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

October 10, 2020

Re: Amending Federal Rule of Evidence 702

Dear Ms. Womeldorf:

The Advisory Committee on Evidence Rules is considering whether to amend Federal Rule of Evidence 702 to clarify that the proponent of expert testimony must establish the admissibility requirements set forth in the rule—*i.e.*, that the testimony be based on sufficient facts or data and be the product of reliable principles and methods that are reliably applied to the facts of the case—by a preponderance of the evidence under Rule 104(a). *See* Daniel Capra, *Memorandum to Rule 702 Subcommittee re: Rule 702(b) and (d) – Weight and Admissibility Questions*, at 1, 26–27 (Oct. 1, 2018) (Agenda Book, Advisory Committee on Evidence Rules (Oct. 19, 2018 meeting) at 171, 196–97). According to Professor Capra, this inquiry into Rule 702 "is necessitated by the fact that a fair number of courts appear to have not read the Rule as it is intended" and instead "appear to be treating sufficiency of basis and/or reliability of application as questions of weight and not admissibility." *Id.* at 1, 5 (Agenda Book at 171, 175). As an attorney who frequently deals with Rule 702-related issues in the context of pharmaceutical, medical device, and toxic tort litigation, I believe that such an amendment is necessary.

I conducted a targeted review of federal cases to assess the extent to which courts treat sufficiency of basis and/or reliability of application as questions of weight rather than admissibility when considering expert testimony on general causation (*i.e.*, whether a product is capable of causing a medical problem) or specific causation (*i.e.*, whether the product caused the problem in a particular plaintiff)—two core issues in pharmaceutical, medical device, and toxic tort litigation.[1] In a significant number of

[1] I conducted a search in the "All Federal" database on Westlaw using the following terms: <<"Rule 702" and (general specific /5 causation) and ((sufficiency sufficient) or (application applied) /s (weight /s admissible admissibility)) and DA(aft 8/1/2010)>>. That search yielded forty-one cases. This letter addresses fourteen of those cases, including *Johnson v. Mead Johnson & Co.*, 754 F.3d 557 (8th Cir. 2014); *Bettisworth v. BNSF Ry. Co.*, 2020 WL 3498139 (D. Neb. June 29, 2020); *Langrell v. Union Pac. R.R. Co.*, 2020 WL 3037271 (D. Neb. June 5, 2020); *King v. Union Pac. R.R. Co.*, 2020 WL 3036073 (D. Neb. June 5, 2020); *Lemberger v. Union Pac. R.R. Co.*, 2020 WL 2793565 (D. Neb. May 29, 2020); *Roohbakhsh v. Bd. of Trustees of Neb. State Colleges*, 2019 WL 5653448 (D. Neb. Oct. 31, 2019); *Murphy-Sims v. Owens Ins. Co.*, 2018 WL 8838811 (D. Colo. Feb. 27, 2018); *Fox v. Omron Healthcare, Inc.*, 2016 WL 7826661 (D. Mass. Aug. 9, 2016); *Rivera v. Volvo Cars of N. Am., LLC*, 2015 WL 11118065 (D.N.M. May 28, 2015); *Bee v. Novartis Pharms. Corp.*, 18 F. Supp. 3d 268 (E.D.N.Y. 2014); *Bowles v. Novartis Pharms. Corp.*, 2013 WL

the cases I reviewed, courts failed to acknowledge or misinterpreted the standards that govern their gatekeeping role under Rule 702 when they admitted expert testimony. This indicates that courts remain uncertain as to the meaning of Rule 702.

First, although the Committee Note relating to the 2000 amendments to Rule 702 indicates that the proponent of expert testimony has the burden under Rule 104(a) of "establishing that the pertinent admissibility requirements are met by a preponderance of the evidence," many courts did not acknowledge this burden. *See, e.g.*, *Bettisworth v. BNSF Ry. Co.*, 2020 WL 3498139, at *2–3 (D. Neb. June 29, 2020) (failing to note that the proponent of expert testimony has the burden of establishing its admissibility, let alone by a preponderance of the evidence); *Bowles v. Novartis Pharms. Corp.*, 2013 WL 5297257, at *2 (S.D. Ohio Sept. 19, 2013) (same); *Ast v. BNSF Ry. Co.*, 2012 WL 252140, at *3 (D. Kan. Jan. 26, 2012) (same); *see also Fox v. Omron Healthcare, Inc.*, 2016 WL 7826661, at *2–3 (D. Mass. Aug. 9, 2016) (acknowledging that the proponent of expert testimony has the burden of establishing its admissibility but failing to note that admissibility must be established by a preponderance of the evidence); *Rivera v. Volvo Cars of N. Am., LLC*, 2015 WL 11118065, at *2 (D.N.M. May 28, 2015) (same); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 424–27, 478 (E.D.N.Y. 2011) (same).

Some of these courts also purported to apply a "liberal" standard of admissibility even though Rule 702 on its face contains no such standard. *See Bettisworth*, 2020 WL 3498139, at *10 (stating that "*Daubert* calls for the liberal admission of expert testimony"); *Rivera*, 2015 WL 11118065, at *2 (citing a Tenth Circuit decision that pre-dates the 2000 amendments to Rule 702 for the proposition that "[t]he Court should liberally admit expert testimony") (citing *United States v. Gomez*, 67 F.3d 1515, 1526 (10th Cir. 1995)); *Deutsch*, 768 F. Supp. 2d at 426, 478 (stating that "Rule 702 codifies a liberal admissibility standard" and quoting a Second Circuit decision that pre-dates the 2000 amendments to Rule 702 for the proposition that "'there should be a presumption of admissibility of evidence'") (quoting *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995)).

These problems were not limited to district court decisions. In *Johnson v. Mead Johnson & Co.*, 754 F.3d 557 (8th Cir. 2014), the Eighth Circuit referred to Rule 104(a) but stated only that the rule required courts to determine if "the proposed testimony is scientific knowledge, derived from the scientific method, that will assist the trier of fact, i.e., is relevant." *Id.* at 561–62. The court did not acknowledge that, under Rule 104(a), the proponent of expert testimony must establish its admissibility by a preponderance of the evidence. Further, the court took the position that the testimony of an expert who performs a differential etiology analysis—*i.e.*, the process of ruling in and then ruling out the possible causes of a plaintiff's condition until the most likely cause remains—is "presumptively admissible." *Id.* at 560 n.2. Neither Rule 702 nor Rule 104(a) provides for a presumption of admissibility, and such a

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5297257 (S.D. Ohio Sept. 19, 2013); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 2012 WL 12920549 (N.D. Ala. Dec. 3, 2012); *Ast v. BNSF Ry. Co.*, 2012 WL 252140 (D. Kan. Jan. 26, 2012); and *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420 (E.D.N.Y. 2011).

presumption is inherently inconsistent with the requirement that the proponent of expert testimony establish its admissibility by a preponderance of the evidence.

Second, many courts dismissed problems with the factual basis of an expert's opinion as relating to the weight of the evidence rather than its admissibility. *See, e.g.*, *Fox*, 2016 WL 7826661, at *4 n.3 (admitting expert's general causation opinion, reasoning that defendant's argument that expert "did not rely upon the appropriate literature, studies, or methods in forming his opinion go to the weight, rather than the admissibility, of his testimony"); *Rivera*, 2015 WL 11118065, at *5 (summarily rejecting defendant's argument that plaintiff's expert failed to review scientific literature in forming his specific causation opinion, and quoting a Tenth Circuit decision that pre-dates the 2000 amendments to Rule 702 for the proposition that "'[t]he sufficiency of factual basis to support [the expert's] opinion goes to its weight, not its admissibility'") (quoting *Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 654 (10th Cir. 1991)); *Bee v. Novartis Pharms. Corp.*, 18 F. Supp. 3d 268, 304–05 (E.D.N.Y. 2014) (rejecting defendant's argument that anecdotal case reports provided an unreliable basis for plaintiff's expert's general causation opinion, reasoning that the argument "go[es] to the weight, and not to the admissibility, of [the expert's] opinion" and that "questions concerning the accuracy or credibility of any such case reports may serve as valuable ammunition in countering [the expert's] opinion, once given on the stand"); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 2012 WL 12920549, at *2–3 (N.D. Ala. Dec. 3, 2012) (concluding that "the factual underpinnings" of expert's specific causation opinion "are a matter for the jury to weigh, and not this court"); *Deutsch*, 768 F. Supp. 2d at 432, 459, 477–78 (stating repeatedly that "mere weaknesses in the factual basis of an expert witness' opinion . . . bear on the weight of the evidence rather than on its admissibility," and holding that court "cannot conclude that Dr. Gelfman's opinion on specific causation is scientifically unreliable," reasoning that "[h]is lack of memory with regard to what he did and did not rule out when performing his differential diagnosis can be explored on cross-examination").

In *Ast*, the court implied that challenges to the factual basis of an expert's opinion went to the weight of the evidence rather than its admissibility even though the court did not explicitly so state. The plaintiff in *Ast* sued his former employer, alleging that he was injured while throwing a railroad switch due to the defendant's negligent maintenance of the switch. *See* 2012 WL 252140, at *1. Although the plaintiff's causation expert visited the work site more than three years after the plaintiff allegedly was injured, the expert opined that the conditions he witnessed during the site visit were substantially similar to the conditions that existed at the time of the plaintiff's alleged injury. *See id.* at *3. Even though the expert did not point to any evidence supporting his three-year extrapolation, the court held that "[t]he lapse in time between the accident and [the expert's] inspection affects the weight of [his] testimony rather than its admissibility, and should be addressed at trial during cross-examination and arguments." *Id.* at *4 & n.18.

Third, other courts dismissed problems with an expert's application of his or her methodology as relating to the weight of the evidence rather than its admissibility. In *Johnson*, for example, the plaintiff/guardian ad litem of a minor child alleged that the child developed severe permanent brain

damage from exposure to a bacterium in powdered infant formula manufactured by the defendant. *See* 754 F.3d at 559–60. The district court excluded the testimony of three of the plaintiff's experts on the ground that they performed unreliable differential etiology analyses by failing to rule out other potential causes of bacterial contamination, including the municipal water supply or the pipes and/or environment in the child's home. *See id.* at 560–61. The Eighth Circuit reversed. The court explained that a differential etiology analysis is the process by which an expert rules in the reasonably plausible causes of injury and then rules them out "from least to more plausible until a most plausible cause emerges." *Id.* at 560 n.2. After noting that expert testimony based on such an analysis is "presumptively admissible" in the Eighth Circuit, the court stated that "experts are not required to rule out all possible causes when performing the differential etiology analysis." *Id.* at 560 n.2 & 563. According to the court, "such considerations go to the weight to be given the testimony by the factfinder, not its admissibility." *Id.* at 563.

Like the court in *Johnson*, other courts took the position that an expert's application of his or her methodology is an issue that goes to weight, not admissibility. *See, e.g.*, *Bettisworth*, 2020 WL 3498139, at *3, 9 (stating that "[i]n general, deficiencies in the application of scientific methodology go to the weight of the expert's testimony, not to its admissibility," and holding that even though cigarette smoking is a "widely known, and well-established" cause of lung cancer, the expert's failure to rule out the plaintiff's smoking as a cause of her lung cancer "go[es] to the weight to be given to the testimony by the factfinder, not the admissibility of the expert's testimony"); *Murphy-Sims v. Owens Ins. Co.*, 2018 WL 8838811, at *7 (D. Colo. Feb. 27, 2018) (rejecting defendant's challenge to expert's differential diagnosis, reasoning that "[c]oncerns surrounding the proper application of the methodology typically go to the weight and not admissibility"); *Bowles*, 2013 WL 5297257, at *5–6 (rejecting argument that expert's differential etiology analysis was flawed because he admitted he could not rule out multiple possible causes of plaintiff's jaw problems, reasoning that "[a]ny disagreements over the sufficiency of that etiology go to the weight of his testimony, not to its admissibility").

Fourth, in a series of decisions out of the District of Nebraska, the court did not even cite to the text of Rule 702 and concluded that challenges to both the factual basis of an expert's opinion *and* the expert's application of his methodology go to the weight of the evidence rather than its admissibility. *See Lemberger v. Union Pac. R.R. Co.*, 2020 WL 2793565, at *5 (D. Neb. May 29, 2020) ("Generally, deficiencies in application go to the weight of the evidence, not its admissibility. As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility.") (internal citation and quotation marks omitted); *Langrell v. Union Pac. R.R. Co.*, 2020 WL 3037271, at *5 (D. Neb. June 5, 2020) (same); *King v. Union Pac. R.R. Co.*, 2020 WL 3036073, at *5 (D. Neb. June 5, 2020) (same); *Roohbakhsh v. Bd. of Trustees of Neb. State Colleges*, 2019 WL 5653448, at *2–3 (D. Neb. Oct. 31, 2019) (same).

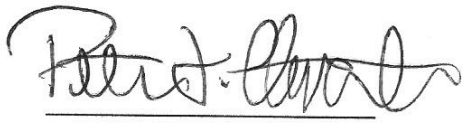
The court's application of these erroneous standards in *King* is particularly troubling. The plaintiff there alleged that he developed multiple myeloma from exposure to diesel fuel, diesel exhaust, benzene, creosote, and herbicides while employed at the defendant railroad company. *See* 2020 WL 3036073, at *1. The plaintiff's expert conducted a differential etiology analysis to determine what caused the

plaintiff's multiple myeloma. *See id.* at *8. Even though the expert could not rule out age, gender, genetics, or smoking as a *sole* cause of the plaintiff's injury and could not opine that one potential cause was more likely than another to have caused the injury, the court admitted his opinion that the alleged chemical exposure contributed to the plaintiff's condition, reasoning that a differential etiology is "presumptively admissible" and that the expert's application of this methodology was "reliable enough." *Id.* at *3, 8–9.

In short, my review demonstrates a pervasive problem in how courts interpret and apply their gatekeeping role under Rule 702. This conclusion is consistent with my experience practicing in the pharmaceutical, medical device, and toxic tort fields over the last approximately twenty years. During that period, I have litigated numerous expert challenges in state and federal courts across the country. While I have found that courts generally take their gatekeeping role seriously, the fact is that assessing the admissibility of general and specific causation testimony can be difficult, and judges sometimes may prefer to admit testimony rather than grapple with complicated scientific issues. That urge is understandable, but it is not compatible with Rule 702.

In *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), Justice Breyer observed that "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." *Id.* at 148 (Breyer, J., concurring). "To the contrary," he wrote, "when law and science intersect, those duties often must be exercised with special care." *Id.* Amending Rule 702 to clarify that courts must establish the admissibility requirements set forth in the rule by a preponderance of the evidence would give courts the added guidance that they need to exercise their gatekeeping duties with the special care that Justice Breyer recommended.

Sincerely,



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