September 30, 2020

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Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, NE
Washington, DC 20544

Re: Amending Federal Rule of Evidence 702

BAYER CORPORATION'S COMMENTS TO THE RULE 702 SUBCOMMITTEE OF THE ADVISORY COMMITTEE ON EVIDENCE RULES

September 30, 2020

Over two hundred expert admissibility rulings decided in federal courts since January 2015 incorrectly state that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility[.]"[1] More than 150 federal gatekeeping decisions issued since January 2015 incorporate the similar problematic statement that "questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility[.]"[2] This widespread misunderstanding of Rule 702's standards has directly impacted Bayer Corporation and the Bayer family of companies ("Bayer"). Bayer appreciates the opportunity to submit these Comments to the Advisory Committee on Evidence Rules (the "Committee") and its Rule 702 Subcommittee (the "Subcommittee"), and urges an amendment to Rule 702 that clarifies the courts' gatekeeping responsibility.

Bayer has observed great inconsistency in how courts assess proposed opinion testimony. The varied application of what is nominally a uniform national standard demonstrates confusion about the admissibility determinations that courts must make. In recent years, Bayer has seen judges fail to apply Rule 702(b)'s requirement that the court must find an expert's opinion has a sufficient factual basis and Rule 702(d)'s direction that the court must conclude the expert has reasonably applied the principles and methods to the facts of the case. Bayer has also experienced courts not employing the applicable burden of production, in which the expert's

[1] A September 14, 2020 Westlaw search for the quoted phrase identified 212 federal cases issued in this period. The referenced statement originated in *Loudermill v. Dow Chem. Co*., 863 F.2d 566, 570 (8th Cir. 1988).

[2] The quoted language was first stated in *Viterbo v. Dow Chem. Co*., 826 F.2d 420, 422 (5th Cir. 1987). A Westlaw search performed on September 14, 2020 returned 152 federal cases decided after 2014 that reiterate this statement.

sponsor must establish by a preponderance of the evidence that the opinion testimony meets the Rule 702 requirements. Stated simply, Bayer has frequently been party to cases where court gatekeeping departs from the intent of Rule 702.[3] Such erroneous rulings may have enormous repercussions.

In Bayer's view, rulings that inadequately evaluate a proffered expert's opinions do not indicate a refusal to accept the Rule 702 standard. Rather, they show that courts may genuinely misunderstand their gatekeeping role in determining the admissibility of expert testimony. Often, the confusion stems from formulations passed down by prior rulings that improperly characterize the standard of admissibility or do not align with Rule 702's requirements. Regardless of the source of the misunderstanding, courts need direction on gatekeeping practices that are consistent with the intent of Rule 702. Only an amendment of Rule 702 will have the weight to displace problematic formulations that have become entrenched and establish a consistent understanding of how courts should determine the admissibility of opinion testimony. Bayer also urges the Committee to address the problem of overstatement in a manner that reaches civil cases.

A. Too Many Courts Misunderstand Rule 702's Expert Admissibility Standard

1. Incorrect rulings influence courts to ignore the expert's factual basis and methodological application in determining admissibility

The numerous decisions incorrectly declaring that the factual basis of an expert's opinion, or the expert's application of the principles and methods to the facts of the case, involve only the weight of the opinion evidence, not its admissibility, have created a great deal of confusion about the gatekeeping responsibility. In Bayer's experience, inaccurate statements in prior decisions often mislead district courts about what assessments the court must make. As a

[3] Bayer understands, based on a number of statements issued by the Advisory Committee and the Reporter, that Rule 702 intends that district judges as a matter of admissibility determine by a preponderance of the evidence that proffered expert testimony meets each of the elements set forth in the text of the rule. *See* Advisory Committee Note to 2000 Amendments to Rule 702 ("The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted."); Hon. Fern M. Smith, Report of the Advisory Committee on Evidence Rules (May 1, 1999) at 5, *in* ADVISORY COMMITTEE ON EVIDENCE RULES OCTOBER 1999 AGENDA BOOK 52 (1999) ("The proposed amendment to Evidence Rule 702 . . . requires a showing of reliable methodology and sufficient basis, and provides that the expert's methodology must be applied properly to the facts of the case."). *See also* Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Possible Amendment to Rule 702* (Oct. 1, 2019) at 1 *in* ADVISORY COMMITTEE ON EVIDENCE RULES OCTOBER 2019 AGENDA BOOK 131 (2019) (Rule 702 "reliability requirements are questions for the court, to be decided by a preponderance of the evidence."); Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Possible Amendments to Rule 702* (April 1, 2019) at 23 *in* ADVISORY COMMITTEE ON EVIDENCE RULES MAY 2019 AGENDA BOOK 95 (2019)("The Rule provides that the requirements of sufficient basis and reliable application must be treated as questions of admissibility, and so must be established by a preponderance of the evidence under Rule 104(a)."); Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Forensic Evidence, Daubert and Rule 702* (April 1, 2018) at 43 *in* ADVISORY COMMITTEE ON EVIDENCE RULES APRIL 2018 AGENDA BOOK 49 (2018)("In sum, the 2000 amendment specifies that sufficient basis and application of method are admissibility requirements – the judge must be satisfied by a preponderance of the evidence that the expert has relied on sufficient facts or data, and that the expert has reliably applied the methods.").

result, many courts do not recognize that Rule 702 requires the judge to scrutinize and determine, as a matter of admissibility, whether an expert has a sufficient factual basis to support the proffered opinions and has reliably applied the methodology to the circumstances at issue in the case.

Bayer has first-hand experience that incorrect caselaw descriptions of the admissibility analysis distract judges from the actual Rule 702 requirements. One example arose in litigation involving Bayer's Mirena IUD contraceptive system. In two of the cases in that litigation, Bayer challenged the admissibility of proffered specific causation opinion testimony due to the expert's inadequate factual basis for concluding that the Mirena device played a role in the development of the plaintiffs' condition.[4] Although the court initially noted Rule 702(b)'s requirement that an expert's opinions are admissible only if "based on sufficient facts or data," an Eighth Circuit ruling convinced the judge that the adequacy of the expert's factual foundation related only to the weight, not the admissibility of, the testimony.[5] The court quoted *Loudermill v. Dow Chem. Co*.,[6] which pre-dates both the current version of Rule 702 and the Supreme Court's *Daubert*[7] ruling, for its foundational perspective of the court's gatekeeping role:

> As a general rule, 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.[8]

This inaccurate Eighth Circuit directive induced the court to shift its duty onto Bayer, stating "[i]t is Defendants[']<u> responsibility to examine the factual basis of Dr. Tang's opinions at trial through cross-examination</u> and through the presentation of contrary evidence[.]"[9] The court, once again citing to *Loudermill*, admitted the challenged expert testimony without analyzing whether sufficient facts or data supported her opinions. This court simply did not grasp the scope of its gatekeeping function.

Bayer saw similar confusion in the MDL proceeding concerning Yasmin and Yaz. In that litigation, Bayer sought to exclude certain case-specific opinions for several reasons, including the expert's inadequate factual basis.[10] Although the court recited the elements of

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[4] Bayer asserted its motions to exclude in multiple cases, and the court issued nearly identical decisions on the same day in *Miller v. Bayer Healthcare Pharms. Inc*., No. 4:14-CV-00652-SRB, 2016 WL 9047152, at *1 (W.D. Mo. Dec. 5, 2016) and *Sellers v. Bayer Healthcare Pharms. Inc*., No. 4:14-CV-00954-SRB, 2016 WL 9049599 at *1 (W.D. Mo. Dec. 5, 2016).

[5] *Miller*, 2016 WL 9047152, at *1 - *2; *Sellers*, 2016 WL 9049599 at *1 - *2.

[6] 863 F.2d 566, 570 (8th Cir. 1988).

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

[8] *Miller*, 2016 WL 9047152, at *2; *Sellers*, 2016 WL 9049599 at *2.

[9] *Miller*, 2016 WL 9047152, at *2 (emphasis added); *Sellers*, 2016 WL 9049599 at *2 (same statement; emphasis added).

[10] *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Product Liability Litigation*, No. 3:09-MD-02100-DRH-PMF, 2011 WL 6732245, at *1, *12 (S.D. Ill. Dec. 16, 2011).

Rule 702, it ruled that judicial gatekeeping focuses only on the expert's methodology. The court drew on the following passage from *Smith v. Ford Motor Co.*,[11] another decision that pre-dates the current Rule 702, to conclude that sufficiency of the expert's factual basis is not an admissibility consideration:

> 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.[12]

Having dismissed the notion that an expert's insufficient factual foundation will render opinion testimony inadmissible, the court addressed only the experts' qualifications and methodological reliability.[13] This court took the same approach in another ruling it issued the same day.[14] This time the court relied on *Walker v. Soo Line R. Co.*[15] to hold that the court's gatekeeping role is "limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound."[16] The court allowed the disputed testimony, dismissing without analysis Rule 702(b) concerns stating "[t]he defendant is welcome to cross examine the witnesses and challenge the bases for their conclusions[.]"[17]

Another example of caselaw misleading a court about its duty to evaluate the sufficiency of an expert's factual basis occurred during the Xarelto MDL litigation. In an initial trial case, Bayer moved to exclude opinion testimony describing the state of mind of both Bayer and the FDA. Bayer asserted that the proffered experts lacked sufficient facts to support their opinions. In rejecting Bayer's motions, the court recognized that "Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony,"[18] but relied instead on the Fifth Circuit case *Moore v. Ashland Chemical Inc.*[19] to conclude that it should examine the expert's methodology exclusively in determining admissibility:

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[11] 215 F.3d 713, 719 (7th Cir. 2000).

[12] *In re Yasmine and Yaz*, 2011 WL 6732245, at *3.

[13] *See id*. at *13:

> The Court finds Drs. Botney, Disciullo, Rinder, and Sehizadeh are all qualified to opine as to the statements for which Bayer seeks exclusion. Further, the methods underlying their opinions are reliable. Accordingly, Bayer's motion to exclude certain statements of plaintiff's experts pursuant to Fed.R.Evid. 702 and *Daubert* is DENIED**.**

[14] *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Prac. and Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH-PMF, 2011 6728885, at *3 (S.D. Ill. Dec. 16, 2011).

[15] 208 F.3d 581, 589-90 (7th Cir. 2000).

[16] *In re Yasmin and Yaz*, 2011 6728885, at *3.

[17] *Id*. at *4.

[18] *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592, 2017 WL 1352860, at *1 (E.D. La. Apr. 13, 2017).

[19] 151 F.3d 269 (5th Cir. 1998).

> The focus is not on the result or conclusion, but on the methodology. *Moore*, 151 F.3d at 275-76. The proponent need not prove that the expert's testimony is correct, but must prove by a preponderance of the evidence that the expert's methodology was proper. *Id*.[20]

Based on this overly narrow understanding of the admissibility analysis, the court ruled that Bayer's challenges did not address the experts' "methodology or qualifications" but were "better reserved for cross-examination at trial," and the court admitted the testimony without considering if the experts had a proper factual foundation.[21]

Bayer's experiences are not unique. Even a cursory review of recent caselaw reveals that many courts are misinformed about Rule 702(b) by earlier rulings stating that the sufficiency of an expert's factual basis is a matter for cross-examination, not an admissibility consideration.[22] Courts can be expected to follow earlier cases,[23] but in the case of expert gatekeeping this has led to a systemic misunderstanding of Rule 702(b)'s admissibility standard.[24]

Of course, some courts properly apply Rule 702 despite the misleading direction of prior rulings, and Bayer has observed courts appropriately examine experts' factual basis and methodological application as part of the admissibility assessment. In another case involving the same Mirena product at issue in *Miller* and *Sellers* (discussed above, where the opinion testimony was allowed), the court excluded a specific causation expert who "had no factual basis for linking the Mirena to the infection" apart from temporal proximity, finding "such an inference is insufficiently scientific to pass muster under *Daubert* and Rule 702."[25] And another

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[20] *In re Xarelto*, 2017 WL 1352860, at *2 (emphasis added).

[21] *Id*. at *2 (testimony of Dr. Laura Plunkett), *3 (testimony of Dr. David Kessler).

[22] *See*, *e.g*., *Hale v. Denton Cty.*, No. 4:19-CV-00337, 2020 WL 4431860, at 4 (E.D. Tex. July 31, 2020)(quoting *Viterbo* for the principle that "questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility" and admitting opinion challenged for insufficient bases finding "cross examination is the proper way to expose these alleged deficiencies."); *Jayne v. City of Sioux Falls*, No. 4:18-CV-04088-KES, 2020 WL 2129599, at *7 (D.S.D. May 5, 2020)(quoting *Loudermill* for the proposition that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility" and allowing testimony because it "is not so fundamentally unsupported that it can offer no assistance to the jury."); *Bakov v. Consol. World Travel, Inc*., No. 15 C 2980, 2019 WL 1294659, at *12 (N.D. Ill. Mar. 21, 2019)(quoting *Smith* that "[t]he soundness of the factual underpinnings of the expert's analysis . . . [is a] factual matter[] to be determined by the trier of fact" and concluding that "an expert's reliance on allegedly faulty information is a matter to be explored on cross-examination.").

[23] Bayer agrees with Judge Schroeder that "courts tend to defer to statements from caselaw, even if it is outdated." Thomas D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony*, 95 NOTRE DAME L. REV. 2039, 2060 (2020).

[24] *Id*. at 2039 ("some trial and appellate courts misstate and muddle the admissibility standard, suggesting that questions of the sufficiency of the expert's basis and the reliability of the application of the expert's method raise questions of weight that should be resolved by a jury, where they can be subject to cross-examination and competing evidence.")(emphasis original).

[25] *Mercado v. Bayer Healthcare Pharms. Inc*., No 14 C 6699, 2017 WL 1477939, at *4 -*5 (N.D.Ill. Apr. 25, 2017).

court, in *In re Mirena IUD Products Liability Litigation,*[26] excluded the opinions of several experts due to an insufficient factual basis to support the opinions expressed.[27] But a national evidence rule should not give rise to such widely differing understandings of the admissibility standard. The divergent approaches that courts currently take on challenges to the sufficiency of an expert's factual basis and the reliability of the expert's methodological application demonstrate a failure in Rule 702 and the need to clarify proper gatekeeping practices.

2. Courts often misunderstand that the proponent bears the burden of production

Consistent with Rule 104(a), courts should require the sponsor of an expert witness to demonstrate by a preponderance of the evidence that the proffered opinion testimony meets each of Rule 702's elements.[28] One court in a Mirena case captured the essence of this burden of production:

> The proponent of expert testimony bears the burden of proving its admissibility, and where the proponent makes no substantive response to a *Daubert* challenge, the district court may decide to exclude the testimony within its sound discretion.[29]

In Bayer's experience, however, judges frequently do not have a firm grasp of how to apply the burden of production and in practice employ a much different threshold.

Bayer witnessed such court confusion about the proponents' burden of production in one of the cases in the Mirena litigation. In ruling on Bayer's motion to exclude the plaintiffs' expert's general causation opinions in that case, the court began its analysis by noting that "expert testimony should be liberally admitted."[30] The court then denied the motion using the lowest imaginable admissibility hurdle, stating "the Court finds the opinions of Plaintiff's experts are not so 'fundamentally unsupported' that they must be excluded."[31] The court did not recognize that the proponent bears a burden of production to Rule 104(a)'s specifications.

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[26] 169 F.Supp.3d 396 (S.D.N.Y. 2016).

[27] *Id.* at 445 (noting that expert's "lack of access to reliable data does not justify use of unreliable data, and militates against admission under *Daubert*."); 460 (excluding opinion "[b]ecause each of the facts on which [the expert] relied in formulating his opinion . . . does not reliably support that conclusion[.]").

[28] *See* Advisory Committee Note to 2000 Amendments to Rule 702 ("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.").

[29] *Mercado*, 2017 WL 1477939, at *2 n.1. *See also In re Mirena*, 169 F. Supp. 3d at 456 ("it is Plaintiffs' burden to prove the reliability of their experts' opinions, which in Dr. Wray's case they have failed to do. See Fed. R. Evid. 702 advisory committee's note to 2000 amendment; *Bourjaily*, 483 U.S. at 175-76").

[30] *Miller v. Bayer Healthcare Pharms. Inc.*, No. 4:14-cv-00652-SRB, 2016 WL 9047163, at *1 (W.D.Mo. Dec. 20, 2016); *Sellers v. Bayer Healthcare Pharms. Inc.*, No. 4:14-cv-00954-SRB, 2016 WL 9045740, at *1 (W.D.Mo. Dec. 20, 2016). The court also quoted a statement from *Lauzon v. Senco Products, Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) that Rule 702 "clearly is one of admissibility rather than exclusion." *Miller*, 2016 WL 9047163, at *1; *Sellers*, 2016 WL 9045740, at *1.

[31] *Miller*, 2016 WL 9047163, at *3; *Sellers*, 2016 WL 9045740, at *3 (both quoting *Neb. Plastics, Inc. v. Holland Colors Americas, Inc.*, 408 F.3d 410, 416 (8th Cir. 2005).

In another case, this one concerning Bayer's YAZ product, the court not only failed to recognize the appropriate burden of production, but actually inverted it. Rather than determine if the proponent had satisfied the Rule 702 requirements, the court put the burden on Bayer to establish that its opponent's opinions did not arise from sufficient relevant data and a reliable methodology.[32] In allowing the opinions, the court cited to the *Joiner*[33] yardstick for exclusion instead of the Rule 104(a) requirement for admission, concluding that "[t]here is not a great analytical gap between the studies relied on by Dr. Rinder and his opinion."[34]

Failing to apply Rule 104(a)'s burden of production eviscerates the admissibility standard. Rule 702 should not be read to prefer an outcome.[35] The burden of production is a fundamental component of Rule 702, and the fact that courts often leave it out of the admissibility analysis demonstrates a flawed understanding of how Rule 702 operates.[36] For Rule 702 to be a national rule, courts must have a consistent understanding that the proponent must satisfy each Rule 702 requirement by a preponderance of the evidence.[37]

B. Rule 702 Should Be Amended To Clarify the Court's Responsibilities

Caselaw demonstrates an inconsistent understanding of the Rule 702 gatekeeping process. With no guidance from either the Committee or the U.S. Supreme Court over the last twenty years, misunderstandings about the court's role have become entrenched as judges carry forward the errors of prior rulings. The fact that more than three hundred fifty federal rulings decided since January 2015 reiterate incorrect statements such as "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility" or "questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather

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[32] *Hamilton v. Bayer Healthcare Pharms., Inc*., No. CIV-18-1240-C, 2019 WL 2448328, at *2 (W.D.Okla. June 11, 2019)("The Court finds that the arguments raised by Defendants fail to provide any basis for excluding the testimony[.]").

[33] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

[34] *Hamilton*, 2019 WL 2448328, at *2.

[35] The *In re Mirena* court aptly observed that descriptions of Rule 702 as a "liberal standard" simply reflect how it compares to the previous "general acceptance" standard followed by some courts and is not a commentary on how courts should rule: "Rule 702 represents a liberal standard of admissibility for expert opinions, as compared to the previous and more restrictive standard set out in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)." 169 F. Supp. 3d at 411 (citing discussion in *Daubert*, 509 U.S. at 588-89, of the *Frye* "general acceptance" standard) (emphasis added).

[36] Courts frequently assert and seemingly employ characterizations of Rule 702 that lower the burden of production. *See*, *e.g*., *Penny v. State Farm Mut. Auto. Ins. Co*., No. C18-5195RBL, 2020 WL 4261370, at *3 (W.D. Wash. July 24, 2020)("Rule 702 should be applied with a 'liberal thrust' favoring admission")(citation omitted); *Chapman v. Tristar Prods., Inc*., No. 1:16-CV-1114, 2017 WL 1718423, at *1 (N.D. Ohio Apr. 28, 2017)("Under this liberal approach, expert testimony is presumptively admissible."); *Hogland v. Town & Country Grocer of Fredericktown Missouri, Inc*., No. 3:14CV00273 JTR, 2015 WL 3843674, at *1 n.4 (E.D. Ark. June 22, 2015)("Rule 702 favors admissibility if the testimony will assist the trier of fact, and doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility.")(citation omitted).

[37] As Judge Schroeder puts it, judges are "bound by Rule 104(a)'s requirement that there be a preponderance of evidence supporting each of the requirements of Rule 702(a) through (d)." Schroeder, 95 NOTRE DAME L. REV. at 2062.

than its admissibility"[38] leaves no room for doubt. Indeed, these flawed conceptions are now so ingrained in the caselaw that recent rulings adopting this phrase often do not directly reference *Loudermill* or *Viterbo*, but instead cite to second- or even third-generation decisions.[39] Without an amendment, the fundamental misconceptions of the court's Rule 702(b) and (d) responsibilities and the proponent's burden of production will perpetuate as courts continue to recycle flawed descriptions of the gatekeeping role.

Bayer urges the Committee to adopt an amendment to Rule 702 that provides courts with critical direction about the steps they must take and gives them the necessary confidence to disregard erroneous caselaw descriptions of the gatekeeping function. Because of the recurrent misunderstanding about the court's responsibility to perform the Rule 702(b) and (d) assessments,[40] the amendment should specify that the court must undertake these steps as part of the admissibility evaluation, rather than defer to the jury. Additionally, because courts have struggled to understand the burden of proof applicable to the gatekeeping function despite the directive in the Advisory Committee Note, the amendment should incorporate that standard into the rule itself. These two goals can be accomplished without a major re-structuring of the text by adding a reference to the court and the burden of production to the end of Rule 702's initial section, such as:

> 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 the court finds by a preponderance of the evidence:

This new language would confirm that the requirements of Rule 702(b) and (d) are questions for the court to decide, and would constitute authority of sufficient weight to displace

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[38] *See supra*, n.1 & n.2.

[39] *See*, *e.g.*, *In re Crash of Aircraft N93PC on July 7, 2013 at Soldotna, Alaska*, No. 3:15-cv-0112-HRH, 2020 WL 1956823, at *6 (D. Alaska Apr. 22, 2020)(quoting *Hangarter v. Provident Life & Acc. Ins. Co*., 373 F.3d 998, 1018 n.14 (9th Cir. 2004), which itself quotes *Children's Broad. Corp. v. Walt Disney Co*., 357 F.3d 860, 865 (8th Cir. 2004), which quotes *Loudermill*, 863 F.2d at 570); *In re RFC & ResCap Liquidating Tr. Litig*., No. 13-CV-3451 (SRN/HB), 2018 WL 4489685, at *2 (D. Minn. Sept. 19, 2018)(quoting *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011), which in turn quotes *United States v. Rodriguez,* 581 F.3d 775, 795 (8th Cir.2009), which reiterates *Loudermill*, 863 F.2d at 570). *See also MCI Commc'ns Serv. Inc. v. KC Trucking & Equip. LLC*, 403 F. Supp. 3d 548, 556 (W.D. La. 2019)(quoting *Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004), which in turn quotes *United States v. 14.38 Acres of Land, More or Less Situated in Leflore County,* 80 F.3d 1074, 1077 (5th Cir.1996), which quotes *Viterbo*, 826 F.2d at 422).

[40] *See* Schroeder, 95 NOTRE DAME L. REV. at 2039; Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.3, at 30 (some courts "routinely state the misguided notion that arguments about sufficiency of basis and reliability of application almost always go to weight and not admissibility"); Apr. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.3, at 23 (rulings indicating that "challenges to the sufficiency of an expert's basis raise questions of weight and not admissibility" are "misstatement[s] made by circuit courts in a disturbing number of cases[.]"); Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.3, at 52 ("[T]he fact remains that some courts are ignoring the requirements of Rule 702(b) and (d). That is frustrating."). *See also* cases referenced at n.1 & n.2, *supra*, and accompanying text.

the influence of misguided caselaw such as *Loudermill* and *Viterbo*.[41] This structure would be consistent with other rules, including Rule 411(b)(2) and Rule 403, that identify that the court will decide if admissibility conditions are established and incorporate the burden of production into the rule's text.[42]

This new language would not change the court's responsibilities or the requirements that a party must establish.[43] The proposed language only makes explicit those elements that are presently implicit to remedy court confusion. Adjustment of the language to align practice with the rule's intent is an appropriate rulemaking action. For example, Federal Rule of Civil Procedure 26 was changed in 2015 to relocate discovery proportionality considerations to a more prominent position. Doing so did "not change the existing responsibilities of the court and the parties" or alter "the burden of addressing" these considerations – but the amendment was enacted to prevent courts from overlooking this factor and to "reinforce" that it must receive consideration.[44] Rule 702, likewise, has produced confusion among the courts, and that situation warrants action to communicate the intent of the rule with greater clarity.

C. If the Committee Proceeds with an Amendment to Address Expert Overstatement, that Amendment Should Be Suited to Civil as Well as Criminal Cases

Bayer understands that the Committee continues to consider an amendment addressing "overstatement" – expression of opinions that go beyond the limits of what the expert's methodology and factual basis will support. Bayer is concerned that the draft under consideration focuses too narrowly on criminal cases and does not reflect the needs of civil

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[41] *See* Schroeder, 95 NOTRE DAME L. REV. at 2060 ("the elements of Rule 702, not the caselaw, are the starting point for the requirements of admissibility.").

[42] Rule 411(b)(2) provides, in relevant part:

> In a civil case, the court may admit evidence offered to prove a victim's sexual behavior or sexual predisposition if its probative value substantially outweighs the danger of harm to any victim and of unfair prejudice to any party. (emphasis added)

Rule 403 states:

> The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence. (emphasis added)

The Advisory Committee Note to the 1994 Amendments of Rule 412 describes the burden of production established by the "substantially outweighs" verbiage as "a balancing test [that] requires the proponent of the evidence, whether plaintiff or defendant, to convince the court that the probative value of the proffered evidence 'substantially outweighs the danger of harm to any victim and of unfair prejudice of any party.'"

[43] *See*, *e.g.*, Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.3, at 1 (Rule 702 "already establishes that the reliability requirements are questions for the court, to be decided by a preponderance of the evidence.").

[44] Advisory Committee Note to the 2015 Amendments to Federal Rule of Civil Procedure 26.

lawsuits. The current draft would add the following language to Rule 702's list of admissibility factors:

> If the expert's principles and methods produce quantifiable results, the expert does not claim a degree of certainty unsupported by the results.[45]

Limited to "quantifiable results," this amendment seemingly would not reach problematic overstatement instances that have occurred in Bayer's civil cases. For example, one expert was allowed, on the basis of a methodology that purported to "rule out" a proportion of known alternative causes and comorbidities, to testify that exposure to a product "in all medical certainty" was the cause of a disease.[46] Another court allowed a witness with expertise in pharmacology and toxicology who simply reviewed certain Bayer and FDA documents to describe opinions about "the state of mind or knowledge of both Defendants and the FDA."[47]

Although some courts will restrict experts in civil cases who try to expand their opinions beyond the available support,[48] rulings permitting experts to exaggerate their conclusions demonstrate a need for an amendment directing courts to regulate overstatement. Less restrictive verbiage than the current proposal, while potentially requiring courts to examine closely the opinions that an expert would express,[49] would ensure that courts are empowered to address all unsupported expressions of confidence or overstatements in an expert's conclusion.[50] Bayer urges the Committee to adopt broader language that would reach these situations that arise in civil cases.

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[45] Hon. Debra A. Livingston, Report of the Advisory Committee on Evidence Rules (Nov. 15, 2019) at 5, *in* COMMITTEE ON RULES OF PRACTICE AND PROCEDURE JANUARY 2020 AGENDA BOOK 439 (2020).

[46] *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-01928, 2010 WL 8354662, at *8(S.D. Fla. Nov. 23, 2010) (product exposure "was a substantial contributing cause to her acute renal dysfunction in all medical certainty."). This case has been identified as one in which expert opinion testimony was allowed that "appears to overstate the conclusions that reliably flow from the expert's methodology." Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.3, at 24-25.

[47] *In re Xarelto*, 2017 WL 1352860, at *2.

[48] The same expert allowed by the *In re Xarelto* court to describe Bayer's state of mind was limited in another case, when the court found that she "extrapolated conclusions beyond the scope of her sources" -- exactly the conclusion the *In re Xarelto* court should have reached. *Rodman v. Otsuka America Pharm., Inc.*, No. 18-cv-03732-WHO, 2020 WL 2525032, at *7 (N.D. Cal. May 18, 2020).

[49] The current draft language "is intended to avoid wordsmithing the testimony of experts who testify to a conclusion that is not grounded i[n] a numerical probability – such as an electrician testifying that 'the house was not properly wired.'" Hon. Debra A. Livingston, Report of the Advisory Committee on Evidence Rules (Nov. 15, 2019) at 5, in COMMITTEE ON RULES OF PRACTICE AND PROCEDURE JANUARY 2020 AGENDA BOOK 439 (2020). While micromanagement of opinion verbiage may be undesirable, restricting the amendment only to quantifiable subjects would be problematic if doing so would allow the practice of overstating conclusions to continue in many expert fields commonly heard in court.

[50] One example of amendment language allowing for broader application to expert overstatement is a prior draft considered by the Advisory Committee for insertion into the Rule 702 list of requirements: "the expert does not claim a degree of confidence that is unsupported by reliable application of the principles and methods." *See* Advisory Committee on Evidence Rules, Conference Agenda for Miniconference on Best Practices of Managing Daubert Questions at 4 (Oct. 25, 2019).

Expert testimony plays a central role in civil litigation, and the improper admission of expert testimony may change the outcome of a case or even an entire MDL collection of cases. The gatekeeping responsibility is too important to leave untouched when courts have demonstrated they do not understand how to apply it. Bayer urges the Committee to adopt an amendment to guide court practices into alignment with Rule 702's intent.

Sincerely,

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