No. 21-1100

Supreme Court of the United States

3M COMPANY; ARIZANT HEALTHCARE, INC.,
Petitioners,

v.

GEORGE AMADOR,
Respondent.

BRIEF OF *AMICUS CURIAE* THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF PETITIONER

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes and Rules

Other Authorities

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae is the National Association of Manufacturers ("NAM"). The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12.5 million men and women, contributes $2.57 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for nearly two-thirds 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 United States.

The NAM is dedicated to manufacturing safe, innovative products that benefit consumers and protect human health, including medical devices that provide life-saving and life-enhancing benefits. The NAM has grave concerns about unsound science driving liability decisions that undermine these benefits, compromise the availability of important medical devices, and needlessly increase health care costs. Given modern mass tort litigation dynamics, the proper application of Rule 702 sometimes is the only safeguard against inappropriate liability. The NAM and its members have a substantial interest in this case.

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[1] Pursuant to Rule 37.6, counsel for *amicus curiae* certifies that this brief was not authored in whole or in part by counsel for any party and that no person or entity, other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of the brief. The parties received timely notice of the intent of *amicus curiae* to file this brief, and provided written consent to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Nearly thirty years ago, the Court began a series of rulings to assure the veracity of scientific evidence in the courtroom. The Court recognized that expert scientific testimony, particularly in the medical field, "can be both powerful and quite misleading" because juries have difficulty evaluating competing experts. *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 595, 595 (1995). As a result, the Court charged district courts with being "gatekeepers," stating "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589. Amendments to Rule 702 reinforced this commitment to science by ensuring such evidence is admissible only when its reliability is established by a preponderance of evidence. *See* Fed. R. Evid. 702, Comm. Notes on Rules—2000 Amend.

Here, the Eighth Circuit did not adhere to this jurisprudence and, therefore, failed to ensure the reliability of expert testimony. First, it asserted that any ruling to exclude evidence is "an exception to the general rule" and that scientific gaps in such testimony go to "weight, not admissibility." *In re Bair Hugger Prods. Liab. Litig.,* 9 F.4th 768, 777 (8th Cir. 2021). Second, although it invoked the "preponderance of the evidence" standard in theory, the court lowered the standard in practice by adhering to an anachronistic Eighth Circuit standard calling "for the liberal admission of expert testimony." *Id.* The court held that "both before and after *Daubert,*" the Eighth Circuit standard is that scientific evidence is admissible unless it is "so fundamentally unsupported" by its factual basis "that it can offer no assistance

to the jury." *Id.* at 778 (*citing Loudermill v. Dow Chem. Co.*, 863 F.2d 566 (8th Cir. 1988)).

In defending this erroneous standard for the admissibility of scientific evidence, the Eighth Circuit misconstrued this Court's statements in *Daubert* that gaps in reliability can be addressed through cross-examination and presentation of contrary evidence. *See id.* The Court made these statements to address contemporaneous concerns about transitioning away from the previous "general acceptance" standard—it still expressly required scientific testimony to meet Rule 702's reliability standards. *Daubert,* 509 U.S. at 595-96. To that end, the Court stated Rule 702 placed the burden on the party to show by a "preponderance of proof," *id.* at 592 n.10, that its expert's testimony is "ground[ed] in the methods and procedures of science." *Id.* at 590. Ensuring "evidentiary reliability," the Court continued, "goes primarily to relevance" (not weight) and is the responsibility of judges (not juries) given the danger experts might mislead. *Id.* at 591, 593. The Court concluded: "Conjectures that are *probably wrong* are of little use" to the courts. *Id.* at 597 (emphasis added).

The importance of this Petition is underscored by the fact that the Eighth Circuit is not alone in failing to apply the Court's jurisprudence on the admissibility of expert evidence. As detailed below, a study two authors of this brief published last year show that trial courts in *all* appellate circuits apply different standards for the admission of expert evidence. A majority of district courts do not cite the proper standards at all, and some cite to conflicting standards in the same case. These errors make it easier for a court to confuse weight with admissibility. As a

result, the quality of expert evidence in federal courtrooms varies greatly—circuit by circuit and judge by judge.

The lack of consistent scientific rigor in the federal judiciary is particularly problematic in the health care arena. Allegations based on unsound science are now regularly used to generate claims, force the formation of a multi-district litigation (MDL), and lead juries in bellwether trials to determine that a beneficial medical device or drug is somehow defective. These products are subject to considerable scientific analysis and review—by the manufacturer and U.S. Food & Drug Administration (FDA)—in determining whether a particular device or drug is safe and effective for use. *See* 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b) (discussing FDA's processes for evaluating medical devices). Often, device designs and warnings balance competing risks, as solving one potential outcome makes the product riskier elsewhere. These highly scientific decisions should not be undone through testimony that is *probably wrong*.

Amicus respectfully requests the Court to grant the Petition, resolve the widespread confusion in the courts on applying Rule 702, and safeguard the scientific underpinnings of the American health care system. The Court should reiterate that the proper standard for the admissibility of expert testimony is that the proponent must establish by a preponderance of the evidence that the expert's opinion meets the applicable indicia for reliability.

ARGUMENT

I. THE EIGHTH CIRCUIT'S MISCONCEPTION ABOUT THE RULE 702 STANDARD FOR THE ADMISSIBILITY OF EXPERT EVIDENCE IS A SYSTEMIC PROBLEM IN NEED OF REVIEW.

In *Daubert*, *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the Court changed the federal judiciary's responsibility for ensuring the reliability of expert testimony. It shifted the focus from the scientific community's general acceptance of a methodology to the need for judges to be gatekeepers of the science presented in their courtrooms by independently assessing the expert's assertions. It was now the job of the trial courts to protect tenets of liability, including defect and causation, from being decided based on unsound scientific allegations.

In 2000, Rule 702 was amended to synthesize these cases, affirming that admissibility of expert testimony must be based on sufficient facts, reliable principles and methods, and a reliable application of these principles and methods to the facts. Also, as the Court stated in *Daubert*, any party seeking to admit such evidence pursuant to Rule 104(a) must meet these Rule 702 standards by a "preponderance of proof." 509 U.S. at 592 n.10. If the threshold is not met, the evidence is inadmissible.

The Eighth Circuit's assertion that, even still, there is a "liberal admission of expert testimony" is incompatible with this jurisprudence. A "liberal admission" standard does not establish any threshold burden of proof or assure the expert testimony is

helpful, reliable, and reasonably supported by an adequate factual basis. The two standards cannot coexist, and the "liberal admission" standard is wrong.

The study by two of the authors of this brief for the organization Lawyers for Civil Justice last year found similar errors and confusion in every circuit in the country, particularly as it relates to the preponderance of the evidence standard. *See* Kateland R. Jackson & Andrew J. Trask, *Federal Rule of Evidence 702: A One-Year Review & Study of Decisions in 2020* (Sep. 30, 2021).[2] In the Eighth Circuit alone, numerous district courts cited both the preponderance and the conflicting liberal admissibility standards in the same rulings. *See Pitlyk v. Ethicon Inc.*, 478 F. Supp. 3d 784, 786-87 (E.D. Mo. 2020) ("The proponent of expert testimony must prove its admissibility by a preponderance of the evidence" *but* "the Eighth Circuit has held that expert testimony should be liberally admitted") (cleaned up); *Lemberger v. Union Pac. R.R. Co.*, 463 F. Supp. 3d 954, 961, 963 (D. Neb. 2020) (citing same conflicting standards); *Fair Isaac Corp. v. Fed. Ins. Co.*, 447 F. Supp. 3d 857, 869 (D. Minn. 2020) (same); *In re ResCap Liquidating Trust Litig.*, 432 F. Supp. 3d 902, 913 (D. Minn. 2020) (same); *Hoekman v. Educ. Minn.*, 335 F.R.D. 219, 236 (D. Minn. 2020) (same).[3]

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[2] https://1eea0198-de10-42c2-adc0-d9497e0cd1d5.filesusr.com/ugd/6c49d6_9aa76ee5643c4cfa847ba28ab8725d1e.pdf (last viewed Mar. 10, 2022).

[3] *See also Archer v. Bond*, 2020 WL 4931397, at *1 (W.D. Ark. Aug. 21, 2020); *Boyle v. Union Pac. R.R. Co.*, 2020 WL 6204342, at *4 (D. Neb. Oct. 22, 2020); *Cox v. Callaway Cnty., Mo.*, 2020 WL 1669425, at *1-2 (W.D. Mo. Apr. 2, 2020); *Gustafson v. Bi-State Dev. Agency*, 2020 WL 409011, at *1-2 (E.D. Mo. Jan. 24,

Of the 1,059 federal opinions that applied Rule 702 around the country in 2020, 61 of the cases similarly cited *both* the preponderance standard *and* a presumption favoring admissibility in the same opinion. These hybrid opinions were spread across federal appellate circuits, including the Southern District of New York and Northern District of California. *See Bobcar Media, LLC v. Aardvark Event Logistics, Inc.*, 2020 WL 1673687, at *2 (S.D.N.Y. Apr. 6, 2020) ("The proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied" *but* "it is nonetheless a well-accepted principle that Rule 702 embodies a liberal standard of admissibility for expert opinions") (cleaned up); *Cyntec Co. Ltd. v. Chilisin Elecs. Corp.*, 2020 WL

2020); *Hughes v. C.R. Bard Inc.*, 2020 WL 9078128, at *1 (W.D. Mo. Apr. 22, 2020); *Jayne v. City of Sioux Falls*, 2020 WL 2129599, at *2-3 (D.S.D. May 5, 2020); *Jorn v. Union Pac. R.R. Co.*, 2020 WL 6261693, at *4-5 (D. Neb. Mar. 25, 2020); *King v. Union Pac. R.R. Co.*, 2020 WL 3036073, at *4-5 (D. Neb. Jun. 5, 2020); *Lampton v. C.R. Bard Inc.*, 2020 WL 7013356, at *1 (W.D. Mo. Nov. 27, 2020); *Langrell v. Union Pac. R.R. Co.*, 2020 WL 3037271, at *4, 6 (D. Neb. Jun. 5, 2020); *Mannacio v. LG Elecs. USA Inc.*, 2020 WL 4676285, at *7 (D. Minn. Feb. 11, 2020); *Meade v. Ethicon, Inc.*, 2020 WL 6395814, at *2 (E.D. Ark. Nov. 2, 2020); *Monroe v. Freight All Kinds, Inc.*, 2020 WL 6588352, at *2 (W.D. Mo. Nov. 10, 2020); *Ranney v. Union Pac. R.R. Co.*, 2020 WL 3036200, at *4-5 (D. Neb. Jun. 5, 2020); *Refrig. Supplies Inc. v. Acadia Ins. Co.*, 2020 WL 7397002, at *3 (E.D. Mo. Dec. 17, 2020); *S. Minn. Beet Sugar Coop. v. Agri. Sys.*, 2020 WL 5105763, at *3 (D. Minn. Aug. 31, 2020); *Trice v. Napoli Shkolnik PLLC*, 2020 WL 4816377, at *10-11 (D. Minn. Aug. 19, 2020); *Washam v. BNSF Ry. Co.*, 2020 WL 5880133 (E.D. Ark. Oct. 2, 2020); *Watkins v. Lawrence Cnty.*, 2020 WL 2544469, at *1 (E.D. Ark. May 19, 2020); *Wegmann v. Ethicon Inc.*, 2020 WL 5814475, at *4 (E.D. Mo. Sep. 30, 2020).

5366319, at *3 (N.D. Cal. Sep. 8, 2020) ("The proponent of expert testimony bears the burden of establishing by a preponderance of the evidence that the admissibility requirements are met," *but* "there is a presumption of admissibility").[4]

Further, only about one-third of 1,059 rulings even mentioned the correct preponderance of proof standard. In the other two-thirds, the trial judge did not mention the appropriate standard at all. And in 13%, the trial court wrongly described the Rule 702 analysis as having a "liberal thrust" or mentioned a presumption favoring admissibility—both of which are incompatible with the Court's considerable Rule 702 instructions. Many courts applying a liberal standard of admissibility echoed the Eighth Circuit's assertion that challenges to an expert's factual basis go to the weight—not admissibility—of the evidence.[5]

Finally, 57 of the 93 judicial districts—including at least one district in every federal appellate cir-

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[4] *See also Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, 2020 WL 4251229, at *2-3 (S.D.N.Y. Feb. 19, 2020); *In re Term Commodities Cotton Futures Litig*., 2020 WL 5849142, at *11 (S.D.N.Y. Sep. 30, 2020); *Med. Soc'y of N.Y v. UnitedHealth Grp., Inc.,* 2020 WL 1489800, at *2 (S.D.N.Y. Mar. 26, 2020); *Packard v. City of New York*, 2020 WL 1479016, at *1, 3 (S.D.N.Y. Mar. 25, 2020).

[5] Those cases include *Katzenmeier v. Blackpowder Prods., Inc.,* 628 F.3d 948, 952 (8th Cir. 2010), which cites *Hose v. Chicago Nw. Transp. Co.,* 70 F.3d 968, 974 (8th Cir. 1995), for the proposition. *Hose,* in turn, cites *Loudermill v. Dow Chem. Co.,* 863 F.2d 565, 570 (8th Cir. 1988), for the same point. The Eighth Circuit's continued holding that the factual basis of expert testimony is a matter of weight, not admissibility, not only flies in the face of the current Rule 702, but it has its roots in cases that predate both the 2000 amendments and *Daubert*.

cuit—exhibited an intra-district split between courts employing a preponderance of proof standard and those that did not. *See* Jackson & Trask, *One-Year Review*, at 4. These results indicate the most active federal courts disagree over the correct interpretation of Rule 702, both substantively and procedurally, which could lead to dissimilar outcomes in substantially similar cases. Testimony that is excluded by one court may be admitted by another.

The end result is extensive variability in the admission of expert testimony. As Justice Ginsburg artfully explained before joining the Court, "it is logically inconsistent to require one judge to apply simultaneously different and conflicting interpretations of what is supposed to be a unitary federal law." *In re Korean Airlines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1175 (D.C. Cir. 1987). The Court should grant the Petition to ensure the federal judiciary speaks with a single voice on expert evidence admissibility.

II. ALLOWING SCIENTIFIC EVIDENCE THAT IS "PROBABLY WRONG" TO DEEM MEDICAL DEVICES DEFECTIVE UNDERMINES THE RIGOROUS SCIENTIFIC PROCESS REQUIRED UNDER FEDERAL LAW FOR MARKETING MEDICAL DEVICES.

Ensuring the veracity of scientific evidence is especially important when juries are asked, as here, to determine whether a medical device is defective in design. Medical devices, as with prescription medicines, have inherent risks, as well as unavoidable failure rates. A medical device is deemed beneficial when it has therapeutic value to a class of people, thereby giving physicians the ability to use, prescribe

or recommend the device when appropriate. The manufacturing and regulatory processes for bringing a device to market are all guided by sound science. The judicial process should reinforce, not undermine, this commitment to medical science.

Before the device can enter the market, the manufacturer must demonstrate its safety and efficacy through a defined, rigorous scientific process. *See* 21 U.S.C. § 360c(a)(1); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-50 (2001). Here, the FDA has cleared numerous iterations of the Bair Hugger as a Class II thermal regulating system as defined in 21 C.F.R. § 870.5900. *See* Dept. of Health & Human Servs., U.S. Food & Drug Admin., Product Classification Database.[6] The FDA cannot clear a Class II device if the device does not pass a safety and efficacy review, which is grounded in assessing scientific data. *See* 21 U.S.C. § 360c(i)(1); 21 C.F.R. § 807.87. This data regularly includes non-clinical data, such as bench testing (testing to tease out mechanical or design flaws) and clinical data in some cases. *See* Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 Food & Drug L.J. 365 (2014) (discussing the scientific process for bringing a medical device to market). In assessing an application, the FDA can request additional data (including clinical data), seek team or advisory panel reviews, or ask the manufacturer to provide certain information to clarify or strengthen a submission. *See* 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b).

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[6] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=830 (last viewed Mar. 10, 2022).

According to FDA records, the manufacturer of the Bair Hugger conducted an assessment of the safety and effectiveness of the device through development, production, and post-production. *See* Summary of Safety and Effectiveness, Arizant Healthcare Inc.[7] The manufacturer confirmed that multiple hazard/risk analyses were performed to identify inherent risks in the Bair Hugger and eliminate them where possible. *See id.* The Bair Hugger was subjected to performance and safety testing, including by third-party testing laboratories to ensure the device would perform as intended and would be effective in treating the conditions identified as the intended uses. *See id.* Further, as detailed in the Petition, the FDA studied the allegations at the heart of this litigation and found they were without clinical support. Pet. at 10. In sum, bringing a medical device to market is a science-driven process subject to substantial federal oversight.

Although courts have allowed juries to reach different conclusions than manufacturers and the FDA (though here the jury did *not* find the Bair Hugger defective), juries should not be able to do so when presented with scientific testimony that is *probably wrong*, *i.e.*, that it fails to meet the preponderance of evidence standard. Here, the District Court overseeing the Bair Hugger MDL initially admitted plaintiffs' expert testimony at this bellwether trial. But, once the testimony was fully presented and after a new round of briefing and argument, the District Court concluded that the testimony did not meet the scientific rigor to satisfy Rule 702's requirements.

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[7] https://www.accessdata.fda.gov/CDRH510K/K060865.pdf (last viewed Mar. 10, 2022)

Exercising its gatekeeping role, the District Court found the gaps in the expert's reasoning too sizable to be reliable enough for a liability finding. Thus, the District Court was guided by medical science.

Assessing the strength of the parties' positions, which is the purpose of the bellwether process, includes evaluating the veracity of the scientific allegations. As this Court directed in *Daubert*, should the trial court, as here, conclude the evidence presented "is insufficient to allow a reasonable juror to conclude that the position *more likely than not* is true, the court remains free to direct a judgment, Fed. Rule Civ. Proc. 50(a), and likewise to grant summary judgment." 509 U.S. at 596 (emphasis added).

By contrast, the Eighth Circuit overturned this ruling—not out of adherence to medical science—but because it applied an erroneous, overly permissive admissibility standard. The problem from a medical science perspective is that a judicial finding that a medical device's design is defective suggests the manufacturer should change the design to address the "flaw." However, redesigning a safe and effective device based on a "flaw" that has not been shown by a preponderance of evidence to actually exist could lead to a design that is less safe. The new design could make the product less valuable and undermine the risk-benefit balancing, which could increase the device's risks in ways not considered in the litigation.

The Court should grant the Petition to reinforce the obligation of the judiciary to prevent these outcomes. Medical device designs and warnings must be guided by sound science at every step of the way.

III. LIABILITY BASED ON UNSOUND SCIENCE REDUCES THE AVAILABILITY OF BENEFICIAL MEDICAL DEVICES AND DRUGS, AND INCREASES COSTS.

The Eighth Circuit's liberal admissibility standard threatens to adversely affect those who rely on the benefits of a medical device, drug or other product—which Petitioner states here is 50,000 people per day. Unfounded liability awards and settlements can lead to significant, unnecessary risks and costs to manufacturers and consumers, as well as threaten the availability of beneficial devices, drugs and other valued products.

The problem is that jurors who are allowed to consider such expert evidence may fall into the trap of falsely assuming that a patient's condition is the result of the device. Designating someone as an "expert" provides the witness with a cloak of authority that cannot be reliably addressed by cross-examination or the introduction of opposing expert testimony, as the Eighth Circuit suggested. *See Mukhtar v. Cal. State Univ.,* 299 F.3d 1053, 1063-64 (9th Cir. 2002) (referring to "the aura of authority experts often exude, which can lead juries to give more weight to their testimony"). In many cases, a plaintiff is severely injured and the expert devises a plausible-enough-sounding theory for finding some source of compensation for that plaintiff. Indeed, it has been the experience of the NAM and its members that when courts admit expert testimony that has not been properly validated, medical device and drug manufacturers along with physicians are particularly susceptible to "deep pocket jurisprudence." Victor E. Schwartz, Phil Goldberg & Christopher E. Ap-

pel, *Deep Pocket Jurisprudence: Where Tort Law Should Draw the Line*, 70 Okla. L. Rev. 359 (2018).

To this end, studies have shown that juries often fill the voids in the experts' testimony with hindsight bias and sympathy, rather than sound science—regardless of the effectiveness of cross-examination or the veracity of opposing expert evidence. *See* David P. 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). "Hindsight bias" refers to the "human tendency to look back upon past events and view them as being expected or obvious" even though they may not be. Michael A. 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 leads those who know the outcome (good or bad) to view the product or care in the same way. *See* Eric J. Thomas & Laura A. Petersen, *Measuring Errors and Adverse Events in Health Care*, 18 J. Gen. Intern Med. 61, 63 (2003).[8]

In *Daubert*, the Court assessed the scientific allegations against the morning sickness pill Bendectin, which was beneficial to many women. The manufacturer withdrew Bendectin from the American market during the litigation "for nonmedical reasons" including "significant adverse publicity and the burdens of litigation," as opposed to any finding that it was unsafe for mothers or fetuses. Margaret M. Dotzel, *Determination That Bendectin Was Not Withdrawn*

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[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494808/pdf/jgi_20147.pdf

From Sale for Reasons of Safety or Effectiveness, 64 Fed. Reg. 43190, 43191 (1999). At the same time, silicone breast implant litigation forced Dow Corning to file Chapter 11 bankruptcy despite the fact that epidemiology studies found no link between the medical devices and autoimmune disorders, cancer or other disease. *See* Marcia Angell, *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* (NY: W Norton & Co, 1997) (by New England Journal of Medicine executive editor).

Today, mass tort litigation involving medical devices and drugs is routinely based upon questionable scientific foundations. For example, in 2019 an online pharmacy made headlines by reporting to the FDA that it "detected extremely high levels" of N-Nitrosodimethylamine (NDMA) in the heartburn medication ranitidine. FDA Docket No. FDA-2019-P-4281. Out of caution, manufacturers and retailers recalled and stopped selling ranitidine medicines. However, the pharmacy's methodology was fundamentally flawed, and the FDA warned the methodology was "not suitable" for testing NDMA in ranitidine. FDA Updates and Press Announcements (Oct. 2, 2019), FDA.[9] Yet, advertisements recruiting plaintiffs for this litigation ran around the country, leading tens of thousands of plaintiffs to file claims over NDMA in ranitidine and the formation of a still ongoing MDL. *See* MDL, No. 20-MD-2924.

In some large MDLs over medical devices and drugs, like the case at bar, proper application of Rule 702 is the only mechanism for avoiding substantial,

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[9] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (last viewed Mar. 10, 2022).

inappropriate liability given the courts' inability to try each claim. *See*, *e.g.*, *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 982 F.3d 113, 123 (2nd Cir. 2020) (explaining in a medical device case that "not only was it appropriate for the district court to take a hard look at plaintiffs' experts' reports, the court was required to do so to ensure reliability"); *In Re: Zoloft (Sertralinehydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3rd Cir. 2017) (upholding the district court's ruling that the scientific testimony was inadmissible because "courts are supposed to ensure that the testimony given to the jury is reliable"). Rule 702 provides a critical safeguard for justice, particularly in large MDLs, and the Court should grant the Petition to enforce it.

CONCLUSION

For these reasons, *amicus curiae* respectfully request that this Court grant the Petition.

Respectfully submitted,

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