24-916(L),
24-2360(Con), 24-1121(Con), 24-2594

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

TIFFANY RUTLEDGE, individually and as mother, general guardian of, *et al.* KRISTOPHER WHITE, BRIDGET MCCONNELL, ALEXANDER HOLLAND, CHRISTINE HOLLAND

Plaintiffs-Appellants,

v.

WALGREEN CO., COSTCO WHOLESALE CORPORATION, CVS HEALTH CORPORATION, CVS PHARMACY, INC., SAFEWAY, INC. WALMART INC., a Delaware Corp., RITE AID CORPORATION, FAMILY DOLLAR INC.,

Defendants-Appellees.

(*For Continuation of Caption See Inside Cover*)

On Appeal from the United States District Court
for the Southern District of New York

AMICUS CURIAE BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF REHEARING AND/OR REHEARING *EN BANC*

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Dated: September 17, 2026

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TARGET CORPORATION, SAM'S WEST, INC., DOLLAR TREE, INC., 7-ELEVEN, INC., FAMILY DOLLAR STORES, INC., THE KROGER CO., DOLLAR TREE STORES, INC., JOHNSON & JOHNSON CONSUMER INC., BIG LOTS, GIANT FOOD LLC, ALBERTSON'S, HARRIS TEETER LLC, DOLGENCORP, LLC,

Defendants-Appellees.

MICHELLE PHIPPEN, individually and as General Guardian of P.P. and L. A., minors, ALISHA DAY, individually and as mother, General Guardian of A.D., a minor, SARAH STOKES, individually and as General Guardian of K.G., a minor, JUAN EMANUEL BORDOY, individually, MARY ELIN ARCE, individually and as Mother of JUAN EMANUEL BORDOY, AMANDA TRIGLOFF, individually and as General Guardian of R.S., a minor, DEANDRE BARBEE, individually, JANTAIL BARBEE, individually and as Mother of DEANDRE BARBEE, LAURIE COURINGTON, HUNTER COURINGTON, JENNIFER MORROW, ALENA MORROW, CALLISTA BASSETT, ANDREW BASSETT, SONNITA ROBY, individually and as General Guardian of D.P., a minor, SHANNON MIKUSKI, BRAYDON MCKENZIE, HEATHER GILLIAM, COLBY GILLIAM, TAYLOR BROWN, TARYNE BURKE, individually and as Mother with Court Appointed Guardian of ASHTON BURKE, SAMARI SIMS, individually, DENISA CULLOM, individually and as Mother of SAMARI SIMS, COLLIN STOVER, individually, DANA STEWART, individually and as Mother of COLLIN STOVER, RIAN CZAR JOHNSON, individually, SHILO RICH, individually and as Mother of RIAN CZAR JOHNSON, SHEENA SCHNEPP, individually and as Mother and Natural Guardian of H.S., a minor, ZAYNE COSTELLO, individually, CRYSTAL ALEXANDER, COURTNEY TILLOTSON, MICHELLE BROWN,

Plaintiffs-Appellants,

– v. –

WALGREEN CO., JOHNSON & JOHNSON CONSUMER INC., WALMART INC.,

Defendants-Appellees.

DISCLOSURE STATEMENTS PURSUANT TO RULES 26.1 AND 29 OF THE FEDERAL RULES OF APPELLATE PROCEDURE

Pursuant to Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, counsel for *amicus curiae* hereby state that the National Association of Manufacturers has no parent corporations and have issued no stock.

Pursuant to Rule 29(a)(4)(E) of the Federal Rules of Appellate Procedure, counsel for *amicus curiae* hereby states that (1) no party's counsel authored the brief in whole or in part; (2) no party or a party's counsel contributed money that was intended to fund preparing or submitting the brief; and (3) no person — other than the *amicus curiae*, its members, or its counsel — contributed money that was intended to fund the preparation or submission of the brief.

Counsel for *amicus* sought consent of all parties to the submission of this proposed brief. Defendants provided consent to the filing of this brief, whereas Plaintiffs stated their position that consent is not available at the rehearing phase and, as a result, did not provide consent.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae is the National Association of Manufacturers (NAM). The NAM and its members have a strong interest in ensuring that courts allow only reliable expert testimony. Allowing unsupported expert opinions can lead to unjust liability, undermine scientifically rigorous regulatory reviews of medicines and other products that are designed to enhance consumer health and safety, and spur more scientifically baseless litigation against manufacturers.

The NAM is the largest manufacturing association in the U.S., representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs 13 million men and women, contributes $3.0 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the U.S.

ARGUMENT

This petition for rehearing presents the Court with a critical opportunity to reconsider a ruling that undermines the district court's gatekeeping obligation to ensure that scientific testimony admitted in federal courts results only from sound

[1] Per the Disclosure Statement, this brief is compliant with FRAP 29(a)(4)(E).

scientific principles. In 2023, the federal judiciary amended Rule 702 to reaffirm this gatekeeping function by instructing trial judges to ensure that proponents of expert testimony show by *a preponderance of the evidence* that the testimony meets admissibility requirements for reliability. It affirmed these determinations are *questions of admissibility for judges* to decide and that expert evidence not meeting these thresholds is inappropriate for jury consideration. The panel's decision in this case fails to apply the amended Rule properly. It applied a lower standard of reliability to allow expert evidence that is merely "plausible" or "not unreasonable" go to a jury, and it wrongly held that questions of reliability above these low standards go to the weight a jury may put on the evidence, not its admissibility.

Here, the district court provided a textbook example of how judges are to assess expert evidence under the amended Rule to ensure that an "expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702. *See Rutledge v. Walgreen Co.*, 182 F.4th 168, 196 (2nd Cir. 2026) (noting "the district court's reasoning was considered and extensive"). Judge Cote conducted an in-depth examination of the reliability factors for each expert's testimony, identifying specific reasons the proffered testimonies did not meet the preponderance of the evidence threshold for reliability—including where experts exceeded limitations that the authors of the studies placed on them and cherry-picked data to advance their conclusions. *See In re Acetaminophen*, 707 F. Supp. 3d 309,

336 (S.D.N.Y. 2023). In the end, she found the opinions "obscured instead of informing the inquiry on causation" and held them inadmissible. *Id*. at 334.

The panel's ruling overturning Judge Cote's conclusions presents the exact situation the 2023 amendments were enacted to avoid. It turns questions of admissibility under Rule 702 into issues of weight for juries to consider. And, it held expert testimony may be admissible even when it has not met the indicia for reliability by a preponderance of the evidence. Specifically, the panel asserted that the gatekeeping role of the court is limited to "shield[ing] the jury" from testimony only that "constitutes 'junk science'" and that testimony, even when riddled with "not insignificant" limitations, may be admissible—stating the expert "discuss[es] the contrary evidence and presented his reasons for discounting it." *Rutledge*, 182 F.4th at 193-94, 199. For example, the panel found that an expert is allowed to cherry pick favorable studies over unfavorable ones merely by providing a purportedly "plausible" reason for doing so. *Id*. at 191. And it held that an expert could offer "counterintuitive" conclusions so long as they are "not unreasonable" or "not without support." *Id*. at 198. These erroneous thresholds for admissibility are extremely low and cannot ensure a testimony's reliability by a preponderance of the evidence—which is the minimum requirement under the Rule.

Further, the panel wrongly faulted the judge for "substituting its own judgments" when adhering to the gatekeeper requirement. However, it *is* the trial

court's responsibility to make determinations of reliability. The Rule specifically charges district courts to prevent juries from considering scientific theories that they have concluded are more likely to be *unreliable*. This obligation is particularly important when, as here, the product has undergone extensive scientific review as part of the government's regulatory regime to manage potential risks. It is important that courts not allow an agency's scientific process and decisions to be undermined by testimony not meeting the "more likely than not" threshold for reliability.

For these reasons, *amicus* urges the Court to grant the Petition for Rehearing/ Rehearing *En Banc* and affirm both the court's gatekeeping role and Rule 702's preponderance of the evidence standard for admissibility. Such a ruling would safeguard the scientific underpinnings of the courts, the federal regulatory review process, and the public health and safety interests of consumers.

I. RULE 702 IMPOSES A RIGOROUS JUDICIAL GATEKEEPING STANDARD THAT WAS AMENDED IN 2023 TO CORRECT COURTS' UNDULY LENIENT APPLICATION OF THE RULE

Under Rule 702 and the U.S. Supreme Court's jurisprudence, district courts are responsible for admitting only expert evidence that is "reliable" and will "help" the trier-of-fact make factual determinations. Fed. R. Evid. 702. In the 1990s, the Supreme Court shifted the focus of this inquiry. Instead of allowing evidence based on support that may be found in the scientific community, as the panel here would allow, it directed judges to assess the expert's assertions independently to ensure

they are based on sound scientific principles. *See Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 595, 595 (1995), *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). The Court understood that expert testimony "can be both powerful and quite misleading" and wanted to safeguard the scientific integrity of the judiciary. *Daubert*, 509 U.S. at 595.

In 2000, the Federal Rules Committee enshrined these principles into Rule 702, explaining in the notes that the courts are to apply a preponderance of the evidence standard when making these determinations. *See* Fed. R. Evid. 702 Advisory Committee Note to 2000 Amendment. Thus, for more than a quarter century, district courts have been charged with ensuring allegations of causation, defect, and other tenets of liability are not supported with scientifically unreliable expert testimony that is more likely to be wrong than right.

Several years ago, studies showed that numerous courts, similar to the panel below, applied outdated admissibility concepts and were not invoking Rule 702 properly. *See, e.g.,* Kateland R. Jackson & Andrew J. Trask, *Federal Rule of Evidence 702: A One-Year Review & Study of Decisions in 2020* (Sep. 30, 2021) (finding errors in every federal circuit). These courts applied "more lenient standards than Rule 702 permits," often by treating challenges to the reliability of an expert's opinions as issues of weight for the jury, rather than admissibility to be decided by the court. David E. Bernstein, *The Misbegotten Judicial Resistance to the Daubert*

Revolution, 89 Notre Dame L. Rev. 27, 30 (2013). This led the federal Advisory Committee on Evidence Rules to issue clarifying amendments, which became effective on December 1, 2023. *See* Mark A. Behrens & Andrew J. Trask, *Federal Rule of Evidence 702: A History and Guide to the 2023 Amendments Governing Expert Evidence*, 12 Texas A&M L. Rev. 43 (2024).

The 2023 amendments emphasize the "essential" importance of gatekeeping. Fed. R. Evid. 702 Advisory Committee Note to 2023 Amendment (hereinafter "2023 Advisory Committee Note"). First, the amendments make clear that the burden is on the proponent of the testimony to demonstrate by a preponderance of evidence to the court that the Rule's admissibility requirements are satisfied. *Id.* This change addressed incorrect decisions by "many courts" 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." Second, to address "overstatements" that "go beyond" the underlying science and may mislead jurors, the amendments "emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." *Id.*

Under these amendments, several circuits have taken opportunities like the one here to reinforce Rule 702's requirements and, in some cases, reevaluate their approach. *See* Lee Mickus, et al., *The Early Returns Are In: A Review of the First Two Years of Amended Federal Rule of Evidence 702*, 94 U. Cin. L. Rev. 915 (2026)

(discussing case law). For example, the Ninth Circuit previously held that Rule 702 "should be applied with a 'liberal thrust' favoring admission." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017). It now is aligned with the amended Rule 702, holding that there is no presumption of admissibility and emphasizing that "a proponent of expert testimony must always establish the admissibility requirements of Rule 702 by a preponderance of the evidence." *Engilis v. Monsanto Co.*, 151 F.4th 1040, 1050 (9th Cir. 2025). Similarly, the Fifth Circuit had a "general rule" that the "bases and sources" of an expert's opinion only "affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987). The Fifth Circuit has since recognized that these decisions were "an incorrect application of Rules 702 and 104(a)" and that expert testimony be "based on sufficient data or facts" and "reflect a reliable application of principles and methods to the facts of the case." *Nairne v. Landry*, 151 F.4th 666, 698 (5th Cir. 2025).

Rehearing is warranted here because the panel's decision revives precisely the permissive approach to expert admissibility the 2023 amendments were designed to correct. Experts are permitted to reach conclusions on a case's ultimate issues, so their conclusions must flow from a well-articulated and reliable methodology.

II. ADMITTING UNRELIABLE EXPERT EVIDENCE MAY LEAD TO PRODUCTS THAT PROVIDE FEWER BENEFITS, ARE LESS SAFE, AND CAUSE MORE HARM

Ensuring the scientific veracity of the courts also has tremendous real-world implications. Admitting evidence that a product can cause an illness, disability, or other harm based on *unreliable* science can jeopardize public health and safety.

Designating someone as an "expert" provides the witness with a cloak of authority. *See Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1063-64 (9th Cir. 2002). Jurors may falsely assume if an expert's testimony is admitted, it must be credible, particularly when the expert devises a plausible-enough-sounding theory for finding a source of compensation for people who are sick or have suffered an injury.

Indeed, studies have shown juries often fill the voids in the experts' testimony with sympathy and hindsight bias, regardless of the effectiveness of cross-examination or veracity of opposing expert evidence. *See* David Sklar, *Changing the Medical Malpractice System to Align with What We Know About Patient Safety and Quality Improvement*, 92 Acad. Med. 891, 891 (2017) (explaining juries may seek to "find someone to blame" to compensate a sympathetic plaintiff); *see also* Michael Haskel, *A Proposal for Addressing the Effects of Hindsight and Positive Outcome Biases in Medical Malpractice Cases*, 42 Tort & Ins. Prac. L.J. 895, 905 (2007). It is a maxim of science, pertinent to the panel's ruling, that "[p]lausibility is not a

substitute for evidence, however great may be the emotional wish to believe." E. Bright Wilson, Jr., An Introduction to Scientific Research 26 (1952).

Jurors imposing such liability also may not appreciate that their findings that a product is defective is not just a compensatory decision for the plaintiff; it instructs the manufacturer to change the product or labeling to address the "flaw." *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 328-29 (2008) (observing "tort duties of care" under state law "directly regulate" a product). Redesigning a safe and effective product or an accurate warning label based on unreliable testimony would lead to products that are less safe, provide fewer benefits, or could cause more harm.

It also would undermine the regulatory process intended to govern these public risks. With acetaminophen, as the district court detailed, the Food and Drug Administration has reviewed literature examining its use during pregnancy and repeatedly found insufficient evidence of a causal relationship between prenatal exposure and adverse neurodevelopmental outcomes. *See In re Acetaminophen*, 707 F. Supp. 3d at 330-31. Other agencies, from the Environmental Protection Agency to the National Highway Transportation Safety Administration, undertake similar science-based assessments of products that have potential risks, even when used as instructed. When social, health, or economic benefits of a product outweigh those risks, the agencies work with the manufacturers to make decisions about product designs and warnings that balance the risks. These decisions are based on sound,

vetted science and should not be undone through unreliable expert testimony that is focused on creating liability, that does not consider these other risks it may be creating, and that does not reliably assess the risks that it does review.

In addition, today, the mere ruling that a plaintiff's causation testimony may be admissible when it has not been shown to be reliable can have major adverse consequences. From a mass torts perspective, as here, it can spark a surge of lawsuit advertising amplifying experts' unfounded concerns, often against a beneficial medicine, device, or other therapeutic product. *See Gaming the System: How Lawsuit Advertising Drives the Litigation Lifecycle* (U.S. Chamber Inst. for Legal Reform, Apr. 2020) (tracking these trends). There are documented trends of viewers stopping their medications or not using a needed product after seeing such ads: they have led elderly people to stop taking blood thinners with dire consequences,[2] people at risk of HIV to stop taking preventative medications,[3] and viewers to mistakenly believe the FDA has recalled devices, when it has not.[4]

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[2] Mohamed Mohamoud, et al., *Discontinuation of Direct Oral Anticoagulants in Response to Attorney Advertisements: Data from the FDA Adverse Event Reporting System*, Annals of Pharmacotherapy, vol. 53, issue 9, at 962-63 (Sept. 2019).

[3] Pedro Serrano, et al., *Effect of Truvada Lawsuit Advertising on Preexposure Prophylaxis Attitudes and Decisions Among Sexual and Gender Minority Youth and Young Adults at Risk for HIV*, 35 AIDS 131-39 (2021).

[4] Christopher Tenggardjaja, et al., *Evaluation of Patients' Perceptions of Mesh Usage in Female Pelvic Medicine and Reconstructive Surgery*, 85 Urology 326, 327 (2015).

The ads also lead to the indiscriminate filing of claims, as people respond to ads even though they did not use the product or experience the injury at issue. *See* Cary Silverman, *Curbing Unsupported Claims in Mass Tort Litigation*, 94 U. Cin. L. Rev. 1097, 1108-11 (2026) (providing examples from several MDLs). Yet these "high volumes of unsupportable claims" can "clog the docket" and "frustrate efforts to assess the strengths and weaknesses of the MDL." Judge M. Casey Rodgers, *Vetting the Wether: One Shepherd's View*, 89 UMKC L. Rev. 873, 873 (2021).

Finally, when important, beneficial products are targeted by people, whether with a political, ideological, or financial motive, it is critical that courts get the science right. The scientific integrity of the courts must be protected.

CONCLUSION

For these reasons, *amicus* urges the Court to grant the Petition, affirm the district court ruling, and instruct judges that Rule 702 requires them to independently determine whether proffered testimony satisfies each admissibility requirement by a preponderance of the evidence.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify pursuant to Fed. R. App. P. 32(g)(1) that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2016 in 14 point Times New Roman font for text and footnotes.

I further certify that this brief contains 2,585 words and complies with the type-volume limitations of Fed. R. App. P. 29 and Second Circuit Rule 32.1.

/s/ Philip S. Goldberg
Philip S. Goldberg

Dated: September 17, 2026

CERTIFICATE OF SERVICE

I certify that on September 17, 2026, I caused service of the foregoing brief to be made by electronic filing with the Clerk of the Court using the ACMS system, which will send a Notice of Electronic Filing to all parties with an e-mail address of record, who have appeared and consent to electronic service in this action.

/s/ Philip S. Goldberg
Philip S. Goldberg

Dated: September 17, 2026