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IN THE

# Supreme Court of the State of Delaware

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| IN RE ZANTAC (RANITIDINE) LITIGATION | **No. 255, 2024** |
| | CASE BELOW: |
| | SUPERIOR COURT OF THE STATE OF DELAWARE C.A. No. N22C-09-101 |

## BRIEF OF THE LAWYERS FOR CIVIL JUSTICE AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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## INTEREST OF AMICUS CURIAE[1]

Lawyers for Civil Justice (LCJ)[2] is a national coalition of defense trial lawyer organizations, law firms, and corporations that promotes excellence and fairness in the civil justice system to secure the just, speedy, and inexpensive determination of civil cases. For over 30 years, LCJ has advocated for procedural reforms that (1) promote balance in the civil justice system; (2) reduce the costs and burdens associated with litigation; and (3) advance predictability and efficiency in litigation. Working through the Rules Enabling Act process, LCJ often urges proposals to reform aspects of the Federal Rules of Civil Procedure and Federal Rules of Evidence. As amicus curiae, LCJ seeks to act as a true friend of the court and to "add value" to the court's "evaluation of the issues presented on appeal." *Prairie Rivers Network v. Dynegy Midwest Generation, L.L.C.*, 976 F.3d 761, 763 (7th Cir. 2020) (Scudder, J., in chambers). LCJ's interest in this case is to provide the Court with its views on the development and meaning of Federal Rule 702, and consequently how this Court should interpret the analogous Delaware Rule of Evidence 702.

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[1] Counsel certifies that (1) no counsel for a party authored this brief in whole or in part; (2) no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and (3) no person or entity—other than amicus curiae—contributed money intended to fund the preparation or submission of this brief.

[2] LCJ's members are listed on its website, at the "About Us" tab. https://www.lfcj.com/about-us.html.

LCJ is one of the entities with the most granular knowledge on the meaning, history, and application of FRE 702 and on interpretation by courts. LCJ has for years focused on FRE 702, drawing on the collective experience of its members who litigate in the federal courts. For example, LCJ submitted several extensive comments, including original research, to the Judicial Conference Advisory Committee on Evidence Rules (referred to in this brief as the Advisory Committee).[3] LCJ's analysis identified many courts which failed to recognize that the sufficiency of an expert's factual basis is an *admissibility* consideration under FRE 702(b) and fail to apply FRE 104(a)'s burden of proof to expert admissibility decisions. In that process, LCJ advocated for specific changes, including adding into the rule's test an explicit reference to the court as the decision-maker, so that Rule 702 would give

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[3] *See, e.g.*, Lawyers for Civil Justice, *Clarity and Emphasis: The Committee's Proposed Rule 702 Amendment Would Provide Much-Needed Guidance About the Proper Standards for Admissibility of Expert Evidence and the Reliable Application of an Expert's Basis and Methodology*, Comment to Advisory Committee on Evidence Rules (Sept. 1, 2021); https://www.regulations.gov/comment/USC-RULES-EV-2021-0005-0007 (henceforth "Clarity and Emphasis"); *Why Loudermill Speaks Louder than the Rule: A "DNA" Analysis of* Rule 702 Case Law Shows that Courts Continue to Rely on Pre-Daubert Standards Without Understanding that the 2000 Amendment Changed the Law, Comment to the Advisory Committee on Rules of Evidence and Rule 702 Subcommittee (Oct. 20, 2020); https://www.uscourts.gov/sites/default/files/20-ev-y_suggestion_from_lawyers_for_civil_justice_rule_702_0.pdf; Lawyers for Civil Justice, Federal Rule of Evidence 702: A One-Year Review and Study of Decisions in 2020, submitted to Advisory Committee on Evidence Rules (September 30, 2021), https://www.regulations.gov/comment/USC-RULES-EV-2021-0005-0008.

unmistakable direction about judges' gatekeeping responsibility. Moreover, LCJ's contributions had direct benefits in the rulemaking process.[4]

LCJ has also recently submitted amicus briefs in both the United States Supreme Court and in federal courts of appeals urging courts to give meaning to Rule 702 and its requirements. *See, e.g.*, *Monsanto Company v. Edwin Hardeman*, 21-241 (United States Supreme Court); *Fischer v. BMW of North America*, No. 20-01399 (United States Court of Appeals for the Tenth Circuit); *Daniels-Feasel et al. v. Forest Pharmaceuticals, et al.*, No. 22-146 (United States Court of Appeals for the Second Circuit); *Harris v. Fedex Corp. Svcs., Inc.*, No. 23-20035 (United States Court of Appeals for the Fifth Circuit); *In re: Paraquat Products Liability Litigation*, Nos. 24-1865, 24-1866, 24-1867, 24-1868 (United States Court of Appeals for the Seventh Circuit). As it does here, LCJ has endeavored in those previous briefs to clarify the proper standards for the admission of expert testimony under FRE 702 and its state analogues.

LCJ and its members have an interest in ensuring that the admissibility standard under FRE 702 and its many state analogues be consistently interpreted

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[4] See, e.g., Memorandum from Daniel J. Captra and Liese L. Richter, Reporters, Advisory Committee on Evidence Rules, to Advisory Committee on Evidence Rules, Possible Amendment to Rule 702 (Oct. 1, 2024), at 4, in Advisory Committee on Evidence Rules November 2021 Agenda Book 135 (2021) ("LCJ's suggestion to reinsert a reference to the court has much to commend it… Given the fact that the reason the rule is being amended is that some courts did not construe the 2000 amendment properly, it makes eminent sense to make it as explicit as possible.").

across the nation, particularly with respect to the burden of production and the reliability criteria set forth in that rule. That standard, and not local variations that modify or remove elements or alter the explicit admissibility requirements, reflect the governing law. LCJ also strongly believes that judges should play a central role as gatekeepers in determining the admissibility of expert witness testimony and thus help ensure the aim of Rule 702 by allowing only what is admissible evidence from experts to be presented to the finder of fact.

The issues presented here are at the core of LCJ's mission and its work over many years on Rule 702. LCJ believes it is essential to the future development of DRE 702 that the Court explain in this case the proper contours of the rule and admissibility in Delaware and urges the Court to do so in this case.

## SUMMARY OF ARGUMENT

This Court has long interpreted Delaware Rule of Evidence 702 to be consistent with its analogue, Federal Rule of Evidence 702. Both rules were promulgated to strike a careful balance. On one hand, litigants may introduce expert testimony that is "reliable" and "helpful" to the trier of fact.[5] On the other, to protect juries from being misled, the trial court has an obligation to ensure that the expert testimony is "the product of reliable principles and methods," is based on "sufficient facts or data," and "reliably appli[es] the principles and methods to the facts of the case."[6] To achieve the right balance, expert testimony may only be admitted where the trial court, acting as gatekeeper "decide[s]" that those crucial indicia of reliability are met.[7]

Over time, it became increasingly apparent to observers that FRE 702 was being fundamentally misinterpreted by some courts. Relying on opinions issued years before FRE 702 was substantively amended in 2000, judges punted the judicial gatekeeping function to the jury, assuming there was a "presumption" of expert admissibility, and denying motions to exclude evidence questioning the expert's

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5 Fed. R. Evid. 702; see also United States v. Barnes, 979 F.3d 283, 307 (5th Cir. 2020) (describing requirements for introduction of expert witnesses).

6 Id.

7 Fed. R. Evid. 104(a)

factual basis or methodological application by stating that such critiques go to the weight and not to the admissibility of the evidence.

LCJ's extensive research, as presented to the Advisory Committee working on amendments to FRE 702, tells the tale. Between January 1, 2015, and August 1, 2021, 179 federal cases stated a variation of the incorrect statement that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility."[8] Other federal cases erroneously reiterated a form of this statement: "[Q]uestions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility."[9] And 90 federal cases incorrectly insisted that the soundness of the "factual underpinnings" of the expert's analysis are "factual matters" for the jury.[10] Such statements cannot be reconciled with Rule 702.

These frequent errors led the Advisory Committee to issue, after long consideration, changes to the text of FRE 702. Those clarifications do not alter the substance of the rule. They do not establish a new regime. Instead, the Advisory Committee's amendments reflect efforts to "clarify and emphasize" the existing Rule. But the amendments make plain that when courts have said that there is a

[8] See Clarity and Emphasis, supra note 3, at 2.

[9] *Id.*

[10] *Id.*

thumb on the scale in favor of admissibility under FRE 702, they were wrong from the beginning. As the Advisory Committee commentary states, rulings that state that "critical questions of the sufficiency of an expert's basis" and the "application of the expert's methodology" are questions of weight and not admissibility are an "incorrect application of Rule 702 and 104(a)."

The Superior Court's decision exemplifies the very same errors that the Advisory Committee discussed. Faced with unsupported scientific claims that could be dispositive for some or all of the almost 75,000 claims filed in Delaware, the trial court denied in its entirety Defendants' motion to exclude. In doing so, the Superior Court abdicated its role as a gatekeeper when it repeatedly stated that crucial questions of methodology and basis were questions for the jury alone. The trial court also adopted the Ninth Circuit's misconception that Rule 702 should be applied with a "liberal thrust" favoring admission of expert testimony, extensively citing that circuit's incorrect understanding of FRE 702. And the Superior Court erroneously appeared to believe that Delaware law was different in some relevant way from FRE 702 but could not explain how or why.

The system-wide consequences of allowing courts to misinterpret DRE 702 are extraordinarily serious. This case tells that story. As the case has been presented to the Superior Court, there is no evidence that the drug *Zantac* is a carcinogen. Plaintiffs may be able to establish such a causal connection or they may not. LCJ

has no interest in that controversy. But the evidence presented here does not reach that standard or come anywhere close. The entire case presumes unsupportable claims about NDMA and how it may be created in the body after ingesting Zantac. That basic scientific contention falls outside the bounds of DRE 702 as properly construed.

This Court should identify DRE 702 as the authority directing the admissibility analysis trial courts must undertake and highlight descriptions of the gatekeeping function that amount to error. In particular, LCJ urges this Court to declare, as the federal Advisory Committee has stated, that any statements suggesting that expert testimony is presumed to be admissible misstate DRE 702. This is the correct result in this case and provides crucial guidance for Delaware courts going forward.

## ARGUMENT

### I. FRE 702 was recently amended to clarify that trial courts are required to vigorously exercise their gatekeeping function.

As shorthand, many courts have stated that the Supreme Court's decision in *Daubert* governs expert admission standards in federal court. That is inaccurate. FRE 702, enacted under the Rules Enabling Act, establishes the governing standard. But some courts have long ignored the standards in FRE 702 to announce a far more permissive standard for expert admission than the rule prescribes. In particular, courts have erroneously adopted a presumption of admissibility, spoken of FRE 702 having "liberal thrust" in favor of expert testimony, and held that all disputes about admissibility should be given wholesale to the jury to decide. The Advisory Committee has now addressed those misunderstandings, clarifying and emphasizing the proper standard in FRE 702. Because Delaware follows federal law on Rule 702, understanding the context of FRE 702 affects this Court's analysis of the admissibility decisions here.

#### A. Federal Rule 702, not *Daubert*, governs the standard for introduction of expert testimony in federal court.

*Daubert* is not the standard for admitting expert testimony. In federal court, that standard has always been set by the Rules of Evidence. The Rules Enabling Act gives the power to make procedural rules to the Supreme Court and the Judicial Conference committees. 28 U.S.C. § 2072(a) and (b). Those rules must include an "explanatory note" on the rule. 28 U.S.C. § 2073(d). The clarification to the expert

witness admissibility standard set forth in Federal Rule of Evidence 702 was adopted by the Supreme Court and submitted to Congress in 2023 following rulemaking actions conducted under the Rules Enabling Act.[11] As a rule of evidence adopted by the Supreme Court, Rule 702 supersedes any other law, including cases decided by the courts of appeal: "All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect." 28 U.S.C. § 2072(b). Thus, the "elements of Rule 702, not the caselaw, are the starting point for the requirements of admissibility." *See* Thomas D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony*, 95 NOTRE DAME L. REV. 2039, 2060 (2020).

Courts applying Rule 702 must decide whether the necessary elements for admission of opinion testimony have been shown by a preponderance of the evidence. *See* Fed. R. Evid. 702 (the proponentmust demonstrate "to the court that it is more likely than not that" the elements are established); *see also Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2316-17 (2016) (identifying Rule 702 as establishing the criteria under which "an expert may testify"). The subsections of Rule 702 enumerate the specific criteria that the expert must meet. For example, Rule 702(b) mandates that opinion testimony must be "based on

[11] Communication from the Chief Justice Transmitting Amendments to the Federal Rules of Evidence (Apr. 24, 2023) at 1, 7, https://www.govinfo.gov/content/pkg/CDOC-118hdoc33/pdf/CDOC-118hdoc33.pdf.

sufficient facts or data" and thus the court must decide the adequacy of an expert's factual foundation as a matter of admissibility. *See* Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, *Forensic Evidence, Daubert and Rule 702* (Apr. 1, 2018), at 43, in ADVISORY COMMITTEE ON EVIDENCE RULES APRIL 2018 AGENDA BOOK 49 (2018).

Corrective action became necessary because some courts went astray. As the Advisory Committee observed prior to adopting the 2023 amendment, "many courts have held that the critical questions of the sufficiency of an expert's basis" are questions of "weight and not admissibility," which is an "incorrect application of Rules 702 and 104(a)." FRE 702 advisory committee's note to 2023 amendment. [12] The Advisory Committee's comment stems from the fact that some federal caselaw misapprehends the controlling law.[13] While litigants "should have paid more

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[12] *See also* Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Forensic Evidence, Daubert, and Rule 702* (Apr. 1, 2018) at 49, in Advisory Committee on Evidence Rules April 2018 Agenda Book 49 (2018) ("[T]here are a number of lower court decisions that do not comply with Rule 702(b) or (d)… [S]ome courts have defied the Rule's requirements, which stem from *Daubert* – that the sufficiency of an expert's basis and the application of methodology are both admissibility questions requiring a showing to the court by a preponderance of the evidence.").

[13] Reinforcing the LCJ study cited in note 3 above, other observers have also shown that federal courts have not followed the gatekeeping standard in Rule 702. *See* Bayer Corp., *Amending Federal Rule of Evidence* 702 at 1 & n. 1, 20-EV-O Suggestion from Bayer -Rule 702 (Sept. 30, 2020), (discussing more than 200 rulings issued since January 2015 including erroneous law quoting erroneous language from *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988); *see also* Ford Motor Co., *Amending Federal Rule of Evidence 702*, at 3 & n. 11, 20-EV-L Suggestion from Ford – Rule 702 (Sept. 26, 2020) (discussing problematic rulings rooted in pre-*Daubert* caselaw within the Fourth Circuit), 20-ev-l_suggestion_from_ford_motor_company_-_rule_702_0.pdf (uscourts.gov).

attention to Federal Rule of Evidence 702, which superseded *Daubert* many years ago," outdated and problematic authority is still cited by courts around the country. *Kansas City S. Ry. Co. v. Sny Island Levee Drainage Dist.*, 831 F.3d 892, 900 (7th Cir. 2016).

Reviewing examples of this misunderstanding of the gatekeeping standard in the federal system illustrates the problem. For instance, the Eighth Circuit incorrectly applied a highly permissive admissibility test taken from precedent that long-predates Rule 702, concluding that opinion testimony can be excluded only if it is "so fundamentally unsupported" by its factual basis that "it can offer no assistance to the jury." *In re Bair Hugger Forced Air Warming Devices Prods. Liability Lit.*, 9 F. 4th 768 (8th Cir. 2021). The Third Circuit similarly declared—directly contrary to the Rule's text—that Rule 702 somehow "embod[ies] a strong preference for admitting any evidence that may assist the trier of fact" and requiring a "liberal policy of admissibility." *In re Sem Crude LP*, 648 F. App'x 205, 213 (3d Cir. 2016). Some courts invoked the Tenth Circuit's statement in *Werth v. Makita Elec. Works Ltd.*, 950 F.2d 643, 654 (10th Cir. 1991) that "doubts concerning" testimony's "factual sufficiency" go simply to the weight of the evidence. And the Ninth Circuit starkly read *Daubert* as "favoring admission" and often affirmed challenged experts' admission based on that diluted standard. *See Hardeman v. Monsanto*, 997 F.3d 941 (9th Cir. 2021), *citing Messick v. Novartis Pharms. Corp.*,

747 F.3d 1193, 1196 (9th Cir. 2014); *accord Wendell v. GlaxoSmith Kline L.L.C.*, 858 F.3d 1227, 1237 (9th Cir. 2017). These decisions misapplied Rule 702.[14]

### B. The United States Supreme Court adopted clarifications to Rule 702 to correct erroneous gatekeeping practices.

Because of the confusion among some courts, as shown above, the Advisory Committee on Evidence Rules engaged in detailed rulemaking work to remedy some courts' misunderstanding of Rule 702 and highlight judicial gatekeeping in the admission of expert testimony without substantively changing the rules. These efforts resulted in the Judicial Conference authorizing and the U.S. Supreme Court adopting important clarifications to Rule 702, driven because "many courts have held that the critical questions of the sufficiency of an expert's basis" and the "application" of the expert's methodology are questions of "weight and not admissibility." FRE 702 advisory committee's note to 2023 amendment. As the Advisory Committee observed, these "rulings are an incorrect application of Rules

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[14] *See* Hon. Patrick J. Schiltz, Report of the Advisory Committee on Evidence Rules (May 15, 2022) at 6, *in* COMMITTEE ON RULES OF PRACTICE & PROCEDURE JUNE 2022 AGENDA BOOK 866 (2022) (emphasis added):

> many courts have declared that the reliability requirements set forth in Rule 702(b) and (d) – that the expert has relied on sufficient facts or data and has reliably applied a reliable methodology – are questions of weight and not admissibility, and more broadly that expert testimony is presumed to be admissible. *These statements misstate Rule 702*, because its admissibility requirements must be established to a court by a preponderance of the evidence.

702 and 104(a).” The 2023 changes to FRE 702 make “quite clear” as “a simple matter of textual analysis” that it is “wrong” to state “[t]here is a presumption in favor of admitting expert testimony.”[15] This is not a change to the rule. It is a clarification of already existing law.

Crucially, these amendments do not impose “any new, specific, procedures,” but instead “clarify” the gatekeeping approach that has always been intended: that Rule 702 is governed by Federal Rule of Evidence 104(a)’s requirement that the *court* must decide “any preliminary question” of a witness’s admissibility. *See* FRE 702 advisory committee’s note to 2023 amendment. *See also* FRE 702 advisory committee’s note to 2000 amendment. (“the trial judge in all cases…must find that [expert testimony] is properly grounded, well-reasoned, and not speculative *before it can be admitted*”) (emphasis added). Because the amendment does not substantively change the expert admissibility standard, but only corrects the misconceptions that some courts have shown in their application of Rule 702, the understanding reflected in the amendment and the Advisory Committee’s analysis should inform courts' gatekeeping assessments now. *See Sardis v. Overhead Door Corp*., 10 F.4th 268, 284 (4th Cir. 2021) (discussing Advisory Committee’s analysis

[15] Memorandum from Daniel J. Capra, Reporter, Advisory Committee on Evidence Rules, to Advisory Committee on Evidence Rules, *Possible Amendment to Rule 702* (Apr. 1, 2021) at 11, *in* ADVISORY COMMITTEE ON EVIDENCE RULES APRIL 2021 AGENDA BOOK 90 (2021).

and concluding "[i]t clearly echoes the existing law on the issue."). That should include state courts that follow federal interpretations of Rule 702.

The 2023 amendment clarified FRE 702 in three key ways. *First*, the amendment confirms as FRE 702 had always required that the *court* must rule on admissibility before allowing the evidence to be shown to the trier of fact—this change emphasizes that such questions are *not* for the jury to decide. *Second*, the amendment places the preponderance of the evidence standard within the text of Rule 702, requiring the proponent of expert evidence to "demonstrate[] to the court that it is *more likely than not*" that all the requirements of Rule 702 are satisfied. *See* FRE 702, 2023 Amendment. This change clarifies that the "preponderance standard applies to the three reliability-based requirements added in 2000," contrary to the incorrect holdings of some courts. *See* FRE 702 advisory committee's note to 2023 amendment. This amendment shows that an even-handed preponderance of proof test, and not some presumption of admissibility of opinion testimony, is how judges must determine experts' admissibility. *Third*, Rule 702(d) is amended to emphasize that each expert opinion must "reflect a reliable application" of her principles and methods to the fact of the case. Although this standard "does not require perfection," the Advisory Committee emphasized that an expert may not make claims that are "unsupported" by the expert's basis and methodology. Again, judicial gatekeeping

is necessary to protect jurors who cannot "evaluate meaningfully" the expert's testimony. *Id.*

## II. The Superior Court misapplied DRE 702.

### A. The Superior Court made the same categories of mistakes as some of its federal counterparts.

The trial court's decision here commits the errors described in the cases cited above. Most starkly, the Superior Court adopted the Ninth Circuit's incorrect conception that "shaky" testimony should be admitted under the auspices of Rule 702 having a "liberal thrust favoring admission." *In re Zantac*, 2024 WL 28121168, at *5, *citing Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014).

The 2023 amendment, which should inform this Court's decision as an expression of FRE 702 consistent meaning, makes clear that Rule 702 does not favor admission over exclusion, and application of Rule 702 should not involve a "liberal thrust" favoring admission. FRE 702 advisory committee's note to 2023 amendment ("expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule.") (emphasis added). Moreover, both the Ninth Circuit and the Superior Court here ignored the crucial context of what the Supreme Court meant when it used that phrase. Although *Daubert* describes the Federal Rules of Evidence as having a "liberal thrust" that "relaxes the traditional barriers to opinion testimony," that statement contrasts Rule 702 (as it existed in 1993) against the "rigid general acceptance" requirement of *Frye v. United States*,

293 F. 1013 (D.C. Cir. 1923). *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579, 588-89 (1993). Nothing in *Daubert* suggested a general rule presuming admissibility for expert testimony.

Moreover, FRE 702 (like DRE 702) "displaced" alternative conceptions of gatekeeping that are "incompatible" with the rule. *Daubert,* 509 U.S. at 588-89. Reading DRE 702 to favor admission would fail to hold the proponent responsible for establishing that the expert's analysis more likely than not meets all Rule 702 requirements. And if cases suggest that courts can presume experts' admissibility and tilt the gatekeeping analysis, these "statements misstate Rule 702." *See* Hon. Patrick J. Schiltz, Report of the Advisory Committee on Evidence Rules (May 15, 2022) at 6, in COMMITTEE ON RULE OF PRACTICE & PROCEDURE JUNE 2022 AGENDA BOOK 866 (2022).

Similarly, the Superior Court here repeatedly stated that Defendants' critiques went to the "weight" of the expert testimony and not to its admissibility. *See In re Zantac*, 2024 WL 2812168, at *6 (lauding the Ninth Circuit's discussion of the "weight not admissibility" misconception); at *18; at *20 (noting that any challenge to Dr. Neugut's application of his methodologies "goes to the jury"); *28 (Dr. Miller); *36 (Emery's simulated environmental test); *36 (Emery's simulated gastric fluid test); *37 (WHO NAP test) *38 (stress testing); n. 164 (Dr. Sawyer's reliance on the Hidajat study). Thus, the Superior Court did not assess the sufficiency

of the experts' factual basis, the reliability of their methodologies, or whether their methodologies were reliably applied here, but presumed Plaintiffs' expert testimony was admissible and could simply be cross-examined at trial.

Each of these invocations of the "weight not admissibility" formula is incorrect. As explained above, the recent federal amendment was adopted to rectify "decisions incorrectly holding that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility." *In re Onglyza (Saxagliptin) and Kombiglyze (SaxaGliptin and MetaFormin) Prods. Liab. Litig.*, 93 F. 4th 339, 348 n. 7 (6th Cir. 2024); *Harris v. Fedex Corp. Svcs., Inc.*, 92 F. 4th 286, 303 (5th Cir. 2024) (district court "abdicated its role as gatekeeper" by allowing expert "to testify without a proper foundation" in contravention of Rule 702). As the Advisory Committee made clear, that was always the correct understanding of Rule 702. Reciting that evidentiary challenges go to weight and not admissibility does not satisfy the trial court's gatekeeping responsibility under a proper understanding of Rule 702, both pre-and post-amendment.

### B. This Court should recognize the corrective effects of amended FRE 702 and adopt those clarifications in Delaware.

At least one state Supreme Court has already recognized that the federal clarifications are relevant to their analogous Rules of Evidence even without any state amendment. The Supreme Court of Maryland observed that the post-

amendment "direction of analogous Federal Rule 702 confirms our understanding of meaningful gatekeeping…" *Katz, Abosch, Windesheim, Gershman & Freedman, P.A. v. Parkway Neuroscience and Spine Institute*, 301 A.3d 42, 68 (Maryland 2023). Based in part on that understanding, the Maryland Supreme Court broadly affirmed the trial court's exclusion of expert testimony, reversing the intermediate appellate court's decision to require admission of the unreliable expert testimony. *Id.* The intermediate appellate court had recited the "weight not admissibility" error in making its decision. *Katz, Abosch, Windesheim, Gershman & Freedman, P.A. v. Parkway Neuroscience and Spine Institute*, 283 A.3d 753, 768 (Md. Court of Special Appeals, 2022). The Supreme Court did not.

Other states have reacted to the amendment of FRE 702 by reforming their own evidentiary rules to mirror the Federal Rules of Evidence. *See* Arizona Rules of Evidence, Rule 702 (Amended January 1, 2024); Kentucky Rules of Evidence, Rule 702 (Amended July 1, 2024),; Ohio Rule of Evidence 702 (Amended July 1, 2024); Michigan Rule of Evidence 702 (Amended March 27, 2024). Each of those states thus also recognized the importance of FRE 702's corrective effects.

The Superior Court here seemed to insist that Delaware law differs substantially from FRE 702—distinguishing a related recent federal case as not "breath[ing] a whisper to the differences in Delaware law implicated here." *In re Zantac*, 2024 WL 2812168, at 6. But the Superior Court's claim that its decision was

driven by Delaware-specific law that splits from federal law is incorrect. As the Superior Court itself recognized in refusing to certify interlocutory appeal, it did not "ma[ke] some declaration of independence from its federal sister." *In re Zantac (Ranitidine) Litig.*, No. N22C-09-101, 2024 WL 3271976, at *4 (Del. Super. July 1, 2024). Nor could it have. This Court has consistently stated that because "Rule 702 is substantively similar to its federal counterpart, [FRE 702]," Delaware follows "the United States Supreme Court's interpretation of FRE 702 in *Daubert*." *Hudson v. State*, 312 A.3d 615, 625 (Del. 2024). In its opinion here, the Court should reaffirm that it seeks consistency with FRE 702 and, like its Maryland counterpart, acknowledge that the 2023 FRE 702 amendments mirror its pre-existing understanding of DRE 702 as well.

## CONCLUSION

The Superior Court's decision highlights the confusion some courts continue to have about the admissibility standard in FRE 702 and DRE 702. This Court was right to grant interlocutory review of this case and should take the opportunity presented to provide clear guidance to Delaware courts on the proper interpretation of DRE 702.

Respectfully submitted,

Dated: October 23, 2024

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**CERTIFICATE OF COMPLIANCE WITH TYPEFACE REQUIREMENT AND TYPE-VOLUME LIMITATIONS**

1. This brief complies with the typeface requirement of Supreme Court Rule 13(a)(i) because it has been prepared in Times New Roman 14-point typeface using Microsoft Word.

2. This brief complies with the type-volume limitations of Supreme Court Rule 28(d) because it contains 4588 words, which were counted by Microsoft Word.

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## CERTIFICATE OF SERVICE

I, Andrew Kinsey, hereby certify that on October 23, 2024, I caused true and correct copies of the foregoing

(i) PROPOSED BRIEF OF AMICUS CURIAE OF LAWYERS FOR CIVIL JUSTICE IN SUPPORT OF APPELLANTS

(ii) CERTIFICATE OF COMPLIANCE WITH TYPEFACE REQUIREMENT AND TYPE-VOLUME LIMITATION.

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