation, it is a necessary first step in applying the Bradford Hill criteria: "the analysis requires a statistician to find a statistically significant association at step one before moving on to apply the factors at step two."[81] Other decisions, however, have rejected the necessity of statistical significance at step one of the Bradford Hill analysis.[82]

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[79] *See In re Testosterone Replacement Therapy*, 2018 WL 4030585, at *3 (allowing an expert to rely on observational studies that "show only 'trends'"); *In re Prempro*, 2012 WL 13033298, at *3 (permitting testimony from an expert who "explained that the studies that lacked statistical significance still revealed a 'trend for association'").

[80] *In re Zoloft*, 26 F. Supp. 3d at 465; *see also In re Abilify*, 299 F. Supp. 3d at 1367 (holding an expert's "five statistically insignificant findings from the clinical trials, and also his characterization of those findings as a trend, must be excluded as unreliable").

[81] *In re Lipitor*, 892 F.3d at 642; *see also In re Mirena (No. II)*, 341 F. Supp. 3d at 265 ("[A]bsent [a demonstrated epidemiological] association, there is no basis to apply the Bradford Hill criteria.").

[82] *See In re Zoloft*, 858 F.3d at 794 n.35 (emphasizing that the lower court declined to hold that "the Bradford-Hill criteria should only be applied after an association is well established"); *In re Testosterone Replacement Therapy*, 2017 WL 1833173, at *9 (rejecting defendant's argument that application of the Bradford Hill criteria requires "an association between the drug at issue and the alleged injury, based on epidemiological studies showing an association that is statistically significant").

We also find substantial disagreement among courts on the degree to which proposed experts may "reinterpret" studies conducted by others to reach conclusions opposite of those made by the studies' authors. Some courts have recognized that if "an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study."[83] Without detailed analysis, other courts have misread Rule 702 as permitting the contrary conclusion.[84]

Finally, MDL courts have differed on the role of studies dealing with drugs other than those at issue in a case. Some courts hold that such studies are generally of limited value in determining causation.[85] Yet other MDL decisions have struggled to grasp the requirements of Rule 702 and uncritically permitted experts to rely on such evidence.[86]

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[83] *In re Mirena (No. II),* 341 F. Supp. 3d at 241 (quoting *In re Accutane Prods. Liab. Litig.,* 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd,* 378 F. App'x 929 (11th Cir. 2010)); *In re Mirena,* 169 F. Supp. 3d at 452 (same); *see also In re Lipitor,* 145 F. Supp. 3d at 593 (holding an expert generally cannot "conduct his own 'reanalysis' solely for the purposes of litigation and testify that the data support a conclusion opposite that of the studies' authors in a peer-reviewed publication").

[84] *See In re Zoloft,* 858 F.3d at 800 (finding no problem with the fact that "in his reanalysis [an expert] drew a different conclusion from a study than its authors did"); *In re Celexa,* 927 F. Supp. 2d at 765 ("There is no requirement that [an expert] reach the same conclusion as [a study's author] just because he relied on [the author's] data.").

[85] *See In re Mirena (No. II),* 341 F. Supp. 3d at 288 ("[C]ourts regularly exclude expert opinions built on analogies to different chemical compounds than the one at issue."); *In re Abilify,* 299 F. Supp. 3d at 1311 (ruling that "extrapolations from drugs within the same class may not support an expert opinion on general causation unless other reliable scientific evidence establishes the validity of the analogy").

[86] *See In re Celexa,* 927 F. Supp. 2d at 762-63 (permitting expert testimony based on an "analysis of studies relating to SSRIs generally, not Celexa and Lexapro specifically"); *In re Prempro,* 2012 WL 13033302, at *4 (rejecting the concern that "if you lump all hormone therapy formulations together, you may mistakenly attribute a risk to all hormone therapy when only some have that risk" by simply quoting an expert's *ipse dixit*, "Oh, I

C. Lack of Uniformity Among MDL Courts is Problematic.

These MDL decisions show that misunderstanding of Rule 702 results in inconsistent outcomes and disagreement on basic questions related to the reliability of general causation opinions. Such differences encourage forum-shopping, undermine confidence in the courts, and diminish the value of the MDL process.

Although a lack of uniformity in cases on a Federal Rule of Evidence is always cause for concern, the foregoing disagreements are particularly troubling in the MDL context. A core purpose of the MDL process is to promote uniformity.[87] Further, structural features of MDLs make it more difficult for appellate review to serve as a meaningful tool to address conflicting decisions.

Rule 702 decisions by district courts in MDLs—particularly those permitting expert testimony—are largely insulated from review. This is because there is no practical mechanism for appealing such rulings.[88] When an MDL decision misstates the law, an aggrieved party faces "an expensive and risky trial conducted under the wrong legal standard" with the potential for liability multiplied by the number of aggregated claims.[89] Because a decision allowing an expert to testify is not subject to interlocutory review, "the lack of an immediate appellate safety valve ensures that the claimed legal

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don't think that's true at all"). Relatedly, courts have permitted experts to analogize between different types of illnesses. *See, e.g., In re Johnson & Johnson Talcum Powder*, No. 3:16-MD-2738(FLW), Slip Op. at 89 n.39 ("[W]hile there are no studies linking these specific metals to ovarian cancer, . . . these metals have been linked to [other] specific types of cancer.").

[87] *See* Abbe R. Gluck, *Unorthodox Civil Procedure: Modern Multidistrict Litigation's Place in the Textbook Understandings of Procedure*, 165 U. PENN. L. REV. 1669, 1682 (2017) ("One of the main problems MDLs aim to solve is therefore horizontal federal duplication and disuniformity.").

[88] *See id.* at 1706 (noting that "the inability for error correction relating to pretrial rulings . . . can have enormous significance for many litigants").

[89] Pollis, *supra* note 7, at 1668.

errors will be repeated in multiple trials in the MDL proceeding."[90] These factors make it far less likely that a party will push on to trial and appeal following an adverse ruling.

Accordingly, few MDL decisions considering Rule 702 issues are ever appealed.[91] And to the extent that Rule 702 issues reach the Courts of Appeals from MDLs, they are highly asymmetrical. Of the decisions we reviewed, only four were appellate rulings, all of which considered district courts' exclusion of expert testimony.[92] Appellate review under current law is thus unlikely to resolve the lack of uniformity we have identified.[93]

IV. THE ADVISORY COMMITTEE SHOULD AMEND RULE 702.

In light of the problems we have identified in some MDL courts' application of Rule 702's core requirements, we urge the Advisory Committee to act. The Committee has considered an amendment to the introductory language of Rule 702 clarifying that "the court must find the following requirements to be established by a preponderance

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[90] U.S. Chamber, Institute for Legal Reform, *supra* note 8, at 9.

[91] Although parties can pursue interlocutory review under 28 U.S.C. § 1292(b), that option has largely proven illusory. A review of 127 mass tort MDL proceedings found no instances in which a court granted a defendant's request for certification of a ruling potentially dispositive of a large number of claims. Letter from John H. Beisner to Rebecca A. Womeldorf 2 (Nov. 21, 2018), https://www.uscourts.gov/sites/default/files/18-cv-bb-suggestion_beisner_0.pdf.

[92] *In re Lipitor*, 892 F.3d at 629 (appeal by plaintiffs from decision excluding expert testimony); *In re Mirena IUD*, 713 F. App'x at 13 (same); *In re Zoloft*, 858 F.3d at 789 (same); *In re Nexium*, 662 F. App'x at 529 (same).

[93] Legislative and rules-based solutions expanding interlocutory review for certain types of MDL decisions have been proposed. *See* The Fairness in Class Action Litigation Act, H.R. 985, 115th Cong. § 105 (2017) (proposed amendment to 28 U.S.C. § 1407); Agenda Book, Advisory Committee on Civil Rules (Apr. 2-3, 2019, meeting) at 212-13 (MDL Subcommittee Report considering amending rules to permit interlocutory review of some MDL decisions).

of the evidence."[94] Our review demonstrates that such clarification is necessary. A specific amendment and an accompanying Committee Note detailing the rationale for the amendment would clarify the courts' gatekeeping responsibilities and encourage them to apply Rule 702 as intended. Similarly, including language specifying that Rule 702's requirements are mandatory and specifically identifying the preponderance standard will focus the courts on their gatekeeping role.

We also support amending the Rule and adding a Committee Note to highlight that an expert's factual basis and applied methods are matters that go to admissibility rather than weight. Specifically, we encourage inclusion of the following proposed language in a Committee Note:

> Unfortunately many courts have held or declared that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).[95]

In addition, we recommend that the Advisory Committee identify the types of rote language that often accompany misapplications of Rule 702. Examples of such language, indicating that an expert's factual basis or application of methodology are matters of weight rather than admissibility, have already been cited to the Committee by Professor Capra.[96] A Note that identifies with particularity the type of problematic analysis the Committee has in mind will best aid courts in applying Rule 702. Regardless of whether the introductory language of Rule 702 is amended, such a

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[94] Capra, *supra* note 1, at 26.
[95] Capra, *supra* note 24, at 34.
[96] *See* Capra, *supra* note 1, at 6, 12-13, 15-16.

Committee Note will encourage courts to make the required reliability findings before permitting an expert to testify.[97]

As the Supreme Court warned in *Daubert*, "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it."[98] Permitting junk science in the courtroom invites verdicts based on inadequate or non-existent supporting science. For this reason, courts cannot delegate to juries their gatekeeping duties. Yet recent MDL decisions suggest that some courts may not be sufficiently guided by Rule 702, leading to a misunderstanding of its essential provisions. Advisory Committee action is needed to correct this misunderstanding and provide courts and parties alike with much needed predictability in the application of Rule 702.

Sincerely,

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[97] A Committee Note to this effect could be added if Rule 702 is amended to include a new subdivision on "overstatement" of expert opinions, which the Advisory Committee is also considering. *See* Capra, *supra* note 24, at 31.

[98] 505 U.S. at 595 (quotation omitted).