No. ______

In the
Supreme Court of the United States

3M COMPANY; ARIZANT HEALTHCARE, INC.,

Petitioners,

v.

GEORGE AMADOR,

Respondent.

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

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, this Court held that, to be admissible, expert testimony must be "not only relevant, but reliable." 509 U.S. 579, 589 (1993). In *General Electric Co. v. Joiner*, the Court firmly rejected the view that there is "a preference for admissibility" that requires a "particularly stringent standard" of appellate review of decisions to exclude expert testimony. 522 U.S. 136, 140-43 (1997). The decision below manages to violate both those clear precedents at once. As to initial admissibility, the Eighth Circuit's lax standard—allowing expert testimony unless the testimony is "so fundamentally unsupported by its factual basis that it can offer no assistance to the jury," App.12—conflates reliability and relevance. As to appellate review, the decision below ignores *Joiner* and undermines the district court's gatekeeping role.

Those errors are particularly glaring here since the expert testimony—made-for-litigation complaints about a medical device that is the industry standard used 50,000 times each day—is precisely the kind of unreliable testimony *Daubert* is designed to exclude. Even the appellate decision reversing the District Court's well-considered decision to exclude acknowledges the testimony's flaws. The result is that thousands of cases in a pending MDL will be adjudicated based on evidence that should be excluded twice-over based on this Court's precedents.

The questions presented are:

1. Whether the Eighth Circuit's "so-fundamentally-unsupported" standard of initial

admissibility for expert testimony conflicts with this Court's precedents and Federal Rule of Evidence 702.

2. Whether the Eighth Circuit's insufficiently deferential standard of appellate review of decisions excluding expert testimony conflicts with this Court's precedents and Federal Rule of Evidence 702.

PARTIES TO THE PROCEEDING

Petitioners are 3M Company and Arizant Healthcare, Inc., which were Appellees below and Defendants in the District Court.

Respondent is George Amador, who was Appellant below and Plaintiff in the District Court.

STATEMENT OF RELATED PROCEEDINGS

John Petitta v. 3M Company, No 19-2932 (8th Cir.) (opinion and judgment issued May 28, 2021).

Nancy Axline v. 3M Company, et al., No. 19-1180 (8th Cir.) (opinion and judgment issued August 5, 2021).

Louis Gareis, et al. v. 3M Company, et al., No. 18-3553 (8th Cir.) (opinion and judgment issued August 17, 2021).

Louis Gareis, et al. v. 3M Company, et al., No. 18-3580 (8th Cir.) (opinion and judgment issued August 17, 2021).

In addition, this case arises from a multidistrict litigation that includes other cases alleging similar product-liability claims as the instant case. *In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation*, MDL No. 15-2666 (D. Minn.).

CORPORATE DISCLOSURE STATEMENT

3M Company is a corporation whose shares are publicly traded. 3M Company does not have a parent corporation, and no publicly held corporation owns 10% or more of 3M's stock.

Arizant Healthcare, Inc. was dissolved entirely in December 2014.

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PETITION FOR WRIT OF CERTIORARI

Petitioner 3M manufactures the Bair Hugger, a medical device that uses convection heating to keep patients warm during knee and hip surgery. It is the most widely used patient-warming system in the world, regarded by the medical profession as the gold standard and cleared by the FDA as safe and effective. For the past several years, however, the Bair Hugger has been the target of litigation instigated by its original inventor—and now bitter competitor—Dr. Scott Augustine, who lost his rights in the Bair Hugger when he pled guilty to fraud. Augustine's efforts have resulted in more than 5,200 pending cases claiming that the Bair Hugger causes infections.

This petition involves the District Court's considered decision to exclude the testimony of plaintiffs' general-causation experts. Those experts had never studied the Bair Hugger before, and they developed their opinions specifically for litigation—drawing in part on questionable studies organized and funded by Augustine himself. Hardly a reflexive excluder of expert testimony, the District Court at first exercised its discretion to admit the testimony. But after holding a bellwether trial—which resulted in a complete defense verdict for 3M—and observing the plaintiffs' experts testify live, the court reconsidered its initial ruling. In a careful and thoroughly reasoned decision, the District Court explained that the analytical gaps and other flaws in the expert testimony rendered it unreliable.

On appeal, the Eighth Circuit acknowledged that the District Court had correctly identified numerous flaws in the experts' opinions. But the court

nevertheless reversed on the ground that the expert testimony was not "so fundamentally unsupported" as to be useless to the factfinder. That holding conflicts with this Court's precedents twice over. First, the "so-fundamentally-unsupported" standard effectively reduces evidentiary *reliability* to mere relevance, opening the courthouse door to all manner of dubious "experts" and defying Federal Rule of Evidence 702, *Daubert*, and *Joiner*. Not surprisingly, no other circuit employs that erroneously lax standard of admissibility. Second, the Eighth Circuit applied an insufficiently deferential standard of appellate review to the District Court's decision to *exclude* expert testimony, based on a perceived "juxtaposition" between circuit precedent "call[ing] for the liberal admission of expert testimony" and abuse-of-discretion review of decisions to exclude, rather than admit, experts. App.10. But *Joiner* makes clear that abuse-of-discretion review applies equally, and no less deferentially, to decisions to exclude experts. The Eighth Circuit thus replicated the very error this Court corrected years ago in *Joiner*.

This Court's intervention is imperative, and this petition presents an ideal vehicle for review. If the decision below is allowed to stand, then the message to district courts in the Eighth Circuit—in this MDL and beyond—will be clear: Expect to be *reversed* for excluding deeply flawed "expert" testimony, unless it is "so fundamentally unsupported" that it is essentially irrelevant. Never mind that Rule 702 and *Daubert* demand actual reliability, and that *Joiner* requires deference to district courts in the exercise of their evidentiary gatekeeping function. The Court should grant review.

OPINIONS BELOW

The opinion of the Eighth Circuit is reported at 9 F.4th 768 and reproduced at App.1-45. The opinions of the District Court are unreported but reproduced at App.47-133.

JURISDICTION

The Eighth Circuit issued its opinion on August 16, 2021, and denied a timely petition for rehearing on November 9, 2021. Judge Loken voted to grant the petition. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Federal Rule of Evidence 702 is reproduced at App.134.

STATEMENT OF THE CASE

A. Legal Background

In its landmark *Daubert* decision in 1993, this Court construed the then-current version of Federal Rule of Evidence 702 and clarified the standard for admissibility of expert testimony. The Court explained that expert opinions (like all evidence) must first meet the basic minimum requirement of relevance, to "assist the trier of fact." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590-91 (1993). But the Court held that relevance alone was not enough when it comes to expert testimony, because Rule 702 *also* requires "that an expert's testimony pertain to 'scientific knowledge,'" which demands "a standard of evidentiary reliability." *Id.* at 590. In other words, expert testimony must be "not only relevant, but *reliable*" before a court may admit

it. *Id.* at 589 (emphasis added). The Court identified several non-exclusive factors to guide the reliability inquiry, including whether the expert's theory has been tested, whether it has been subjected to peer review or publication, its known or potential rate of error, and whether it is generally accepted. *Id.* at 593-94. The Court emphasized that district courts should play a "screening" or "gatekeeping role" in determining whether expert testimony "rests on a reliable foundation." *Id.* at 596-97.

Four years later, in *Joiner*, the Court clarified the reliability standard, holding that a district court may properly refuse to admit expert testimony if the court concludes "that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The Court explained that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Id.* District courts are therefore free to reject, as unreliable, expert opinions that are analytically disconnected from the underlying data or studies on which the opinions rely.

Joiner also confirmed that appellate courts should review a district court's decision to admit *or exclude* expert testimony under a deferential abuse-of-discretion standard of review. The district court in *Joiner* had excluded the plaintiff's proffered expert testimony after concluding that the experts failed to establish a link between exposure to a chemical substance and cancer. *Id.* at 140. The Eleventh Circuit reversed, reasoning that "[b]ecause the Federal Rules of Evidence governing expert testimony

display a preference for admissibility," the deferential appellate review standard for decisions to admit expert evidence was inapposite when it came to decisions to exclude such evidence. Instead, it was appropriate to apply a "particularly stringent standard of review to the trial judge's exclusion of expert testimony." *Id.* (quoting 78 F.3d 524, 529 (1996)).

This Court firmly rejected the Eleventh Circuit's approach of skewing the standard of review based on a perceived "preference for admissibility." *Id.* Instead, the Court held that the deferential abuse-of-discretion standard applies to *all* district court rulings on expert testimony. *Id.* at 142. Thus, "[a] court of appeals applying 'abuse-of-discretion' review to such rulings may not categorically distinguish between rulings allowing expert testimony and rulings disallowing it." *Id.* The Court expressly rejected the Eleventh Circuit's suggestion that *Daubert* had somehow "altered this general rule in the context of a district court's decision to exclude scientific evidence." *Id.* As the Court explained, by "applying an overly 'stringent' review" to the district court's exclusion of expert testimony, the Eleventh Circuit "failed to give the trial court the deference that is the hallmark of abuse-of-discretion review." *Id.* at 143.

Rule 702 was amended in 2000 to align it with *Daubert* and *Joiner* and "affirm[] the trial court's role as gatekeeper" to "exclude unreliable expert testimony." Advisory committee note to 2000 amendments. Before the 2000 amendments, Rule 702 required only that expert testimony "assist the trier of fact to understand the evidence or to determine a fact

in issue." Act of Jan. 2, 1975, Pub. L. No. 93-595, 88 Stat. 1926, 1937 (1975). The current version of the rule adds explicit reliability requirements, providing that a qualified expert may offer testimony only if the proponent of the testimony shows that: (a) the testimony "will help the trier of fact to understand the evidence or to determine a fact in issue"; (b) the testimony "is based on sufficient facts or data"; (c) the testimony "is the product of reliable principles and methods"; and (d) the expert "has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

The advisory committee note elaborates that "the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case." Fed. R. Evid. 702 advisory committee note to 2000 amendments. The note also specifies several factors that should guide the district court's reliability determination, including whether the expert's opinion was developed for litigation, whether the expert has "unjustifiably extrapolated from an accepted premise to an unfounded conclusion," and whether the expert "has adequately accounted for obvious alternative explanations." *Id.* In short, the amended rule "requires that the testimony must be the product of reliable principles and methods that are reliably applied to the facts of the case." *Id.*

B. Factual Background

1. Invented in 1987 by Dr. Scott Augustine, the Bair Hugger system is a convective or forced-air warming device used to keep patients warm and

maintain normal body temperature during surgery. 3M.App.103, 8¶4.[1] The Bair Hugger consists of a heating unit, blower, hose, and perforated blanket that is placed over the patient's chest and arms. 3M.App.8¶4, 103. After the heating unit draws in ambient air through a filter and warms it, the blower pushes the warmed air through the hose and into the perforated blanket. 3M.App.8¶4, 103. The perforated blanket gently distributes the warmed air over the patient's upper body, helping to regulate body temperature.

The Bair Hugger system is the most widely used patient-warming device in the world. Since its invention, the Bair Hugger has been used in more than 300 million surgeries.[2] It is currently used in approximately 50,000 surgeries around the world *each day*.[3] The FDA considers the Bair Hugger to be safe and effective. 3M.App.103, 462 (Tr.1234:14-23). As recently as 2017, the FDA issued an alert "reminding health care providers" that the use of forced-air warming systems (such as the Bair Hugger) has "been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients." 3M.App.103.

Numerous studies back the FDA's recommendation. Every medical organization and government publication to address forced-air warming

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[1] "3M.App." refers to 3M's appendix in the Court of Appeals.

[2] *See Proven Temperature Management Solutions*, 3M, https://bit.ly/3J2hDsS (last visited Feb. 7, 2022).

[3] *See* 3M, *3M Bair Hugger System Research Compendium* at 2, https://bit.ly/3rvpg5e (last visited Feb. 7, 2022).

systems has concluded that there is no reliable evidence linking them to an increased risk of surgical-site infections. In the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection, for example, more than 400 physicians from 52 countries reached a "strong consensus" that "no studies" showed an increase in surgical-site infections related to the use of forced-air warming devices. 3M.App.162-64. In 2018, the International Consensus again endorsed the conclusion that there is "no evidence to definitively link" forced-air warming to an increased risk of surgical-site infection, and the group added that forced-air warming is used to "prevent hypothermia and maintain intraoperative normothermia," *reducing* complications such as surgical-site infections. 3M.App.350.

Many other independent medical and scientific organizations have reached the same conclusion, including a 2013 review by the Association of periOperative Registered Nurses, 3M.App.147, a 2013 review by the ECRI Institute, 3M.App.132, a 2014 literature review in the *Journal of Bone & Joint Surgery*, 3M.App.153-59, and a 2015 review by the Duke University School of Medicine's Infection Control Outreach Network, 3M.App.172-73.

2. Fighting that medical and scientific consensus is Dr. Scott Augustine, the original inventor of the Bair Hugger and now its bitter competitor. Augustine marketed and sold the Bair Hugger from 1987 until the early 2000s, when he pled guilty to Medicare fraud and lost his rights in the invention. *See In re 3M Bair Hugger Litig.*, 924 N.W.2d 16, 19 (Minn. Ct. App. 2019); 3M.App.2-3. After losing his rights in the Bair

Hugger, Augustine developed a new (conduction-based) patient-warming device that he dubbed the "HotDog." *In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19, 21.

Since developing the HotDog, Augustine has waged a ceaseless campaign to discredit his old invention and promote his new one. App.4. Between 2004 and 2009—while he was still barred from participating in federal health-care programs—Augustine "deprecated the Bair Hugger in other countries, leading the UK National Institute for Health and Clinical Excellence to reject his claim that [forced-air warming devices] increase the risk of [surgical-site infections] and a German court to enjoin him from making false claims that the Bair Hugger increased bacterial contamination in operating rooms." *In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19. Between 2009 and 2014, Augustine organized and helped fund eight different studies intended to show that the Bair Hugger causes surgical-site infections. Despite Augustine's efforts, the studies carefully disclaimed finding any causal link between forced-air warming devices and an increased risk of surgical-site infections. *See* A1297, A1323, A1152, A1170, A1157, A1260, A1163; 3M.App.217.[4]

3. 3M acquired the rights to the Bair Hugger system in 2010. For years afterward, Augustine used threats against 3M and the Bair Hugger to try to force 3M to purchase the rights to the HotDog. *In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19. In 2012, for example, he threatened that 3M would suffer "a lot of

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[4] "A" refers to plaintiffs' appendix in the Court of Appeals.

negative marketing rhetoric about 3M causing infection" unless 3M accepted his offer. 3M.App.5. Two years later, Augustine told 3M he planned to have "at least five more" negative studies about the Bair Hugger published unless 3M agreed to "explore a distribution or licensing relationship" covering the HotDog. 3M.App.383, 385. And in 2017, Augustine attempted to follow through with his threat, publishing an article about a study that supposedly showed that switching from the Bair Hugger system to the HotDog decreased surgical-site infections. 3M.App.292-95. That "study," discovery later revealed, has been "discredited." App.96.n.28; *see* 3M.App.50; 3M.App.25; 3M.App.298-99¶9; *see also In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19, 20-24.

The FDA has repeatedly rebuked Augustine's attacks on the Bair Hugger. From 2009 to 2010, the FDA investigated and ultimately rejected Augustine's claim that the Bair Hugger increased the risk of surgical-site infections. *See In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19. When that failed to deter Augustine, the FDA sent him a 2012 warning letter, stating that his claims were without clinical support. *Id.*; 3M.App.289. And in 2017, the FDA issued a safety alert to dispel "concerns of a potential increased risk" of surgical-site infections from forced-air warming devices. 3M.App.103. The alert reiterated that "the FDA continues to recommend" such devices, rejected any "association between" the use of forced-air warming devices and surgical-site infections, and reminded healthcare providers that the evidence in fact "demonstrated" that the use of such devices results in "decreased risk of infection for patients." 3M.App.103.

C. Proceedings Below

As part of his campaign against the Bair Hugger, Augustine hired a law firm to promote litigation against his old invention. *See In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19; 3M.App.19. By December 2015, more than 60 plaintiffs had filed cases against 3M in federal district courts around the country, alleging that they had contracted deep-joint infections during surgeries that used the Bair Hugger. The Judicial Panel on Multidistrict Litigation transferred the cases to the District of Minnesota for consolidated pretrial proceedings. *See* 28 U.S.C. §1407(a). Since then, nearly 6,000 lawsuits have been filed as part of the MDL. *See* App.4. Additional lawsuits were filed in state court in Minnesota, where 3M is headquartered, and discovery in the two fora was coordinated.

1. Plaintiffs' Theories of General Causation and Expert Evidence

Relying on the "studies" Augustine instigated and funded, the plaintiffs in this litigation alleged two theories of general causation. The first, called the "airflow disruption" theory, alleges that the Bair Hugger's warm air flow creates turbulence in the operating room, in the process lifting "squames"—shed flakes of skin tissue that can carry bacteria—into the air and carrying them to the surgical site. The second, called the "dirty machine" theory, alleges that the Bair Hugger system itself contains bacteria that are blown through the perforated blanket and reach the surgical site. *See* App.48.

To advance those theories, the plaintiffs offered three medical experts and one engineering expert. All

four formed their opinions for litigation; none had previously studied the Bair Hugger. The engineering expert did not testify directly to general causation, but instead created and ran a computer simulation showing how the Bair Hugger system might affect airflow and squame circulation in a hypothetical operating room. A1629 (Tr.880:3-17). For their part, the medical experts did not conduct any experiments, laboratory work, or epidemiological studies. App.71-72. Instead, two of the medical experts relied on existing medical literature and the engineering expert's simulation, and the third medical expert relied on Augustine's studies together with his own clinical experience. App.71-73.

2. 3M's Motions to Exclude Expert Evidence

3M moved to exclude the plaintiffs' general-causation experts and requested summary judgment, and in October 2017, the state and federal courts held a joint hearing on the motions. A2342-2574, A2575-2803, A2804-2943. The Minnesota state court excluded the experts and granted summary judgment to 3M, and the state appellate court later affirmed. *See In re 3M Bair Hugger Litig.*, 924 N.W.2d at 19-20. The District Court, however, allowed the plaintiffs' claims to proceed to a bellwether trial. *See* Add.54-83; App.49-51.[5] The first trial resulted in a complete defense verdict for 3M. App.50-51; 3M.App.483-86.

After the bellwether trial, 3M moved for reconsideration of its previous motions to exclude the plaintiffs' general-causation experts and for summary

[5] "Add." refers to plaintiffs' addendum in the Court of Appeals.

judgment. In support of its reconsideration motion, 3M cited both the evidence from the bellwether trial and new scientific evidence that had been published since its first motion. 3M.App.332-33.

The District Court held a second round of briefing and argument on 3M's motions and reconsidered the earlier rulings, excluding the plaintiffs' general-causation experts and granting summary judgment to 3M in the MDL. App.47. In a meticulous 49-page opinion, the 2,064th entry on the MDL docket, the District Court analyzed the plaintiffs' general-causation experts under this Court's decisions in *Daubert* and *Joiner* and held that several factors weighed in favor of excluding the expert opinions as unreliable.

First, the District Court concluded there was too great an analytical gap between the data the general-causation experts considered and the opinions they offered. With respect to the engineering expert's computer simulation, there was too great a gap between the expert's conclusion that the Bair Hugger was the but-for cause of squames reaching the surgical site and his own admission that the simulation failed to account for multiple other sources of airflow turbulence that exist in real operating rooms, such as medical personnel moving about, doors opening and closing, and equipment generating heat or blowing air. *See* App.57-68. The engineering expert's attempt to bridge that gap by assuming those other factors would necessarily amplify the Bair Hugger's effect was mere *ipse dixit*, and "more like a leap of faith than an inferential leap." App.65. As for the medical experts, there was an excessive gap between the scientific

literature they relied on—*none* of which had found a causal link between the Bair Hugger and deep-joint infections—and the experts' conclusions, which "ignore[d] the underlying studies' limitations" and relied on the studies "to support conclusions that the study authors were themselves unwilling to reach." App.76, 85; *see* App.70-88. Similarly, the medical experts made "too great an inferential leap" in relying on the engineering expert's computer simulation, while failing even to acknowledge its deficiencies. App.82.

Second, the medical experts failed to consider, let alone rule out, obvious alternative causal explanations. The author of the only study to identify a purported association between the Bair Hugger and infection, for example, identified "significant confounding factors," such as the introduction of new bacterial screening, that might undermine the association. App.90. Yet the medical expert who relied on that study "never mentioned—let alone investigated—this alternative explanation." *Id.*

Third, the causal inferences made by the plaintiffs' medical experts had not been generally accepted by the scientific community. To the contrary, the medical and scientific community—including the International Consensus and the FDA—had "repeatedly rejected the causal inferences made by Plaintiffs' experts." App.94.

Finally, the District Court weighed the fact that the engineering expert's model was developed for litigation and relied heavily on materials provided by the plaintiffs' attorneys rather than the expert's own

measurements, raising "concerns about the objectivity and reliability of the findings." App.69.

Weighing all those factors, the District Court concluded that the plaintiffs' experts' opinions did not meet the reliability requirement of Rule 702, and the court excluded their general-causation testimony and "unsupported extrapolations" that the Bair Hugger causes deep-joint infections. App.96. With the plaintiffs' general-causation theories excluded, the court granted summary judgment to 3M. App.96-99.

3. The Eighth Circuit's Decision

The plaintiffs appealed, and a panel of the Eighth Circuit reversed. App.1-46. The panel agreed that the factors the District Court considered were proper, *see* App.9-13, 23, 33-35, and that the flaws the court identified in the experts' opinions were real, *see* App.16, 21-23, 33-38. Nevertheless, the Eighth Circuit held that the District Court abused its discretion by excluding the expert evidence. Two factors drove the Eighth Circuit's analysis: its characterization of the underlying standard for determining admissibility under Rule 702, and its characterization of the standard of appellate review.

As to the standard of initial admissibility, the Eighth Circuit recited the various indicia of reliability that this Court has articulated, App.9-10, but then proceeded to equate that reliability standard with a very different standard entrenched in Eighth Circuit law: namely, that a district court may exclude expert evidence only if it is "'so fundamentally unsupported' by its factual basis 'that it can offer no assistance to the jury.'" App.12 (quoting *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988)). The court

acknowledged that its permissive "so-fundamentally-unsupported" standard of reliability—a standard "frequently" employed by the Eighth Circuit, App.12, but never by this Court—created an "intriguing juxtaposition," setting the District Court's broad discretion to determine reliability against that liberal admission standard for expert testimony. *Id.* The Eighth Circuit resolved that "juxtaposition" in favor of its pre-*Daubert* "so-fundamentally-unsupported" standard, citing that standard four times in its opinion, *see* App.12, 29, 33, 34, and deploying it to narrow the District Court's discretion to exclude flawed expert testimony by dismissing "lingering questions of reliability and objectivity" as questions of "weight" for the jury, App.23; *see also* App.13, 29.

As to the standard of appellate review, the Eighth Circuit recited the abuse-of-discretion standard and the importance of giving deference to the District Court's "gatekeeping function." App.10. But the court then noted another "intriguing juxtaposition" between that deferential standard of review and the "'liberal thrust' of Rule 702 regarding the admissibility of expert testimony." App.10 (quoting *Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014)); *see also* App.12. Without acknowledging that the same supposed juxtaposition precipitated the Eleventh Circuit's reversal in *Joiner*, the Eighth Circuit emphasized the "legion" circuit cases that "call for the liberal admission of expert testimony." App.10. The panel then proceeded to systematically override the District Court's judgment calls, dismissing the made-for-litigation nature of the expert opinions and holding that most disputes about reliability should be left to the jury.

3M filed a petition for rehearing and rehearing en banc, which the Eighth Circuit denied over the vote of Judge Loken. App.46.

REASONS FOR GRANTING THE PETITION

When it comes to expert testimony, the Eighth Circuit employs a diluted standard of initial admissibility and an insufficiently deferential standard of appellate review when the district court excludes such testimony. The combined effect is to force district courts that know better to admit "expert" testimony like that at issue here, which bears no resemblance to the scientific consensus and threatens a leading medical device that has been vindicated by the FDA and in study after study. That outlier approach defies this Court's precedents twice over and cannot stand.

First, the Eighth Circuit continues to apply an erroneously permissive standard for admitting expert testimony. That standard, which traces back to pre-*Daubert* circuit law, provides that expert testimony *must* be admitted, unless it is "so fundamentally unsupported" as to be useless to the jury. Far from representing the "exacting" standard of reliability this Court has required, that standard demands little more than relevance—a throwback to the regime that prevailed before *Daubert*, *Joiner*, and the revisions to Rule 702. It thus comes as little surprise that no other court of appeals employs that erroneously lax standard of admissibility, not even those that are widely regarded as welcoming when it comes to dubious "experts."

Second, the Eighth Circuit exacerbates the problem—and the disconnect with this Court's

precedents—by employing an insufficiently deferential standard of appellate review when it examines district court decisions to exclude expert testimony. The Eighth Circuit purports to discern an "intriguing juxtaposition" between deferential abuse-of-discretion review and its own lenient standard for initial admissibility, without acknowledging that this same juxtaposition is what caused the Eleventh Circuit to be reversed in *Joiner*. While giving lip service to abuse of discretion, in application, the Eighth Circuit's standard is all leniency to so-called "experts" and no deference to district courts that exclude experts based on their deep knowledge of the case formed over countless proceedings. Here, even after *agreeing* that the District Court considered all the proper factors and identified substantial gaps and flaws in the testimony, the Eighth Circuit *still* reversed, on the ground that the testimony was not completely useless to the jury.

This case presents an ideal vehicle for resolving these important questions. The expert testimony here is so flawed and out-of-step with the scientific consensus and FDA opinion that it took the perfect storm of the Eighth Circuit's lax standard of admissibility and insufficiently deferential standard of appellate review to reverse a district court that knew better than to admit it. The Eighth Circuit's decision turned entirely on its application of erroneous standards of initial admissibility and appellate review, as the Eighth Circuit took no issue with the District Court's articulation of the relevant factors and even acknowledged the serious flaws in the testimony. The fact that this case involves an MDL magnifies both the egregiousness of the error and the stakes.

Because this case arises from an MDL, the District Court is uniquely familiar with the case and the flaws in the expert reports when judged against all the other evidence in the case. Indeed, the District Court initially allowed the testimony, only to reconsider after seeing the testimony play out in the first bellwether trial. To overturn that considered decision based on a half-hour of argument and 188 pages of appellate briefing is a stark illustration of why appellate courts should defer to the district court's gatekeeping role. And because this case involves an MDL, the decision below is the difference between stopping this frivolous litigation in its tracks and green-lighting thousands of suits against an industry-standard medical device based on the precise kind of junk "science" that *Daubert* and *Joiner* and Rule 702 are all designed to weed out. The Court should grant review.

I. The Eighth Circuit's "So-Fundamentally-Unsupported" Standard Of Admissibility Defies This Court's Precedents And Rule 702.

The Eighth Circuit's standard for admitting expert testimony eviscerates the reliability requirement that this Court articulated in *Daubert* and refined in *Joiner*, and that is now embodied in Rule 702. The Eighth Circuit has watered down the reliability standard so that it requires little more than relevance, reflecting an outlier approach that no other court of appeals has adopted and that conflicts with this Court's precedents and the text of Rule 702.

1. This Court in *Daubert* made abundantly clear that expert testimony must be "not only relevant, but

reliable" before a court may admit it. 509 U.S. at 589. And in *Joiner*, the Court reaffirmed that reliability demands more than mere relevance, holding that a court may appropriately exclude expert testimony where it finds that "there is simply too great an analytical gap between the data and the opinion proffered" (and that appellate courts should review those exclusion decisions deferentially, *see infra*). 522 U.S. at 146. The reliability requirement was then codified in the 2000 amendments to Rule 702, which now provides four requirements for the admission of expert testimony. One of those requirements focuses on baseline relevance (that "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"), but the other three focus on and demand reliability (that the testimony be "based on sufficient facts or data," that it be "the product of reliable principles and methods," and that the expert "reliably applied the principles and methods to the facts of the case"). *See also* Fed. R. Evid. 702 advisory committee note to 2000 amendments (listing further factors "relevant in determining whether expert testimony is sufficiently *reliable* to be considered by the trier of fact" (emphasis added)). In short, the 2000 amendments sharpen Rule 702's focus on reliability, "requir[ing] that the testimony must be the product of *reliable* principles and methods that are *reliably* applied to the facts of the case." *Id.* (emphasis added).

The standard of initial admissibility in the Eighth Circuit looks nothing like the one described in *Daubert*, *Joiner*, and amended Rule 702, and looks astonishingly like an articulation of the standard for mere relevance, and a lenient one at that. As the

decision below made abundantly clear, in the Eighth Circuit, expert testimony *must* be admitted unless it is "*so* fundamentally unsupported by its factual basis that it can offer no assistance to the jury." App.12 (emphasis added). That standard is so undemanding that it affirmatively suggests there is a universe of "expert" testimony that is fundamentally unsupported, but nonetheless should be admitted because it provides the jury some minimal assistance. That standard deprives the reliability standard of any independent function. Testimony that is *so fundamentally unsupported* that it can offer *no assistance* to the jury is not just unreliable, it is not even relevant. By reducing the reliability inquiry to the toothless "so-fundamentally-unsupported" standard, the Eighth Circuit has effectively read reliability—and *Daubert*, *Joiner*, and the text of Rule 702—out of the law.

There is no serious question that this Court's precedents and Rule 702 require more of experts than avoiding testimony that is utterly useless, and that they empower district courts to exclude as unreliable so-called "experts" whose testimony is fundamentally unsupported (but not extremely *so*) and provides the jury with only minimal assistance (but not zero). *Daubert* and *Joiner* both emphasized that expert testimony must be "not only relevant, but reliable." 509 U.S. at 589. And in a world where the trial court can exclude evidence *only* where it provides "no assistance" to the jury, the amended Rule 702 could have stopped after subsection (a), allowing experts to testify so long as their testimony merely "help[s] the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. The remaining

three subsections of the rule—providing that the data, methodology, and application all must be "reliable"—would be superfluous. Fed. R. Evid. 702(b)-(d). That result would be irreconcilable with this Court's admonitions that those reliability prongs are, in fact, "exacting." *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000).

That the Eighth Circuit's standard speaks to relevance—not reliability—is evident from its origins. It dates back to the circuit's pre-*Daubert* case law applying the old version of Rule 702, which required only that expert testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." Pub. L. No. 93-595, 88 Stat. at 1937. Applying that sparse text, the Eighth Circuit initially employed the "so-fundamentally-unsupported" language in dictum explaining that expert testimony "should not be admitted" if it is "so fundamentally unsupported that it can offer no assistance to the jury." *Loudermill*, 863 F.2d at 570. There is no disputing that uncontroversial statement, because expert testimony that is "so fundamentally unsupported" that it cannot assist the jury is neither relevant nor reliable and has no business being admitted in any case. But later cases flipped the standard around and articulated it as a (mis)statement of when expert testimony should be admitted. Thus, what started as a sensible description of when testimony must be *excluded* as irrelevant (and, thus, *a fortiori*, unreliable) has morphed into a plainly wrong requirement that a district court must *admit* expert testimony whenever it is relevant, even if unreliable. *See, e.g.*, *Williams v. Wal-Mart Stores, Inc.*, 922 F.2d 1357, 1361 (8th Cir. 1990) (applying "so-fundamentally-unsupported"

standard and holding that a district court must admit testimony that "could only reasonably be understood as relevant" to a fact in issue).[6]

The Eighth Circuit has never revised its "so-fundamentally-unsupported" standard in the wake of *Daubert*, *Joiner*, or the 2000 amendments to Rule 702. *See, e.g.*, *McKnight ex rel. Ludwig v. Johnson Controls, Inc.*, 36 F.3d 1396, 1408 (8th Cir. 1994) (expert opinion should be excluded only where it is "so fundamentally unsupported that it can offer no assistance to the jury"); *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (same); *Smith v. BMW N. Am., Inc.*, 308 F.3d 913, 918, 921 n.11 (8th Cir. 2002) (same). Instead, it has doubled down, time and again, while insisting that its lax "so-fundamentally-unsupported" standard is consistent with those binding authorities. *See, e.g.*, *McKnight*, 36 F.3d at 1406, 1408; *Bonner*, 259 F.3d at 929.

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[6] As some evidence that the use of *Loudermill*'s "so-fundamentally-unsupported" standard to *exclude* irrelevant evidence need not have morphed into a diluted reliability requirement that forces the admission of experts that clear the low relevance threshold, *Loudermill* itself borrowed the standard from a pre-*Daubert* Fifth Circuit decision *excluding* expert testimony, *see* 863 F.2d at 570 (citing *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987)). Yet in the Fifth Circuit, the language *Loudermill* borrowed never became an all-purpose standard that all but requires the admission of unreliable expert evidence that passes the relevance threshold. *See, e.g.*, *Edmonds v. Ill. Cent. Gulf R.R. Co.*, 910 F.2d 1284, 1287 (5th Cir. 1990) (quoting *Viterbo*'s "fundamentally unsupported" language but correctly applying reliability criteria); *Jacked Up, L.L.C. v. Sara Lee Corp.*, 807 F.App'x 344, 348-49 (5th Cir. 2020) (citing *Viterbo* but correctly applying reliability criteria).

The decision below is a case in point. The Eighth Circuit fully acknowledged *Daubert* and *Joiner*, but then declared that it would employ "the language [it] ha[d] frequently used both before and after *Daubert* and *Joiner*"—namely, that expert testimony is admissible unless it is "so fundamentally unsupported" that "it can offer no assistance to the jury." App.12 (quoting, *inter alia*, *Loudermill*, 863 F.2d at 570). The decision below invoked that standard four times, *see* App.12, 29, 33, 34, and deployed it to override the District Court's judgment calls and to characterize "lingering questions of reliability and objectivity" as questions of "weight" for the jury, App.23; *see also* App.13, 29. That approach flies in the face of the text of Rule 702 and both *Daubert*'s seminal holding that expert testimony must be "not only relevant, but *reliable*," 509 U.S. at 589 (emphasis added), and *Joiner*'s admonition that a district court can and should exclude experts if it concludes "that there is simply too great an analytical gap between the data and the opinion proffered." 522 U.S. at 146.

The "so-fundamentally-unsupported" standard of admissibility conflicts with this Court's precedents in an additional respect: It eliminates any meaningful discretion for the district court to make judgment calls and exercise a gatekeeping function based on its deep knowledge of how the proposed expert testimony fits into the broader evidence. To the extent any traces of a "reliability" inquiry can still be found in the Eighth Circuit's standard, it undoubtedly removes the district court's discretion to decide which reliability factors to emphasize and how to weigh them. Instead, it forces courts to focus myopically on just one consideration—

whether the testimony is so fundamentally unsupported that it is essentially useless to the factfinder. But again, in *Daubert*, this Court emphasized that the Rule 702 reliability inquiry is "flexible," 509 U.S. at 594, and "the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination," *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142 (1999). The Eighth Circuit's standard leaves no room for that flexibility, compounding the conflict with this Court's precedents and Rule 702.

The Eighth Circuit's track record shows that it will not correct course on its own. Not only did the Eighth Circuit deny en banc review here, but the error here is neither an isolated example nor a blip. The Eighth Circuit has repeatedly applied the lax "so-fundamentally-unsupported" standard since it first articulated the standard in *Loudermill*, despite this Court's intervening decisions in *Daubert* and *Joiner* and the amendments to Rule 702. The result has been the admission of a steady stream of expert testimony that should have been, but was not, held to the "exacting" standard of reliability articulated in *Daubert* and *Joiner* and embodied in Rule 702. *See, e.g.*, *Johnson*, 754 F.3d at 562-63 (applying so-fundamentally-unsupported standard to reverse district court's exclusion of expert testimony); *First Union Nat'l Bank v. Benham*, 423 F.3d 855, 862 (8th Cir. 2005) (same); *see also, e.g.*, *Klingenberg v. Vulcan Ladder USA, LLC*, 936 F.3d 824, 828-30 (8th Cir. 2019) (affirming admission of expert testimony under so-fundamentally-unsupported standard); *United States v. Finch*, 630 F.3d 1057, 1062-63 (8th Cir. 2011)

(same); *United States v. Rodriguez*, 581 F.3d 775, 795 (8th Cir. 2009) (same).

2. No other circuit employs the Eighth Circuit's "so-fundamentally-unsupported" standard of admissibility for expert evidence, and for good reason. According to the Third Circuit, "*Daubert*'s requirement" of reliability means that "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible," *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017), regardless of "whether the step completely changes a reliable methodology or merely misapplies that methodology," *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994). *Contra City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1047 (9th Cir. 2014) (expressly disagreeing with the Third Circuit's "any step" standard). The Fourth Circuit takes a similarly faithful approach, holding that a district court "abandon[s] its gatekeeping function" by "dismiss[ing]" reliability concerns as "going to the weight, not admissibility, of [the expert's] testimony." *Nease v. Ford Motor Co.*, 848 F.3d 219, 230 (4th Cir. 2017) (reversing the admission of expert testimony); *see also, e.g.*, *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 279 (4th Cir. 2021).

To be sure, while the Eighth Circuit stands as an outlier, it certainly is not alone in narrowing the gap between reliability and relevance and dismissing serious analytical gaps as matters for the jury to weigh. The Ninth Circuit is widely recognized for its lax approach to admissibility, as it permits the trial judge to "screen the jury" only from "unreliable

nonsense opinions." *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013); *see also, e.g.*, *United States v. Magana-Gonzalez*, 781 F.App'x 615, 616 (9th Cir. 2019). Like the Eighth Circuit's "so-fundamentally-unsupported" standard, the Ninth Circuit's lax "nonsense" standard allows district courts to ask only whether the expert's testimony "has substance such that it would be *helpful* to a jury." *Alaska Rent-A-Car*, 738 F.3d at 969-70 (emphasis added); *see also Pomona*, 750 F.3d 1036 (same).[7] The First Circuit, for its part, follows the Eighth Circuit's lead of dismissing analytical gaps and conceptual flaws as questions of weight or credibility for the jury to decide. *See, e.g.*, *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 13-23 (1st Cir. 2011) (reversing the district court's exclusion of general-causation expert); *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77 (1st Cir. 1998) (same);

[7] Although the Ninth Circuit recently insisted that it does not in fact apply a "more forgiving" standard of reliability than its sister circuits, *Hardeman v. Monsanto Co.*, 997 F.3d 941, 961 (9th Cir. 2021), others would beg to differ. Courts and commentators alike have recognized that the Ninth Circuit places special emphasis on what it views as Rule 702's liberal standard for admitting expert testimony, resulting in more tolerance for "borderline expert opinions" and "a wider range of expert opinions (arguably much wider)" than would be admissible in other circuits. *In re Roundup Prods. Liab. Litig.*, 358 F.Supp.3d 956, 959-60 (N.D. Cal. 2019) (comparing Ninth Circuit precedent with decisions from Fourth and Sixth Circuits); *see also, e.g.*, Thomas D. Schroeder, *Toward A More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039, 2050 (2020) ("Ninth Circuit caselaw appears to interpret *Daubert* as liberalizing the admission of expert testimony, which may explain decisions from that circuit that set it apart from most others.").

Baker v. Dalkon Shield Claimants Tr., 156 F.3d 248, 251-53 (1st Cir. 1998) (same); *see generally* Schroeder, *supra* note 7 (discussing examples).

As these cases make clear, expert testimony that is held to a demanding reliability standard grounded in this Court's precedents and Rule 702 in some circuits will be held to a far more lax relevance standard in others, including, especially, the Eighth Circuit. This Court should intervene to ensure that *Daubert*, *Joiner*, and Rule 702 continue to supply a nationwide standard that demands more of so-called "experts" than that their testimony not be so fundamentally flawed that it is unhelpful to the jury.

II. The Eighth Circuit's Insufficiently Deferential Standard Of Appellate Review Defies This Court's Decision In *Joiner*.

The Eighth Circuit couples its erroneous approach to the initial admission of expert testimony with an insufficiently deferential standard of appellate review for district court decisions to exclude expert testimony. The result of that pairing is a regime that reverses a district court decision excluding the kind of deeply flawed "expert" opinions here, while conflicting with this Court's precedents not once, but twice, and replicating the exact error this Court corrected nearly 25 years ago in *Joiner*.

The Eighth Circuit purported to apply an abuse-of-discretion standard and even acknowledged that this Court instructed that decisions to admit or exclude expert testimony are equally subject to that standard. Yet the Eighth Circuit nevertheless highlighted an "intriguing juxtaposition" between that deferential standard of review and the "'liberal thrust'

of Rule 702 regarding the admissibility of expert testimony." App.10 (quoting *Johnson*, 754 F.3d at 562). The Eighth Circuit seemed to forget that this juxtaposition and the temptation to allow a perceived "liberal thrust" favoring admissibility to dilute the deference owed to district courts in excluding testimony is precisely what got the Eleventh Circuit reversed in *Joiner*.

The Eighth Circuit first noted this supposed tension in 2014, in *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014). There, the district court had excluded the plaintiff's proffered expert testimony after concluding that the experts' methodology was not reliable, in part because the experts failed to rule out other sources of contamination that could have caused the plaintiff's infection. *Id.* at 560-61. The Eighth Circuit reversed. While acknowledging that abuse of discretion was the appropriate standard of review, *id.* at 561, the Eighth Circuit posited an "intriguing juxtaposition" between that highly deferential standard and a perceived "liberalization of the standard for admission of expert testimony," *id.* at 562. The court thus claimed that it would "adhere" to the abuse-of-discretion standard, while emphasizing that its cases calling for "the liberal admission of expert testimony" are "legion." *Id.* (citing in-circuit examples). The Eighth Circuit then proceeded to fault the district court for "resolving doubts in favor of keeping the testimony out" and characterized the acknowledged flaws in the experts' methodology as issues for the jury. *Id.* at 562-63.

The decision below replicated *Johnson*'s error and carried it further, making the conflict with *Joiner*

inescapable. After paying lip service to the District Court's "broad discretion" and acknowledging the deferential standard of review, App.10, the panel turned back to *Johnson*: "That said, we have recognized that the 'liberal thrust' of Rule 702 regarding the admissibility of expert testimony creates 'an intriguing juxtaposition with our oft-repeated abuse-of-discretion standard of review.'" App.10 (quoting *Johnson*, 754 F.3d at 562). Underscoring its more stringent review in practice of district court decisions *excluding* expert testimony, the Eighth Circuit made clear that the "intriguing juxtaposition" arises only when "a district court excludes an expert's opinion." App.12. In the Eighth Circuit's view, when the trial court follows "the liberal thrust" of circuit precedent and admits the expert evidence, the Eighth Circuit will engage in a juxtaposition-free and genuinely deferential review of the admission decision.

Having placed that gloss on the standard of review, the decision below proceeded to systematically override the District Court's judgment calls on the admissibility of the plaintiffs' expert testimony, dismissing the made-for-litigation nature of the opinions and leaving disputes about reliability to the jury. App.13-35. That searching review looks nothing like ordinary abuse-of-discretion review, and by allowing the perceived "juxtaposition" and the undoubtedly liberal "so-fundamentally-unsupported" standard to fuel its non-deferential review, the Eighth Circuit replicated the exact error that this Court reversed in *Joiner*.

Finally, the combined effect of the Eighth Circuit's admitted "liberalization" of the initial admission decision and deferential-in-name-only standard of appellate review vitiates the district court's role as a gatekeeper. This Court's decisions have recognized that a fair application of *Daubert* and Rule 702 requires some close and discretionary calls. A district court judge, especially one who has sat through an entire bellwether trial, is in a materially better position than an appellate court reviewing a cold record to make those calls. The abuse-of-discretion standard as articulated in *Joiner* honors the comparative advantage of the trial court and preserves its gatekeeping function by deferring to those difficult judgment calls. The abuse-of-discretion standard as applied by the Eighth Circuit gives little actual deference to the trial judge and forces the jury to be its own gatekeeper, which is contrary to the whole thrust of *Daubert*, *Joiner*, and Rule 702.

III. This Case Presents An Ideal Vehicle To Review Two Important Questions.

The Eighth Circuit's mutually reinforcing errors caused it to force a district court to admit the kind of dubious "expert" evidence that is the *raison d'être* of *Daubert*, *Joiner*, and Rule 702. This Court should not stand by while the Eighth Circuit blatantly disregards its clear teachings and unleashes a torrent of frivolous litigation against an industry-standard medical device used to comfort patients and aid healing thousands of times each day.

This case presents an ideal vehicle for resolving the questions presented. The expert testimony at issue here is the poster child for the kind of dubious

made-for-litigation "expert" opinions that *Daubert*, *Joiner*, and Rule 702 were designed to weed out. In the real world, outside of litigation, not a single treating physician, epidemiologist, public-health official, or regulatory body has agreed with plaintiffs' experts' claims that the Bair Hugger system causes infections. Instead, the Bair Hugger remains the most-used patient-warming device in the world. It has been used successfully in more than *300 million* surgeries (and counting). It is currently used in approximately 50,000 surgeries around the world *each day*. The FDA considers the device safe and effective, and went out of its way to reaffirm its safety and efficacy in light of Augustine's self-interested smear campaign. Countless studies, some partially funded by Augustine, have reached the same conclusion. Yet while the rest of the medical profession views the Bair Hugger as safe and effective, one bitter competitor with a self-interested vendetta has generated made-for-litigation "expert" testimony that defies reality. The Rule 702 gatekeeping regime was designed to keep exactly that kind of so-called "science" out of the courtroom, and to "help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones." *Joiner*, 522 U.S. at 148-49 (Breyer, J., concurring).

At the same time, the District Court here was careful in the exercise of its gatekeeping function. Far from indulging in a reflexive exclusion of this dubious testimony, the court initially *denied* 3M's motion to exclude, even as the state-court judge in the parallel litigation excluded it. The court was initially

persuaded by the plaintiffs' arguments and exercised its discretion to allow the claims to proceed to trial. But as the case progressed, the court came to understand the record and context in ways no reviewing court could—seeing the experts testify live at a two-week bellwether trial, reviewing thousands of filings, and watching the plaintiffs' arguments evolve and unravel. Only after becoming steeped in the details of the case and seeing the experts testify did the court reconsider its initial ruling and reach the highly informed conclusion that the plaintiffs' general-causation experts were in fact unreliable. And with the plaintiffs' general-causation experts excluded, the stage was set to bring this massive litigation to a close.

The Eighth Circuit then reversed on a cold record and with two thumbs on the scales, one in favor of the initial admission of expert testimony, and the other demanding more searching appellate review because the "experts" had been excluded. The questions presented were dispositive of the appeal, and if answered correctly would have resolved the whole MDL. The Eighth Circuit's decision turned on its application of the erroneously lenient "so-fundamentally-unsupported" standard of admissibility, together with an erroneously stringent standard of review. That is clear from the Eighth Circuit's own analysis, which *agreed* with both the District Court's consideration of the Rule 702 reliability factors and the District Court's identification of various flaws, gaps, and weaknesses in the plaintiffs' proffered expert testimony. *See* App.9-13, 23, 33-35, 16, 21-23, 33-38. In other words, the Eighth Circuit did not disagree with the District Court's statement of the law, the selection of

discretionary factors to consider, or even the identification of analytical gaps. Rather, the Eighth Circuit's decision turned entirely on its own second-guessing of the District Court's reliability judgment calls—second-guessing fueled by the "so-fundamentally-unsupported" standard and a standard of appellate review that was anything but deferential in practice.

There can be no serious dispute that the questions presented are important, both in this litigation and beyond. In this MDL alone, more than 5,200 individual cases hang in the balance. Without the plaintiffs' dubious general-causation "experts," this litigation was at its end, with summary judgment entered in favor of 3M. But by subverting the District Court's gatekeeping function and allowing unreliable "expert" testimony into the courtroom, the Eighth Circuit's decision unjustifiably tilts the balance strongly against a product that, outside the world of this litigation, is universally regarded as safe and effective. This case thus presents a textbook example of the "engine of tort liability" gone awry: Indeed, if left to stand, the Eighth Circuit's decision will "generate strong financial incentives" to "reduce" or "eliminate" production of items, including important medical devices, that are safe and effective. *Joiner*, 522 U.S. at 148-49 (Breyer, J., concurring); 3M.App.103, 350.

The impact is hardly limited to this MDL. Massive product-liability MDLs continue to account for an enormous share of federal civil cases each year. In recent years, MDLs have made up roughly half of the entire federal civil docket, and that share

rose to "an unprecedented 62.7% of the federal civil docket" in 2020. Lawyers for Civil Justice, *MDLs Reach 1 Million Case Milestone*, Rule4MDLs (Mar. 18, 2021), https://bit.ly/3rrK65C. A primary driver of the "explosive MDL growth" has been "the surge in mass tort product liability cases," which now account for approximately 97% of all MDL cases. *Id.* Given that the ever-growing number of product-liability MDL cases frequently turn on (often dubious) expert testimony, it is essential that courts of appeals and district courts take the gatekeeping function seriously and screen out unreliable scientific hypotheses that can have a disproportionately large impact on the federal civil litigation docket nationwide.

Moreover, if there is one context where *Joiner*'s teaching that the decision to exclude expert evidence should be reviewed deferentially, it is the MDL context. Unlike a district court judge preparing for a typical trial, an MDL judge has seen hundreds of filings and in this case has presided over a bellwether trial. To say that such a district court is in a better position to identify truly unreliable expert testimony and perform a gatekeeping function than an appellate court reviewing a cold record is a considerable understatement. If the Eighth Circuit will not give meaningful deference to the trial court in these circumstances, *Joiner* is plainly a dead letter in practice.

The Eighth Circuit has had ample opportunities to reconcile its "so-fundamentally-unsupported" standard for admissibility and its insufficiently deferential standard of appellate review with *Daubert*, *Joiner*, and the 2000 amendments to Rule 702. It may

describe the disconnect between its cases and this Court's precedents as nothing more than a series of "intriguing juxtapositions," but it is far better described as an "irreconcilable conflict." The proof is in the evidence that the District Court will now be forced to admit, and jury after jury will be allowed to consider, despite its acknowledged analytical gaps and its complete deviation from consensus medical opinion and practice outside the courtroom. Plaintiffs' experts do not know something that eludes 50,000 surgeons every day. Instead, their testimony is wholly unreliable and was properly excluded by a district court judge who saw the testimony live. This Court should grant review and restore that sensible judgment while making clear that expert testimony must be not just relevant, but reliable, and that a district court's decision to exclude should not be lightly second-guessed.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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