No. 21-1100

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

REPLY BRIEF

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April 26, 2022

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REPLY BRIEF

The decision below managed to violate not just one, but two fundamental precedents governing the admissibility of expert testimony and to do so in a ruling with dispositive effect on the 6,000 cases in this MDL. After embracing a lax standard of initial admissibility that conflates relevance and reliability and mandates the admission of any expert testimony not *so* fundamentally unsupported as to be useless to the jury, the Eighth Circuit applied a non-deferential standard of appellate review for *excluding* expert testimony that looks more like de novo review than any abuse-of-discretion standard. The net effect was to second-guess the District Court's considered decision to exclude expert testimony that had proven unreliable during a bellwether trial and to force the trial of thousands of MDL cases based on junk science that contradicts the real-world judgments of surgeons in some 50,000 surgeries each day. That decision defies this Court's precedents and the text of Rule 702. It cannot stand.

Respondent's efforts to resist review do not withstand scrutiny. He dedicates most of his effort to insisting that the petition amounts to a plea for error correction. But reviewing a decision that defies this Court's decisions, revives some 6,000 cases in an MDL, and mandates countless trials based on junk science that has proven unreliable and contradicts the daily judgments of life-saving professionals who have sworn to do no harm is no exercise in mere error correction. Moreover, the negative impact of the decision below goes well beyond this MDL, as the Eighth Circuit has now sent an unmistakable message to district courts

that the only sure path to avoiding appellate reversal is to abdicate judicial gatekeeping and let the jury sort out reliability. No other circuit applies the lax "so-fundamentally-unsupported" standard or gives mere lip service to abuse-of-discretion review of decisions to exclude. And only the combination of those misguided standards could lead to reversal of a decision to exclude reached only after observing a full trial, based on nothing more than a varying assessment of whether acknowledged analytical gaps in the expert testimony were too wide. Respondent's final plea to leave all this to the Rules Committee is equally unavailing. That Committee is not directly considering the issues raised here, and the Committee does not review appellate decisions disregarding this Court's precedents and reviving thousands of otherwise foreclosed trials. That is the office of this Court. A decision that in one fell swoop overrides the discretion of trial courts, disregards the daily medical judgments of thousands of surgeons, and revives thousands of cases fully merits this Court's review.

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

Respondent does not dispute that under *Daubert*, *Joiner*, and Rule 702, expert testimony is inadmissible unless it meets the exacting standard of reliability. But under Eighth Circuit precedent, expert testimony *must* be admitted, unless it is "so fundamentally unsupported" that it is useless to a jury. App.12. That standard collapses relevance and reliability and forces the jury to serve as its own gatekeeper. No amount of

hand-waving can rewrite circuit law or reconcile the Eighth Circuit's relaxed admissibility standard with this Court's rigorous one.

1. Respondent starts by denying the existence of the Eighth Circuit's lax standard of admissibility, suggesting that it "cannot be found anywhere" in the panel's decision and is merely a "verbal sleight of hand." BIO.13-14. That is a startling about-face. Below, Respondent insisted that the "so-fundamentally-unsupported" standard not only existed, but made admission "mandatory" for any expert that cleared its low bar. BIO.14. He argued, for example, that "exclusion of expert testimony is permissible *only where*, unlike here, 'it is *so fundamentally unsupported* that it can offer no assistance to the jury.'" CA8.Reply.10 (quoting *Johnson v. Mead Johnson*, 754 F.3d 557, 562 (8th Cir. 2014) (emphasis added)); *see also* CA8.Opening.Br.19-20. Respondent emphasized, moreover, that the Eighth Circuit had "applied that permissive standard to expert testimony in over 30 cases" since 2001. CA8.Reply.10.

The panel was persuaded: It recited the "so-fundamentally-unsupported" standard four times and made it the express basis of its decision. App.29 (District Court erred in concluding that expert opinions "were 'so fundamentally unsupported' that they had to be excluded"); App.33 ("clear error of judgment" for District Court to conclude that expert opinions "were so fundamentally unsupported that they should be excluded"); App.34 (question for District Court was "whether the opinions were 'so fundamentally unsupported' that they should be

excluded rather than admitted"); App.34 ("clear error of judgment" for District Court to conclude that expert opinions "were so fundamentally unsupported that they had to be excluded"). Respondent may have buyer's remorse now, but he got exactly what he asked for from the Eighth Circuit.

As Respondent emphasized below, the Eighth Circuit's skewed standard mandating admission of anything not so-fundamentally-unsupported is deeply entrenched in Eighth Circuit precedent. And there is nothing "discretionary" about the standard. BIO.14. While it originated as a description of evidence properly excluded (and never went further in the Fifth Circuit where it originated), Pet.23.n.6, the Eighth Circuit now applies it to *require* district courts to admit any expert testimony that is not *so*-fundamentally-unsupported that it *must* be excluded. The post-*Daubert* decision that the panel cited for the "so-fundamentally-unsupported" standard, *see* App.12, is typical. It frames the standard in mandatory terms: "*Only if* an expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011) (emphasis added).[1] And the decision

[1] *See also, e.g.*, *United States v. Bowers*, 638 F.3d 616, 620 (8th Cir. 2011) ("To be excluded, an expert's testimony *must* be so fundamentally unsupported that it can[]not assist the jury." (emphasis added)); *Sappington v. Skyjack*, 512 F.3d 440, 448 (8th Cir. 2008) ("The exclusion of an expert's opinion is proper *only if* it is so fundamentally unsupported that it can offer no assistance to the jury." (emphasis added)); *Synergetics v. Hurst*, 477 F.3d 949, 956 (8th Cir. 2007) ("An expert's opinion should be excluded

below makes the standard's mandatory nature crystal clear. The panel faulted the District Court at every turn for admitting evidence that was not so-fundamentally-unsupported that it provided no help to the trier of fact. *See* App.29, 33-34.

Respondent's effort to deem the "so-fundamentally-unsupported" standard "*synonymous*" with the standard in *Joiner* ignores what this Court said and did in *Joiner*. BIO.14-15. *Joiner* never employed the "so-fundamentally-unsupported" language; rather, it held that a district court that excluded expert evidence because of "too great an analytical gap between the data and the opinion proffered" did not abuse its discretion. 522 U.S. 136, 146 (1997). The District Court made the same finding here but received no comparable deference. *See infra.* Moreover, as 3M explained (and Respondent ignores), the Eighth Circuit's "so-fundamentally-unsupported" standard long predates *Joiner* and reflects pre-*Daubert* case law applying the old version of Rule 702, which had no express reliability requirement. *See* Pet.22-23. That approach was plainly ruled out by the reliability requirement imposed in *Daubert*, *Joiner*, and the revised Rule 702. *See* PLAC.Amicus.Br.11. Yet the Eighth Circuit has stubbornly clung to its pre-*Daubert* standard. *See* Pet.23 (citing examples).

Nor does the Eighth Circuit's "actual analysis" show that the standards are equivalent. BIO.15-19. The decision below recited the "analytical gap" language from *Joiner* only to decline to defer to the

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only if that 'opinion is so fundamentally unsupported that it can offer no assistance to the jury.'" (emphasis added)).

District Court's analysis by using the "so-fundamentally-unsupported" standard to suggest that even agreed-upon "deficiencies" "go to weight and not admissibility" because the opinions were not "so fundamentally unsupported that they had to be excluded." App.29.

Respondent emphasizes the panel's partial affirmance of the District Court's exclusion of one aspect of one expert's testimony. BIO.19. But far from showing fidelity to this Court's precedents, that just shows the so-fundamentally-unsupported standard's flaws in action. The Eighth Circuit upheld the exclusion of mere *ipse dixit*, App.22, while refusing to exclude other aspects of the same expert's dubious opinion—despite acknowledging some of the same difficulties the District Court highlighted, just not deeming them beyond the pale. At the same time, the panel green-lighted medical experts despite acknowledged flaws, the District Court's considered judgment after seeing them testify, a contrary medical consensus, and the daily contrary judgment of thousands of medical professionals. The standard that allowed all that in cannot be reconciled with the precedents of this Court or other circuits.

2. Respondent insists there is no circuit split and that the Eighth Circuit's outlier "so-fundamentally-unsupported" standard is just a linguistic variation of the reliability standard that other circuits apply. BIO.19-20. But to the extent there is not a circuit split on the admissibility of the precise made-for-litigation testimony at issue here, that is a product of the MDL, which has concentrated thousands of cases from across the country within the junk-science-friendly

confines of the Eighth Circuit. That said, the two courts most familiar with this evidence—the District Court here and the Minnesota trial court overseeing the non-diverse cases—excluded it, with only the Eighth Circuit reaching a different conclusion based on a cold appellate record.

Moreover, Respondent cannot deny that no other circuit—including the Fifth Circuit, which originated the so-fundamentally-unsupported language—applies the Eighth Circuit's standard. Nor does he deny that the Ninth Circuit is widely recognized for its lax approach to admissibility, while the First Circuit follows the Eighth Circuit in punting reliability issues to the jury. *See* Pet.26-28; LCJ.Amicus.Br.13-17. Instead, he claims that other circuits would have reached the same result, but that blinks reality. Other circuits routinely defer to district court decisions to exclude expert evidence under standards that invoke *Daubert*, *Joiner*, and Rule 702 directly without the distorting influence of the "so-fundamentally-unsupported" standard. *See, e.g.*, *Electra v. 59 Murray Enters.*, 987 F.3d 233, 254 (2d Cir. 2021); *In re Lipitor Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II) MDL 2502*, 892 F.3d 624, 644-45 (4th Cir. 2018); *Hall v. Conoco*, 886 F.3d 1308, 1316 (10th Cir. 2018); *In re Zoloft Prods. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017).

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

1. Respondent insists that the Eighth Circuit applied a properly deferential standard of appellate review and merely noted the "intriguing

juxtaposition" of a permissive admissibility standard and a deferential standard of appellate review. But the Eighth Circuit did far more than muse about the juxtaposition and failed to recognize that the self-same juxtaposition led the Eleventh Circuit into error in *Joiner*. Thus, even adverting to the juxtaposition post-*Joiner* is a sure sign that the Eighth Circuit was not applying the correct, neutral form of deferential appellate review that this Court has mandated for decisions to admit and exclude expert testimony alike. Instead, the Eighth Circuit made the classic mistake of letting a policy preference (whether pro-admissibility or pro-arbitration) that informs the District Court's initial judgment distort the standard of appellate review, which "should depend upon the respective institutional advantages of trial and appellate courts." *First Options of Chi. v. Kaplan*, 514 U.S. 938, 948 (1995) (citation omitted); *accord Joiner*, 522 U.S. at 143; *United States v. Tsarnaev*, 142 S.Ct. 1024, 1040 (2022).

Here, determining the "respective institutional advantages" is not a close call. The District Court made its exclusion decision as the 2,064th docket entry in the MDL after watching the experts testify in the bellwether trial, while the appellate court reversed based on a cold record and 188 pages of appellate briefing. Rather than proceed with deference or a healthy sense of the respective institutional advantages, the Eighth Circuit applied what amounts to de novo review. The proof is in the opinion. With one minor exception already discussed, the Eighth Circuit reversed every close call on a cold record. For example, it acknowledged "gaps" between the engineering expert's computer simulation and the

medical experts' general-causation opinions, App.24-25, as well as "limitations" in the studies that the experts used to try to overcome the gaps—such as that the studies did not even test the Bair Hugger's "effects on airflow disruption" with "all potentially relevant variables," App.26-27—but thought the "deficiencies" in the "factual basis" should "go to weight and not admissibility." App.29. That non-deferential mode of review cannot be reconciled with *Joiner*, as it replicates the Eleventh Circuit's error.

2. That direct conflict with *Joiner* alone calls out for this Court's review, while the combined effect of the Eighth Circuit's stringent appellate standard and its lax standard of initial admissibility creates a double conflict that only reinforces the need for certiorari. Moreover, the two errors reinforce each other. By instructing district courts to admit expert testimony unless it is "so-fundamentally-unsupported" as to be useless, rather than exercising the gatekeeping function envisioned by *Daubert*, *Joiner*, and Rule 702, the Eighth Circuit gives district courts precious little discretion to exercise. By then skewing appellate review by reference to that lax standard and the liberal policy favoring admissibility, there is essentially nothing left of the neutral and deferential standard of appellate review mandated by *Joiner*. Admission of all but the most dubious experts is essentially commanded by the "so-fundamentally-unsupported" standard (and then reviewed deferentially), while a decision to exclude must overcome a permissive admissibility standard and skeptical appellate review. The decision below, and

others like it, place two thumbs on the scale in favor of admitting dubious expert testimony.[2]

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

1. Respondent does not dispute the scale and importance of this MDL or the heightened importance of the gatekeeping function in the MDL context. *See* Chamber.Amicus.Br.8, 14; LCJ.Amicus.Br.23-24; NAM.Amicus.Br.15-16; ALF.Amicus.Br.17. Instead, he tries to rehabilitate his dubious experts at the margins. BIO.3-6, 25. But a few pages of appellate briefing is no substitute for the considered judgment of the District Court. Moreover, even Respondent cannot dispute that *none* of his experts studied the Bair Hugger before this litigation, and none conducted any experiment or lab work before testifying. App.72. Nor can he dispute that the FDA considers the Bair Hugger safe and effective and has rebuked Augustine's self-interested attacks on the device. Respondent ignores all that, pausing only to misleadingly quote the conclusions of the International Consensus, BIO.5—which in 2013 "recommend[ed] further study but no change to current practice" and in 2018 reached a 93% consensus that there was "no evidence to definitively link" forced-air warming to an increased risk of surgical-site infection. App.95.[3] But more telling even

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[2] *See, e.g.*, *Klingenberg v. Vulcan Ladder USA*, 936 F.3d 824, 830 (8th Cir. 2019); *Bowers*, 638 F.3d at 620; *First Union Nat'l Bank v. Benham*, 423 F.3d 855, 861-63 (8th Cir. 2005); *Miles v. Gen. Motors*, 262 F.3d 720, 724 (8th Cir. 2001).

[3] Respondent also misattributes to the CDC a supposed "recommendation" against blowing air in an operating room.

than that scientific consensus is the fact that thousands of surgeons continue to employ the Bair Hugger to treat their patients. This is not some abstract debate among experts about whether some long-discontinued practice causes some obscure side effect. The Bair Hugger is employed in 50,000 surgeries every day. Made-for-litigation testimony that contradicts the real-world choices and experiences of countless learned intermediaries who have each sworn to do no harm is the very definition of junk science.

2. Respondent suggests that 3M's arguments should be redirected to the Rules Committee, which he asserts is "*currently*" considering amendments to Rule 702 that "might obviate" 3M's concerns. BIO.28. But the Rules Committee does not sit to correct decisions that fail to abide by this Court's precedents and revive some 6,000 meritless claims in the process. That is the office of this Court. Nor does the Rules Committee have before it either the "so-fundamentally-unsupported" standard of initial admissibility or the proper standard for appellate review of decisions to exclude. The fact that the Committee is considering alternative possibilities for tightening reliability standards prospectively is evidence that juries continue to hear too much junk science even in circuits that faithfully apply this Court's precedents, but prospective solutions to different problems will do nothing to fix the errors that already occurred here.

BIO.5. In fact, that view was expressed not by the CDC itself, but by someone on a committee addressing the CDC, and did not concern joint infections, or even forced-air warming, but heater-cooler units.

In short, the Rules Committee activity is evidence of a serious ailment, but no substitute for a cure. In that regard, it is telling that this Court granted certiorari in *Kumho Tire v. Carmichael*, 526 U.S. 137 (1999), while Rules Committee action on Rule 702 was pending and Congress was actively considering *Daubert* issues. *See* U.S.Amicus.Br.27.n.12, *Kumho Tire*, 1998 WL 541947 (U.S. 1998); *Preliminary Draft of Proposed Amendments to the Federal Rules of Civil Procedure and Evidence* 109-10 (Aug. 1998), *available at* https://tinyurl.com/2p97t4hc.

3. Ultimately, Respondent's effort to pass this petition off as a plea for mere error correction all but concedes that an error occurred. And by virtue of the nationwide MDL, that error means that 6,000 cases filed based on manufactured claims and spurious made-for-litigation studies will be revived. This Court routinely grants certiorari to review decisions on legal issues that will directly affect far fewer cases. *See, e.g.*, *Cassirer v. Thyssen-Bornemisza Collection Found'n*, No. 20-1566; *Shurtleff v. City of Boston*, No. 20-1800; *LeDure v. Union Pac. R.R. Co.*, No. 20-807. But the impact of the decision below goes much further. Innumerable patients will hear advertisements second-guessing the medical judgments of their surgeons and sowing confusion and anxiety based on manufactured and unreliable theories. The District Court put an end to all that, only to be reversed by a decision employing standards of initial admissibility and appellate review irreconcilable with this Court's precedents. This Court should review and reverse that decision.

CONCLUSION

The Court should grant certiorari.

Respectfully submitted,

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