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Submitted via Email: Rules Committee Secretary@ao.uscourts.gov

Committee on Rules of Practice and Procedure Administrative Office of the United States Courts Thurgood Marshall Federal Judiciary Building One Columbus Circle, NE Room 7-300 Washington, D.C. 20544

Attention: Rebecca A. Womeldorf, Secretary

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Re: Comment on Potential Amendment to Federal Rule of Evidence 702

GlaxoSmithKline LLC ("GSK") respectfully submits this Comment to the Advisory Committee on Evidence Rules ("Committee") in support of amendment to Federal Rule of Evidence 702. As a science-led global health leader, GSK's mission is to help people do more, feel better, and live longer. We achieve these goals through rigorous application of scientific principles and adherence to the integrity of the scientific method. With these guiding values in mind, we believe that amending Rule 702 is both necessary and important.

Rule 702 is intended to ensure that unreliable evidence is barred from consideration by juries. Yet decades of experience make it apparent that there is confusion among courts regarding the application and parameters of Rule 702, sometimes with consequences felt well outside the courtroom. Indeed, federal courts are divided on some of the bedrock principles of Rule 702, such as whether their gatekeeping function requires analysis of the factual basis of a proposed expert's testimony, and whether the application of a proposed expert's methodology is within the scope of review. Because Rule 702 as currently drafted is failing to provide clear guidance to properly inform and guide courts on these important issues, the Advisory Committee should amend the Rule to provide greater clarity, ensure consistent decision-making, and protect juries and the public from unreliable pseudo-science.

I. Rule 702 requires an amendment to clarify the courts' gatekeeping role

Scholars and other commentators have recognized for some time that many federal courts do not apply Rule 702 as intended, even after the adoption of amendments in 2000 to "implement[] the standards of *Daubert* and its progeny and provid[e] a uniform structure for assessing expert testimony in light of all the case law." A seminal 2015 law review article noted several fundamental issues that have arisen since the 2000 amendments. Clear examples of confusion regarding Rule 702 include: (1) continued application of pre-amendment standards, (2) holding that the application of an expert's methodology is not subject to the gatekeeping function, and (3) statements that the factual basis of an expert's opinion is an issue of weight rather than admissibility. More recent reviews of the case law confirm that courts continue to misapply Rule 702. For example, many decisions hold that Rule 702 establishes a presumption of admissibility, which when applied in practice serves to exclude only the most egregious and patently nonsensical expert opinions. No presumption of admissibility exists within Rule 702, and applying a presumption undermines the intent of the rule and judges' responsibility to independently assess the reliability of proffered expert opinions.

Such decisions are not "one-off" aberrations, but rather constitute a troubling pattern of confusion regarding Rule 702 and courts' mandated gatekeeping function. Misapplication of Rule 702 is especially prevalent in mass tort actions in the pharmaceutical industry, an area of particular importance to GSK. Given the size and importance of these cases,

¹ Daniel Capra, Memorandum to the Advisory Committee on Evidence Rules, n.6 (April 1, 2018), Agenda Book for Advisory Committee on Rules of Evidence April 26-27, 2018, https://www.uscourts.gov/sites/default/files/agenda_book_advisory_committee_on_rules_of_evidence_-_final.pdf), at 92 [hereafter Capra, Memorandum I].

Memorandum IJ.

² David E. Bernstein & Eric G. Lasker, Defending Daubert: It's Time to Amend Federal Rule of Evidence 702, 57 Wm. & Mary L. Rev. 1 (2015).

³ Id. at 19-25, 27-30, 33 (discussed at length in Capra, Memorandum I, supra n.1); see David E. Bernstein, The Misbegotten Judicial Resistance to the Daubert Revolution, 89 Notre Dame L. Rev. 27 (2013) (arguing that further amendment to Rule 702 is necessary to address misapplication of the standard for admitting expert testimony); Victor E. Schwartz & Cary Silverman, The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts, 35 Hofstra L.

Rev. 217, 218 (2006) (identifying "five general areas of inconsistency in the application of expert testimony standards").

Lee Mickus, Gatekeeping Reorientation: Amend Rule 702 to Correct Judicial Misunderstanding About Expert Evidence, Washington Legal Foundation, Critical Legal Issues Working Paper Series, Number 217 (May 2020) https://www.wlf.org/wp-content/uploads/2020/05/0520MickusWPfinal-for-web-002.pdf.

mass tort opinions influence Rule 702 decisions in other contexts, thereby fostering continued misunderstanding and misapplication of the Rule, continued reliance on pre-2000 decisions, and application of incorrect standards.5

Misunderstanding and misapplication of Rule 702 can have important consequences outside the courtroom. In some instances, safe and effective drugs have been pulled from the market due to the threat of lawsuits based on unsound science. For example, litigation alleging that the drug Bendectin caused birth defects resulted in large jury awards based on unreliable science, after which the manufacturer withdrew the medication from the United States market.6 The market withdrawal left an absence of any approved treatment for serious nausea and vomiting impacting pregnant women in the United States. Years later, the same drug was re-approved as safe and efficacious for use in pregnancy. but the decade-long damage based on unfounded and unscientific litigation claims had been done.8

Junk science in the courtroom also can have a pernicious influence on doctor-patient relationships, and even influence individual patients to discontinue recommended therapies. An analogy to the harm of unfettered expert testimony at trial can be seen in research on attorney advertising for mass tort cases. Research demonstrates that patients exposed to unscientific information with an imprimatur of authority may perceive greater risks than exist and stop taking necessary medications. In some cases, the consequences are tragic. Perhaps less obvious, but nonetheless unfortunate, is the stifling effect unfounded science can have on innovation, ultimately denying new and better treatment options to patients. 11 Treatment decisions, like all decisions concerning public health, should be driven by sound science. That goal is undermined when individuals cloaked with the authority of experts offer unscientific testimony in a manner completely at odds with Daubert and the gatekeeping mandate of Rule 702.

II. Courts apply inconsistent standards to Rule 702 decisions

Notably, and contrary to the purposes of the Federal Rules of Evidence, Rule 702 is not applied in a consistent manner across jurisdictions. Instead, federal courts have diverged sharply over the scope of their gatekeeping responsibilities on two important issues. Some have concluded that problems in the application of an expert's methodology or shortcoming in an expert's factual basis are matters to be considered by a jury. Although other courts have hewn closely to the intent of Rule 702, Committee action is needed to clarify the Rule and provide uniformity in federal courts' consideration of proffered expert evidence.

Under Rule 702(b), courts must ensure that expert "testimony is based on sufficient facts or data." But several circuits have misunderstood this directive and held that factual basis is not an issue of admissibility. In Milward v. Acuity Specialty Prods. Grp., Inc., the district court identified several key defects in the factual basis of a proffered expert and excluded his testimony, but the First Circuit reversed. 12 It criticized the district court for "repeatedly challengling] the factual underpinnings of [the expert's] opinion," holding 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 trier of fact."13

In Manpower, Inc. v. Ins. Co. of Pennsylvania, 14 the Seventh Circuit similarly reversed the exclusion of expert testimony. holding that a "district court usurps the role of the jury, and therefore abuses its discretion, if it unduly scrutinizes the quality of the expert's data and conclusions rather than the reliability of the methodology the expert employed."15 It ruled that a district court may not "assess the quality of the data inputs [an expert] selected" because "the selection of

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⁵ Thomas Sheehan et al., Letter to the Advisory Committee (June 9, 2020), https://www.uscourts.gov/sites/default/files/20-ev-

e_suggestion_from_thomas_sheenan__rule_702_0.pdf

§ See Brent R. Bendectin: Review of the medical literature of a comprehensively studied human non-teratogen and the most prevalent tortogen–litigen, Reprod Toxicol. 1995;9:337–349; Brent R. Bendectin and birth defects: hopefully, the final chapter, Birth Defects Res A Clin Mol Teratol. 2003;67:79-87. Recognizing the importance of sound science in the courtroom, the Supreme Court established the Daubert standard to guide judges' gatekeeping function in a Bendectin case. See Kutcher JS, Engle A, Firth J, Lamm SH. Bendectin and Birth Defects. II: Ecological Analyses, Birth Defects Res A Clin Mol Teratol. 2003;67(2):88-97, at 96

⁽noting that that hospitalizations for nausea and vomiting in pregnancy doubled after Bendectin became unavailable in the United States).

§ See Lars Noah, Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs, 54 S.C. L. Rev. 741, 760 (2002); W. Kip Viscusi, Corporate Risk Analysis: A Reckless Act?, 52 Stan. L. Rev. 547, 583-84 (2000).

§ Jesse King & Elizabeth Tippett, Drug Injury Advertising, 18 Yale J. Health Pol'y L. & Ethics, 148 (2019).

10 Maren McBride, Legislative Director for Appropriations, U.S. Food & Drug Admin., to Hon. Andy Harris, M.D., U.S. House of Rep. (Feb. 6, 2019), available at https://www.agingresearch.org/app/uploads/2019/05/2019-0206-Harris-Letter.pdf (stating the FDA received reports indicating that 58 patients who were prescribed antidiabetic, antidepressant, or anticoagulant medications discontinued taking their medication after viewing a negative lawsuit or other advertisement, and subsequently experienced an adverse event or death).

¹¹ David J. Damiani, Expert Testimony Reform Proposals, 13 Alb. L. J. Sci. 518, 523 (2003) ("Mass tort litigation that damages nontortious companies often leads to unintended consequences such as the disappearance of needed drugs and devices from the market and a disincentive to innovate.").

^{12 639} F.3d 11, 13 (1st Cir. 2011). ¹³ *Id.* at 22 (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). ¹⁴ 732 F.3d 796, 801 (7th Cir. 2013).

¹⁵ Id. at 806.

data inputs to employ in a model is a question separate from the reliability of the methodology reflected in the model itself."16

The Fourth Circuit has also taken the view that assessing the factual basis of an expert's proposed testimony is not part of the court's gatekeeping function. In Bresler v. Wilmington Tr. Co., defendants pointed to errors that an expert made in assigning "certain variables, including the cost of insurance and future interest rates." The court ruled that such arguments were not cognizable under Rule 702 because "challenges to the accuracy of [an expert's] calculations affect the weight and credibility of [the expert's] assessment, not its admissibility."18 The Fifth and Eighth Circuits have also stated that, in general, the factual basis of an expert's proffered testimony is an issue for a jury to consider rather than a part of the courts' gatekeeping role.

Other circuits have taken an entirely different view and properly concluded that an expert's factual basis must be assessed by a judge prior to admission of expert testimony. The Third Circuit rejected the "suggestion that the reasonableness of an expert's reliance on facts or data to form his opinion is somehow an inappropriate inquiry under Rule 702," stating that such an argument reflects "an unduly myopic interpretation of Rule 702 and ignores the mandate of *Daubert* that the district court must act as a gatekeeper." The Second Circuit recognizes that "[i]n deciding whether a step in an expert's analysis is unreliable, the district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand."20 The Eleventh Circuit has also held that it is "entirely proper—indeed necessary—for the district court to focus on the reliability of [an expert's] sources and methods," although it acknowledged "that courts in other circuits have taken a more expansive approach and permitted expert testimony" despite problems with an expert's factual basis.²¹ Such acknowledgment underscores that there is substantial disagreement among circuits regarding the scope and application of Rule 702(b), meaning opinions may rest more on where a complaint is filed than the text of the Rule itself.

The same split in authority exists as to Rule 702(d), which provides that a court must find an "expert has reliably applied the principles and methods to the facts of the case." As with factual basis, not all courts apprehend the scope of review under this provision. In City of Pomona v. SQM N. Am. Corp., a district court excluded an expert's opinion because he failed to adhere to published protocols for the test he administered.²² The Ninth Circuit reversed, explaining that "[i]n the Ninth Circuit" expert opinion testimony should be excluded only if it "is the result of a faulty methodology or theory as opposed to imperfect execution of laboratory techniques whose theoretical foundation is sufficiently accepted in the scientific community."23 Notably, the court specifically rejected the "any step" approach described in In re Paoli R.R. Yard PCB Litigation.²⁴ a case cited in the Advisory Committee's note to the 2000 amendment of Rule 702 as exemplifying the proper analysis.25

Similarly, while finding it a "close question," the Ninth Circuit reversed exclusion of expert testimony in Wendell v. GlaxoSmithKline LLC, and faulted the trial court for looking "too narrowly at each individual consideration [under Dauberf], without taking into account the broader picture of the experts' overall methodology."26 In particular, the court criticized the trial judge's "overemphas[is]" on the experts' failure to conduct independent research or to cite to epidemiological studies, as well as the trial judge's finding that the experts did not rely on studies supporting causation.²⁷ Instead, the appellate court effectively endorsed the experts' differential diagnosis as sufficient to overcome the hurdles of Daubert without sufficiently evaluating whether differential diagnosis was a sound methodological basis for the experts' opinions.²⁸ Wendell is illustrative of a reading of Rule 702 that swallows the instruction of the Rule and the purpose of its amendments by eschewing Daubert factors in favor of a broad brush approach to admissibility.

^{17 855} F.3d 178, 195 (4th Cir. 2017).

¹⁹ Id. at 196 (internal quotation marks omitted).

¹⁹ IF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 294 (3d Cir. 2012).

²⁰ Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002).

²¹ Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1336, 1343 (11th Cir. 2010).

^{22 750} F.3d 1036, 1047 (9th Cir. 2014).

²³ Id. at 1047-48 (quoting United States v. Chischilly, 30 F.3d 1144, 1154 & n.11 (9th Cir.1994).

In at 1047-46 (quoting officed states 1 - 24 35 F.3d 717, 745 (3d Cir. 1994).
 Sit Property of Pomona, 750 F.3d at 1047; see Fed. R. Evid. 702 advisory committee's note to 2000 amendment.
 858 F.3d 1227, 1233 (9th Cir. 2017).

²⁸ Id.; see also Schwartz & Silverman, 35 Hofstra L. Rev. at 250 (noting the sometimes "fine line between differential diagnosis and pure guesswork").

The Eleventh Circuit applied a similar rule in Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., distinguishing "between the reliability of computational fluid dynamics generally and of [an expert's] application of [that method] in this case."29 Although the court appeared to recognize that an expert had used an incorrect variable in an important formula, it held that "[t]he identification of such flaws in generally reliable scientific evidence is precisely the role of crossexamination."30 Because defendants' "argument is that [the expert] misused a method that, in the abstract, is reliable," the court concluded that the issue went "to the weight, not the admissibility, of the evidence he offered."31 Determining that opinions are admissible because the methodology employed is "in the abstract" reliable, even where the methodology was not reliably applied, strikes at the very purpose of the Rule 702 amendments: to preclude unreliable expert opinions.

Courts in other circuits have adopted a view of Rule 702(d) consistent with the intent of the Rule. In the Third Circuit, courts have adhered to the "any step" approach described in Paoli. There, the court explained that "after Daubert, we no longer think that the distinction between a methodology and its application is viable."32 Accordingly, "any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible" and "despite the fact that [a] methodology is generally reliable, each application is distinct and should be analyzed for reliability."³³ The Tenth Circuit has also explicitly rejected the argument "that Daubert should not [be] used to assess the application of the experts' methodologies, but rather should have been used to assess only the methodologies upon which [an expert] relied. 34 It explained that "[i]t is an elusive process to divine the difference between a methodology and what constitutes a change from that methodology" and thus any faulty step renders expert evidence inadmissible regardless of "whether the step completely changes a reliable methodology or merely misapplies that methodology."35 These different approaches among the circuits, however, remain unresolved and evidence the need for an amendment to help judges consistently and uniformly apply Rule 702.

Differences among the circuits also create substantial uncertainty and drive courts to reach different outcomes when considering the same issues or even the same experts. For example, district courts in the Seventh Circuit have denied Rule 702 challenges to experts suggesting a causal relationship between the GSK drug Paxil and suicide, citing that circuit's rule that "the court should avoid passing judgment on the 'factual underpinnings of the expert's analysis and the correctness of the expert's conclusions,' a role better left to the fact-finder."³⁶ But a court that considered the sufficiency of an expert's factual basis on that same issue excluded testimony in part because the expert "failed to account for a substantial body of evidence which has found no causal link between Paxil and suicide or suicidal behavior in adults."37 Similarly, courts with different interpretations of Rule 702(b) have reached different conclusions about the admissibility of the same proposed expert's testimony, with one court ruling that Rule 702 "applies to all aspects of an expert's testimony" including "the facts underlying the expert's opinion," 38 but another stating that that "the factual basis for an expert's findings goes to the weight of his testimony not the admissibility."39 These outcomes should not be driven by the location in which suit is filed, but by the text of the Rule.

The lack of a uniform approach to Rule 702 requires Advisory Committee action III.

Courts' differing approaches to Rule 702 have not gone unnoticed. In addition to the Advisory Committee's own work noted above, many scholars have described splits among the courts on the application of the Rule. 40 Perhaps more importantly, courts themselves are increasingly identifying differences in the way different circuits apply Rule 702.

^{29 326} F.3d 1333, 1343 (11th Cir. 2003).

³⁰ Id. at 1345.

³² In re Paoli R.R. Yard PCB Litig., 35 F.3d at 745.

³³ In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 858 F.3d 787, 795 (3d Cir. 2017)

³⁴ Attorney Gen. of Oklahoma v. Tyson Foods, Inc., 565 F.3d 769, 779 (10th Cir. 2009) (emphases in original).

³⁶ Tucker v. SmithKline Beecham Corp., 701 F. Supp. 2d 1040, 1055 (S.D. Ind. 2010) (quoting Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000)); see also Dolin v. Smithkline Beecham Corp., No. 12 C 6403, 2015 WL 7351678, at *3 (N.D. III. Nov. 20, 2015) (adopting the reasoning of Tucker). ³⁷ Vanderwerf v. SmithKlineBeecham Corp., 529 F. Supp. 2d 1294, 1307 (D. Kan. 2008).

³⁸ In re Zoloft (Sertraline Hydrocloride) Prods. Litig., No. 12-MD-2342, 2015 WL 7776911, at *16 (E.D. Pa. Dec. 2, 2015).
³⁹ In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig., No. 3:11-MD-2244-K, 2014 WL 3557345, at *13 (N.D. Tex. July 18, 2014).
⁴⁰ Bernstein & Lasker, 57 Wm. & Mary L. Rev. at 27, 30 (noting differences on whether "review of an expert's application of his methodology is beyond the scope of a court's gatekeeping power" and whether courts may "assess the reliability of the factual foundations of such testimony"); David L. Faigman, Christopher Slobogin, John Monahan, Gatekeeping Science: Using the Structure of Scientific Research to Distinguish Between Admissibility and Weight in Expert Testimony, 110 Nw. U. L. Rev. 859, 874 (2016) ("While some courts have taken to heart the change in focus signaled by Joiner and Rule 702, many other courts, perhaps most, continue to insist on the methodology-conclusions distinction when determining whether an expert evidentiary proposition goes to admissibility or weight.") (footnote omitted); Jim Hilbert, The Disappointing History of Science in the Courtroom: Frye, Daubert, and the Ongoing Crisis of "Junk Science" in Criminal Trials, 71 Okla. L. Rev. 759, 795 (2019) (citing "judges' lack of consistency in applying Daubert"); Alexandra Kennedy-Breit, Admissibility of Expert Evidence to Prove Causation in Toxic Torts, 53 Tort Trial & Ins. Prac. L.J. 139, 146 (2017) stating that "more than twenty years after the Supreme Court's decision in Daubert," Rule 702 is "still being applied inconsistently").

As a district judge recently noted with candor, decisions applying Rule 702 "are impossible to read without concluding that district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits."41 The same court noted that this lack of uniformity "has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits. This is a difference that could matter in close cases."42 Another district court judge explained that "the approach of the Eighth and Third Circuits [to Rule 702] is somewhat more restrictive than the approach of the First and other Circuits" and expressed difficulty in attempting "to choose between these two approaches."43

Confusion regarding Rule 702 among federal courts has also been cited by other tribunals considering the admissibility of expert testimony. In deciding whether to adopt federal standards as a matter of state law, the Supreme Court of New Jersey acknowledged that "there is no monolithic body of case law uniformly or even consistently applying Daubert," and thus the court "hesitate[d] to sweep in adherence to the various approaches taken among the circuits and state jurisdictions when applying the Daubert factors."44 The court accordingly did "not adopt a 'standard' that [it] cannot fully discern in its application" and noted it "cannot ignore that there are discordant views about the gatekeeping role among Daubert jurisdictions."45 The District of Columbia Court of Appeals, likewise considering whether to apply the federal rule, noted that although "there are substantial benefits to be gained from adopting a test that is widely used," the court was "not proceeding with any illusions that the cases are uniform or even consistent." 46

This discordance demands correction. "One of the shaping purposes of the Federal Rules is to bring about uniformity in the federal courts "47 Yet Rule 702 as written is not providing sufficient guidance. As noted above, judges themselves have decried the inability to discern a uniform standard and acknowledged that the case law is inconsistent. The absence of a national standard applied consistently across jurisdictions permits forum shopping and makes it difficult for interstate companies to plan their affairs based on legitimate science rather than threats of litigation. Those threats are exacerbated when parties can seek out lowest-common-denominator jurisdictions that permit unreliable expert evidence in contravention of the intent of Rule 702. In short, whether proffered expert opinions are deemed reliable and admissible has become a question more of where the opinion is being offered, rather than the impartial and consistent application of Rule 702.

The Advisory Committee has received numerous comments from legal organizations and industry leaders urging Rule 702 reform.⁴⁸ GSK joins those voices in exhorting the Advisory Committee to avoid further delay and draft an amendment to Rule 702 to clarify that courts can and indeed are obligated by the Rule to engage in rigorous gatekeeping of proposed expert testimony. Committee action is needed to ensure that litigation is based on reliable evidence and that public health decisions are guided by scientific principles.

Yours sincerely,

James Ford,

James Ford Senior Vice President & General Counsel

 ⁴¹ In re Roundup Prods. Liab. Litig., 358 F. Supp. 3d 956, 959 (N.D. Cal. 2019).
 ⁴² In re Roundup Prods. Liab. Litig., 390 F. Supp. 3d 1102, 1113 (N.D. Cal. 2018) (citations omitted).
 ⁴³ United States v. McCluskey, 954 F. Supp. 2d 1224, 1255 (D.N.M. 2013).
 ⁴⁴ In re Accutane Litig., 191 A.3d 560, 595 (N.J. 2018)

⁴⁵ Id.

⁴⁶ Motorola Inc. v. Murray, 147 A.3d 751, 757 (D.C. 2016).

⁴⁷ Hanna v. Plumer, 380 U.S. 460, 472 (1965).

⁴⁸ Chief Legal Officers of 50 Companies, Letter to Advisory Committee (March 2, 2020), https://www.uscourts.gov/sites/default/files/20-ev-

b_suggestion_from_50_companies_-_rule_702_0.pdf; Federation of Defense & Corporate Counsel, Letter to Advisory Committee (June 30, 2020), https://www.uscourts.gov/sites/default/files/20-ev-f_suggestion_from_federation_of_defense_and_corporate_counsel_-_rule_702.pdf; International Association of Defense Counsel, Letter to Advisory Committee (July 31, 2020), https://www.uscourts.gov/

sites/default/files/20-ev-h_suggestion_from_international_association_of_defense_counsel_-_rule_702_0.pdf