

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*

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The plaintiffs' general-causation experts opined that 3M's Bair Hugger device was capable of causing periprosthetic joint infections. After initially admitting this evidence, the district court reversed course and excluded their opinions because it found that "analytical gaps" existed between them and the scientific evidence. The Eighth Circuit reviewed the record evidence—including epidemiological and medical studies that the district court *had* found reliable—and concluded that the district court had overlooked "substantial empirical support" for the experts' opinions. It therefore partially reversed the district court's exclusion decision.

The questions presented are:

1. Did the Eighth Circuit err in applying Rule 702 and this Court's precedents in *Daubert* and *Joiner* to the facts of this case?
2. Was the Eighth Circuit's application of the abuse-of-discretion standard in this case insufficiently deferential to the district court?

TABLE OF CONTENTS

Questions presented..... i
Table of authorities iii
Introduction 1
Statement 3
Reasons for denying the writ..... 13
 I. The Eighth Circuit’s factbound
 application of *Daubert* and *Joiner* does
 not warrant review. 13
 II. The Eighth Circuit, like all other circuits,
 reviews district-court decisions to exclude
 expert evidence for abuse of discretion. 21
 III. 3M’s overblown policy arguments about
 “junk” science are not presented by this
 case and best directed to the advisory
 committee currently considering possible
 changes to Rule 702..... 24
Conclusion 30

TABLE OF AUTHORITIES

Cases

<i>Barrett v. Rhodia, Inc.</i> , 606 F.3d 975 (8th Cir. 2010)	16, 24
<i>Bland v. Verizon Wireless, (VAW) L.L.C.</i> , 538 F.3d 893 (8th Cir. 2008)	16, 24
<i>Bonner v. ISP Technologies, Inc.</i> , 259 F.3d 924 (8th Cir. 2001)	23
<i>Cooter & Gell v. Hartmarx Corp.</i> , 496 U.S. 384 (1990)	22
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 43 F.3d 1311 (9th Cir. 1995)	26
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993)	1, 18, 20
<i>First Union National Bank v. Benham</i> , 423 F.3d 855 (8th Cir. 2005)	23
<i>General Electric Co. v. Joiner</i> , 522 U.S. 136 (1997)	<i>passim</i>
<i>Glastetter v. Novartis Pharmaceuticals Corp.</i> , 252 F.3d 986 (8th Cir. 2001)	16, 23
<i>In re Paoli Railroad Yard PCB Litigation</i> , 35 F.3d 717 (3d Cir. 1994)	20
<i>In re TMI Litigation</i> , 193 F.3d 613 (3d Cir. 1999)	20
<i>In re Wholesale Grocery Products Antitrust Litigation</i> , 946 F.3d 995 (8th Cir. 2019)	16, 24
<i>J.B. Hunt Transport, Inc. v. General Motors Corp.</i> , 243 F.3d 441 (8th Cir. 2001)	16, 23

<i>Johnson v. Mead Johnson & Co., LLC,</i> 754 F.3d 557 (8th Cir. 2014)	23
<i>Karlo v. Pittsburgh Glass Works, LLC,</i> 849 F.3d 61 (3d Cir. 2017)	20
<i>Klingenberg v. Vulcan Ladder USA, LLC,</i> 936 F.3d 824 (8th Cir. 2019)	23
<i>Knight v. Kirby Inland Marine Inc.,</i> 482 F.3d 347 (5th Cir. 2007)	6
<i>Kumho Tire Co., Ltd. v. Carmichael,</i> 526 U.S. 137 (1999)	26
<i>Marmo v. Tyson Fresh Meats, Inc.,</i> 457 F.3d 748 (8th Cir. 2006)	15, 16, 24
<i>McKnight By & Through Ludwig v. Johnson</i> <i>Controls, Inc.,</i> 36 F.3d 1396 (8th Cir. 1994)	23
<i>Menz v. New Holland North America, Inc.,</i> 507 F.3d 1107 (8th Cir. 2007)	16, 24
<i>Pereida v. Wilkinson,</i> 141 S. Ct. 754 (2021)	28
<i>Polski v. Quigley Corp.,</i> 538 F.3d 836 (8th Cir. 2008)	16, 24
<i>Pro Service Automotive, LLC, v. Lenan Corp.,</i> 469 F.3d 1210 (8th Cir. 2006)	16, 24
<i>Ruiz-Troche v. Pepsi Cola,</i> 161 F.3d 77 (1st Cir. 1998)	27
<i>Smith v. BMW North America, Inc.,</i> 308 F.3d 913 (8th Cir. 2002)	23
<i>Smith v. Cangietter,</i> 462 F.3d 920 (8th Cir. 2006)	16, 24

<i>United States v. Finch</i> , 630 F.3d 1057 (8th Cir. 2011)	23
<i>United States v. Schiff</i> , 602 F.3d 152 (3d Cir. 2010)	20
<i>Weisgram v. Marley Co.</i> , 169 F.3d 514 (8th Cir. 1999)	16, 23
Rules	
Federal Rule of Evidence 702	27
Supreme Court Rule 10	1
Other Authorities	
86 Fed. Reg. 41087 (July 30, 2021)	28
86 Fed. Reg. 8039 (Feb. 11, 2022)	28
Advisory Committee on Evidence Rules, Agenda for May 6, 2022 Committee Meeting, U.S. Courts, (May 6, 2022), https://perma.cc/5VVB-8275	28
John G. Brock-Utne, Justin T. Ward & Richard A. Jaffe, <i>Potential Sources of Operating Room Air Contamination: A Preliminary Study</i> , J. Hosp. Infection (2021), https://perma.cc/SZ9X-CP9C	26
Carnegie Commission on Science, Technology, and Government, <i>Science and Technology in Judicial Decision Making</i> (1993)	27
Gary Edmond & David Mercer, <i>Trashing “Junk Science”</i> , 1998 Stan. Tech. L. Rev. 3 (1998)	28
X. He et al., <i>Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room</i> , 34 International Journal Numerical Methods Biomedical Engineering, May 2018	8

National Resource Council of the National Academies, Reference Manual on Scientific Evidence (3d ed. 2011).....	4
Sean Ryan, <i>Backfire: Abandoning the Abuse of Discretion Standard of Review for Daubert Rulings Shoots Trial Courts in the Foot</i> , 47 U. Tol. L. Rev. 349 (2016).....	27
Stephen M. Shapiro et al., <i>Supreme Court Practice</i> (10th ed. 2013).....	1
Brie D. Sherwin, <i>Anatomy of A Conspiracy Theory: Law, Politics, and Science Denialism in the Era of Covid-19</i> , 8 Tex. A&M L. Rev. 537 (2021)	27
Michael Vlessides, <i>Warming Devices May Be Source of Airborne Microbial Contamination, but Fix Is Possible</i> , Anesthesiology News (March 11, 2021), https://perma.cc/5BQN-SL2A	26

INTRODUCTION

It is well established that “error correction” is outside “the mainstream of the Court’s functions and . . . not among the ‘compelling reasons’ . . . that govern the grant of certiorari.” Stephen M. Shapiro et al., *Supreme Court Practice* § 5.12(c)(3), p. 352 (10th ed. 2013). Certiorari, under this Court’s rules, is thus “rarely” warranted when “the asserted error” is “the misapplication of a properly stated rule of law.” S. Ct. R. 10.

Yet error correction is precisely what 3M seeks here. In a thorough 35-page opinion, the Eighth Circuit applied Federal Rule of Evidence 702 and this Court’s settled precedents in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), to the facts and concluded that the district court erroneously excluded the general-causation opinions of the plaintiffs’ medical and engineering experts. Before arriving at this admittedly “narrow” conclusion, App. 35, the Eighth Circuit painstakingly reviewed the epidemiological literature, peer-reviewed medical studies, deposition and trial testimony, and the results of a computational-fluid-dynamics model. The Eighth Circuit credited part of the district court’s analysis, even “limit[ing]” the engineering expert’s testimony. App. 23–24. But, because the district court had overlooked significant “empirical support bridging the analytical gap” between the scientific evidence and the experts’ opinions, it partially reversed the district court’s exclusion decision. App. 27.

Nothing about that case-specific, factbound holding cries out for this Court’s review. So 3M reimagines the Eighth Circuit’s opinion. It plucks language from the opinion to claim that the Eighth Circuit invented a new

“fundamentally unsupported” standard of admissibility—even though the Eighth Circuit explicitly noted that such language is shorthand for the settled rule that “a district court may exclude expert testimony if it finds ‘that there is simply too great an analytical gap between the data and the opinion proffered.’” App. 12 (quoting *Joiner*, 522 U.S. at 146). 3M also baldly asserts (at 20) that the Eighth Circuit reduced Rule 702’s reliability requirement into a “standard for mere relevance”—ignoring that the decision below carefully considered whether the experts’ opinions were reliably connected to the scientific literature and even affirmed the partial exclusion of one of the plaintiffs’ engineering expert’s opinions *precisely because* it was deemed unreliable. And while 3M claims that the Eighth Circuit’s “lax” standard is different from those in other circuits, it does not (and cannot) contend that any other circuit would reach a different conclusion on these facts.

3M’s second question fares no better. 3M doesn’t argue that there is any conflict in the lower courts over the proper standard of appellate review for district-court decisions to exclude expert testimony. And 3M cannot dispute that the decision below identified and applied the correct standard: abuse of discretion. *See* App. 10, 22, 24, 35. All 3M points to is the Eighth Circuit’s observation that there is an “intriguing juxtaposition” between that standard and Rule 702. App. 10. Yet this observation played no role at all in the Eighth Circuit’s actual analysis of the district court’s exclusion decision—and 3M does not even try to show otherwise.

In the end, a sophisticated plea for error correction—even one prepared by eminent counsel and supported by multiple *amici*—is still a plea for error correction. This Court should deny the petition.

STATEMENT

1. 3M's Bair Hugger is a "a forced-air device used to keep patients warm during surgery." App. 3. It works by drawing in air from the unsterile operating room floor, heating it, and blowing it through a hose into a perforated blanket placed directly over the patient. App. 3. The unit that draws in the air has a filter, but not a high-efficiency particulate air ("HEPA") filter. CA8 App. A268–A271.¹ And the hose that blows air into the blanket and near the wound site has no air filter at all. App. 48. 3M admits that Bair Hugger is "not sterile," and does not dispute that the device harbors and grows bacteria. CA8 App. A569.

Periprosthetic joint infections ("PJIs") are caused by bacteria that is introduced at the time of surgery, typically through airborne (or "aerosolized") particles. "Bacterial contamination is a particularly significant threat in orthopedic-implant surgeries because a PJI can be caused by very few microbes, possibly even a single bacterium." App. 4. Periprosthetic joint infections are enormously consequential: They can lead to additional surgeries, amputation, and even death. CA8 App. A878–A881.

Over the last decade, evidence has steadily emerged showing that the use of Bair Hugger may increase the risk of periprosthetic joint infections. In 2011, for example, an epidemiological study (McGovern 2011, CA8 App. A1172–A1180) reviewed infection data from approximately 1,500 hip- and knee-replacement surgeries performed at a hospital that shifted from using Bair Hugger to "conductive patient-warming devices," which do not use forced air. App. 14. That peer-reviewed and published

¹ "CA8 App." refers to the plaintiffs' appendix in the Court of Appeals.

study found nearly a 400% increased risk of infection among those patients who were warmed by Bair Hugger—a large and statistically significant association. App. 14–15. Consistent with ordinary epidemiological practice, the authors explained that the study did “not establish a causal basis for this association.” App. 15; *see* Nat’l Res. Council of the Nat’l Academies, Reference Manual on Scientific Evidence 598 (3d ed. 2011) (“Epidemiology cannot prove causation; rather, causation is a judgment for epidemiologists and others.”). Since McGovern 2011, there have been no epidemiological studies disproving this statistically significant association between Bair Hugger and periprosthetic joint infection.

In addition, dozens of non-epidemiological studies and reports dating back to 1997 have reached similar conclusions. *See* App. 25–27, 31–33.² These studies identify two distinct mechanisms by which forced-air-warming devices like Bair Hugger could cause periprosthetic joint infections. *First*, the devices are internally contaminated with bacteria, “which are blown through the blanket into the operating room, where they become ambient and eventually reach the surgical site.” App. 5. The parties and courts in this case have dubbed this mechanism the “dirty machine” theory. *Second*, the heat generated by the device produces “convection currents that carry ambient bacteria from nonsterile areas of the operating room to the surgical site”—what is known in this case as the “airflow disruption theory.” App. 5. Because “[d]ocumented complications from [Bair Hugger] use

² These studies and reports, all of which were in the appendix below, are listed chronologically in the plaintiffs’ Eighth Circuit reply brief. *See* Pls. Reply Br. 3–6, *In re Blair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, No. 19-2899 (8th Cir. Sept. 25, 2020).

include an increased incidence of surgical site infections,” CA8 App. A3428, independent scientists and health experts have determined that Bair Hugger is a “reservoir[] of infection,” CA8 App. A3392, A662. And even some scientists within 3M agree. *See, e.g.* CA8 App. A217 (sealed).

As the potential risk of infection has been increasingly recognized, some scientists have called for surgeons to discontinue the use of forced-air warming devices like Bair Hugger, or to take additional precautions to prevent infection. *See, e.g.*, CA8 App. A3048 (referencing recommendation not to use forced-air warming “because of its high risk for patients to develop a surgical site infection”).³ These conclusions and recommendations are consistent with the CDC’s more general recommendation that “[n]othing that blows air should be in an operating theater.” CA8 App. A883. And even organizations that 3M tries to portray as having concluded that Bair Hugger is safe—including the International Consensus that 3M repeatedly mentions in its petition—agree that the “literature is conflicting” and that forced-air warming poses a “theoretical risk” of infection. App. 36–37.

The increasingly understood links between Bair Hugger and periprosthetic joint infections also led to

³ *See also, e.g.*, Baker 2002 (CA8 App. A1133) (“[T]here seems insufficient evidence to justify the routine use of forced air warming units ... during ultraclean orthop[ed]ic surgery”); ECRI 2017 (CA8 App. A3401) (“A warming unit should have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into wounds”); Tsai 2017 (CA8 App. A3428) (“Documented complications from [forced-air warming] use include an increased incidence of surgical site infections”); Wood 2014 (CA8 App. A1214) (“We conclude that [forced-air warming] does contaminate ultra-clean air ventilation.”).

lawsuits against 3M and its defunct subsidiary Arizant Health by individuals who developed infections from the use of Bair Hugger during their orthopedic-implant surgeries. App. 2. In late 2015, the Joint Panel on Multidistrict Litigation centralized these lawsuits, which now number nearly 6,000, in the District of Minnesota for consolidated pretrial proceedings. App. 4.

2. The plaintiffs in the multidistrict litigation sought to introduce expert testimony on the issue of general causation—that is, “whether the Bair Hugger *can* cause a PJI,” not whether it in fact did so for any particular plaintiff. App. 35 (emphasis added); *see, e.g., Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007) (“General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual’s injury.”). As relevant here, the plaintiffs offered testimony from four general-causation experts: three medical experts (Dr. Jonathan M. Samet, a world-renowned epidemiologist; Dr. William Jarvis, an infectious-disease specialist who “formerly worked at the Center for Disease Control with a focus on infectious diseases associated with healthcare,” App. 70; and Dr. Michael J. Stonnington, an orthopedic surgeon); and an internationally acclaimed engineering professor (Dr. Said Elghobashi).

Dr. Elghobashi, “a recognized expert in the field of computational fluid dynamics,” App. 54, developed a model that used “large eddy simulation”—a sophisticated type of computational fluid dynamics (“CFD”) used to study turbulence—“to simulate the Bair Hugger’s effect on airflow and dispersion of squames,” which are “skin flakes capable of carrying bacteria that are present in

operating rooms.” App. 19–20. The “model replicated an orthopedic operating room, including details such as laminar airflow, an operating table, surgical drapes, a patient underneath the drapes prepared for knee surgery, four surgeons (two with hands extended over the patient, two with hands down), two side tables, two surgical lamps, the Bair Hugger blanket applied to the patient’s torso under the drapes, and the Bair Hugger central unit sitting on the floor near the head of the operating table.” App. 20. It also “accounted for the heat generated by the Bair Hugger as well as heat emanating from other sources, including the surgeons, patient, surgical lamps, and even the exposed surface of the patient’s knee.” App. 20. “After inputting a number of airflow-related details, Dr. Elghobashi simulated whether the Bair Hugger could lift these 10- μ m-sized squames—particles undisputedly large enough to carry bacteria and thus be ‘dangerous’—up to four ‘regions of interest’ in the operating room, such as where the surgical tools are kept and the surgical site itself.” App. 20–21.

The simulation showed that, with the Bair Hugger turned off, the operating room’s “ventilation air circulation alone cannot disperse the squames to the surgical site.” App. 21. But with the Bair Hugger on, the model showed a statistically significant number of squames dispersed to the “dangerous” regions of interest. App. 20–21. Dr. Elghobashi thus concluded that “the hot air from the blower and resultant thermal plumes are capable of lifting [squames] and transporting them to the side tables, above the operating table, and the surgical site.” App. 21. He further opined that “if other variables were introduced into the model, such as movement of medical staff, ‘then the probability of dispersing the squames to the surgical site will be increased even

further.” App. 21. Dr. Elghobashi “published his model with several coauthors in a peer-reviewed journal.” App. 20; see X. He et al., *Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room*, 34 Int’l J. Numerical Methods Biomedical Eng’g, May 2018.

The three medical experts offered testimony that the “use of the Bair Hugger device increases the risk of PJI compared to the risk of infection when the device is not used.” App. 48–49. They based their opinion in part on the McGovern 2011 epidemiological study finding “a statistically significant association between the Bair Hugger and infection,” as well as a “number of non-epidemiological studies and Dr. Elghobashi’s CFD model, which together describe the mechanism[s] by which the Bair Hugger transmits contaminated airborne particles into the sterile surgical site.” App. 70. Together, these two lines of scientific evidence—epidemiologic and mechanistic studies—provided a solid foundation for the plaintiffs’ medical experts’ general-causation opinions: Bair Hugger can cause periprosthetic joint infections.

3M moved to exclude the above experts’ testimony, as well as other experts not at issue in this appeal. It also moved for summary judgment contingent on the exclusion of this evidence. App. 6–7. 3M did not challenge the experts’ qualifications or experience; it disputed only their conclusions. App. 54, 70.

3. The district court initially denied 3M’s motion to exclude these experts, concluding that their testimony was reliable, relevant, and ultimately admissible. As to Dr. Elghobashi’s testimony, the court found that (1) the “physics” of Dr. Elghobashi’s CFD model was “reliable”; (2) the CFD model relied on 3M’s own “representations”; and (3) 3M could “contradict Elghobashi’s inputs by

presenting their own fluids expert Abraham.” App. 104–06. The district court also admitted the medical experts’ opinion that, “compared to warming devices that warm patients through modes other than forced air, the Bair Hugger increases the risk of deep-joint infection from orthopedic-implant surgery.” App. 109.⁴ This opinion was reliable, the court found, in part because it was based on the McGovern 2011 study and “Elghobashi’s testimony [about the results of the CFD model], buttressed by scientific publications.” App. 109–12. The district court then held the first bellwether trial in this multi-district litigation, at which some but not all of the experts testified. The jury in that first trial returned a verdict for 3M. App. 7.

After the bellwether trial, 3M moved for reconsideration of the district court’s exclusion order. Reversing course, the district court this time granted 3M’s motion. Although it conceded that Dr. Elghobashi’s model was generally reliable, the court excluded his testimony because it rested on an “unproven and untested premise” and he failed to account for “other sources of heat and air movement” that might occur in an operating room. App. 22, 61–62. Under *Joiner*, it thus concluded that there was too great “an analytical gap between the CFD results and Dr. Elghobashi’s conclusion.” App. 63. Dismissing the fact that his model had been peer-reviewed and published, the court also found Dr. Elghobashi’s testimony unreliable because it was developed for litigation. App. 68–70.

Next, the district court deemed the medical experts’ opinions unreliable because there was supposedly “too

⁴ The district court and the Eighth Circuit “generally treated the medical experts as a collective set,” as “their opinions were essentially the same and were founded on much of the same evidence.” App. 8.

great an analytical gap between the literature and the experts' general causation opinions." App. 71. It acknowledged that the scientific literature, including the McGovern 2011 study, reliably supported an association between forced-air warming and infection, but faulted the medical experts for drawing causal links where the individual studies had not and for ignoring alternative explanations for the association. App. 74–93. It also found that the medical experts' opinions were inadmissible, because they were not "generally accepted" by the medical and scientific community. App. 94–96.

Having excluded the plaintiffs' general-causation evidence, the district court granted 3M summary judgment on all claims and entered an MDL-wide final judgment. App. 7, 97.

4. The Eighth Circuit affirmed in part and reversed in part the district court's exclusion decision. The court "first recite[d] the principles that govern our analysis." App. 9. It then cited this Court's *Daubert* standard: "Federal Rule of Evidence 702 governs the admissibility of expert testimony, and under this rule the district court is vested with a gatekeeping function, ensuring that any and all scientific testimony or evidence admitted is not only relevant, but reliable." App. 10.⁵ After recounting various reliability factors that *Daubert* identified, it turned to this Court's decision in *Joiner*, which "clarified that 'conclusions and methodology are not entirely distinct from one another.'" App. 11 (quoting *Joiner*, 522 U.S. at 146). Under *Joiner*, the court explained, "a district court may exclude expert testimony if it finds 'that there is

⁵ Unless otherwise indicated, all internal citations, quotation marks, and alterations are omitted.

simply too great an analytical gap between the data and the opinion proffered.” App. 12 (quoting 522 U.S. at 146). It continued: “Or, to put it in the language we have frequently used both before and after *Daubert* and *Joiner*, a district court may exclude an expert’s opinion if it is ‘so fundamentally unsupported’ by its factual basis ‘that it can offer no assistance to the jury.’” App. 11.

As to the standard of appellate review, the Eighth Circuit explained that “the district court has broad discretion, and on appeal we will not disturb a decision concerning the exclusion of expert testimony absent an abuse of that discretion.” App. 10.

The Eighth Circuit then considered whether the district court had abused its discretion here. After thoroughly reviewing the district court’s analysis in light of the scientific evidence in the record, the Eighth Circuit concluded that the district court had erred in excluding the testimony of the three medical experts and had partially erred by categorically excluding Dr. Elghobashi’s testimony instead of limiting it.

As to the medical experts: *First*, the Eighth Circuit determined that “it was not necessarily unreliable for the experts to rely on McGovern 2011 to draw an inference of causation just because the study itself recognized, consistent with [general epidemiological] principles, that the association did not establish causation.” App. 14–16. *Second*, it held that even if the medical experts “did not adequately address McGovern 2011’s limitations,” they had other evidentiary support for their opinions—including “studies and reports ostensibly showing plausible mechanisms by which forced-air warming can cause PJIs.” App. 17–19. *Third*, it held that the district court overlooked “significant support for the proposition

that the Bair Hugger independently is capable of disrupting airflow so as to transmit bacteria to the surgical site when other airflow-disruptive variables are controlled for,” as well as additional “empirical support for the proposition that those other variables can facilitate the Bair Hugger’s airflow-disruptive effect in a real-world operating room.” App. 25–29. *Fourth*, the Eighth Circuit determined that the “published studies and reports” in the record sufficiently supported the experts “dirty machine” theory, even if they had some “weaknesses.” App. 29–34. *Fifth*, it held that “the lack of general acceptance does not independently justify exclusion of [the plaintiffs’] general-causation medical experts,” particularly given that some of 3M’s own evidence “acknowledge[d] that ‘concerns exist’ about a link between forced-air warming and surgical-site infections.” App. 35–38.

Turning to Dr. Elghobashi, the Eighth Circuit agreed with the district court’s exclusion of one aspect of his testimony—namely, that “if additional real-world conditions (such as personnel movement) that have a significant impact on airflow disruption were introduced into his model, then the Bair Hugger’s effect on the dispersion of squames would be exaggerated in a real-world operating room.” App. 22. This opinion was unreliable, the Eighth Circuit held, because it found no support in Dr. Elghobashi’s published study or his report. And as the court recognized: “[N]othing 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.” App. 22 (quoting *Joiner*, 522 U.S. at 146). Nevertheless, the Eighth Circuit disagreed with the district court’s “categorical exclusion of Dr. Elghobashi and his model.” App. 22–23. Properly limited to the conclusion “that forced-air warming does

play a role, at least in certain operating-room conditions” in transporting squames to the surgical site, his opinion “was tested and supported by the CFD model, and the problematic analytical gap found by the MDL court is gone.” App. 23.

The Eighth Circuit cautioned that its “conclusion [wa]s a narrow one” that “turn[ed] greatly on the fact that the opinions at issue here address general causation (whether the Bair Hugger can cause a PJI) rather than specific causation (whether the Bair Hugger did cause a particular plaintiff’s PJI).” App. 35. It noted that the plaintiffs still could face “significant hurdles for the specific-causation showing [they] must make to prevail.” App. 35. All it held was “that the MDL court abused its discretion in excluding these experts’ general-causation opinions on the basis of excessive analytical gaps.” App. 35. Given its reversal of the district court’s exclusion decision, the Eighth Circuit also reversed the grant of summary judgment to 3M. App. 38.

REASONS FOR DENYING THE WRIT

I. The Eighth Circuit’s factbound application of *Daubert* and *Joiner* does not warrant review.

3M repeatedly asserts (at 2, 17, 33) that this Court’s review is needed to correct the Eighth Circuit’s “erroneously lax” and “lenient” standard of admissibility for expert testimony. But 3M’s argument on the first question presented suffers from a fundamental problem: That purported “lax” standard cannot be found anywhere in the decision below. Instead, the Eighth Circuit meticulously applied Rule 702’s reliability inquiry to the facts of this case, guided by this Court’s settled precedents in *Daubert* and *Joiner*. While it agreed with the district court’s analysis in some respects, it ultimately concluded

that the district court had ignored key “empirical support” in the record that “bridged” the alleged analytical gaps that drove the exclusion decision on reconsideration. App. 27, 29. This conclusion is consistent with the approaches of all other circuits—and 3M doesn’t even try to argue otherwise. There is simply no need for this Court to step in.

A. In a verbal sleight of hand, 3M attributes to the Eighth Circuit a rule that it neither endorsed nor applied. According to 3M, the decision below applied a mandatory circuit-specific rule that “expert testimony *must* be admitted, unless it is so ‘fundamentally unsupported’ as to be useless to the jury.” Pet. 17; *see also id.* at 21.

But this rule does not appear even once in the opinion. Instead, the Eighth Circuit correctly stated only that “a district court *may* exclude an expert’s opinion *if* it is ‘so fundamentally unsupported’ by its factual basis that it can offer no assistance to the jury.” App. 12 (emphasis added). Even 3M admits (at 22) that this discretionary standard is an “uncontroversial statement” that properly reflects this Court’s precedent. *See also* Pet. 23 n.6. The “so-fundamentally-unsupported” rule, in other words, is a rule of 3M’s own making. So the entire premise of 3M’s first question presented is unfounded.

3M nonetheless contends (at 20–21) that the “standard of initial admissibility” that the decision below applied “looks nothing like the one described in *Daubert*, *Joiner*, and amended Rule 702.” That is also incorrect. The Eighth Circuit explained that the “fundamentally unsupported” language derived from its case law is *synonymous* with *Joiner*’s “analytical gap” standard. *See* App. 12. Indeed, it expressly equated the two:

[T]he question the MDL court ultimately had to answer was whether these shortcomings left ‘too great an analytical gap’ between the factual bases for the experts’ opinions and the general-causation opinions themselves, *see Joiner*, 522 U.S. at 146; *or, in other words*, whether the opinions were “so fundamentally unsupported” that they should be excluded rather than admitted and left to be impeached through cross-examination at trial

App. 34 (emphasis added).

The Eighth Circuit’s actual analysis also reflected the framework that this Court developed for assessing the admissibility of expert testimony in *Daubert* and *Joiner*, as reflected in the 2000 amendments to Rule 702. The decision below repeatedly (and expressly) applied this framework to determine whether the district court abused its discretion in finding “too great an analytical gap” between each of the general-causation experts’ opinions and the data they relied upon. *See, e.g.*, App. 12, 13, 15, 22, 23, 24, 25, 27, 34, 35, 38. In other words, no matter how 3M tries to describe the Eighth Circuit’s standard, it cannot change the fact that the Eighth Circuit simply applied this Court’s precedents to the facts of this case.

Moreover, contrary to 3M’s assertions (at 23, 25–26), the Eighth Circuit has *consistently* applied this framework to evaluate the reliability of expert testimony. In a previous case upholding the exclusion of expert testimony, for instance, the Eighth Circuit explained that while Rule 702 favors admissibility over exclusion, its precedent did not “provide[] a blanket rule” of admissibility. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006). Instead, the question

whether expert evidence is unreliable turns on “the circumstances of each case” and whether “the analytical gap between the data and proffered opinion is too great.” *Id.* The Eighth Circuit’s faithful application of the *Joiner* framework on numerous occasions to uphold the *exclusion* of expert testimony undermines 3M’s claim that the Eighth Circuit improperly reads Rule 702 as an admissibility mandate.⁶

In sum, this Court’s standards in *Daubert* and *Joiner*—not 3M’s wayward reformulation—are what guided the Eighth Circuit’s analysis at every step. The petition’s first question is therefore not even presented by this case.

B. Nevertheless, 3M asserts—citing nothing—that the decision below “turned entirely on [the Eighth Circuit’s] application” of 3M’s invented standard. Pet. 18. Yet 3M’s petition spends curiously little time supporting this assertion with any discussion of the Eighth Circuit’s actual analysis of the expert testimony and underlying record. That’s because, on a fair reading of the opinion, the decision below faithfully and carefully applied this Court’s

⁶ This list is not exhaustive. *See, e.g., Weisgram v. Marley Co.*, 169 F.3d 514, 521 (8th Cir. 1999); *J.B. Hunt Transport, Inc. v. Gen. Motors Corp.*, 243 F.3d 441, 444 (8th Cir. 2001); *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001); *Smith v. Cangieter*, 462 F.3d 920, 924–25 (8th Cir. 2006); *Marmo v. Tyson Fresh Meats*, 457 F.3d 748, 758 (8th Cir. 2006); *Pro Service Auto., LLC, v. Lenan Corp.*, 469 F.3d 1210, 1216 (8th Cir. 2006); *Menz v. New Holland N. Am., Inc.*, 507 F.3d 1107, 1114–15 (8th Cir. 2007); *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008); *Polski v. Quigley Corp.*, 538 F.3d 836, 840–41 (8th Cir. 2008); *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 981 (8th Cir. 2010); *In re Wholesale Grocery Prods. Antitrust Litig.*, 946 F.3d 995, 1002 (8th Cir. 2019).

settled precedent in *Joiner* to hold that the district court abused its discretion in excluding the plaintiffs' experts.

The district court here based its exclusion of the plaintiffs' general-causation medical experts on two grounds—that there was, in its view, (1) “too great an analytical gap between the literature and the experts' general causation opinions” under *Joiner*; and (2) that “the causal inferences made by the experts have not been generally accepted by the scientific community” under *Daubert*. App. 8–9. The Eighth Circuit methodically examined both conclusions and found them lacking—not because of any disagreement on the applicable law but based instead on the district court's erroneous application of the *Joiner* and *Daubert* standards to the facts.

The Eighth Circuit held, for instance, that the district court erroneously faulted the medical experts for relying on an epidemiological study finding that “forced-air warming was associated with an increased rate of [periprosthetic joint infections].” App. 14–19. Although that study did not itself conclude a causal link, the Eighth Circuit correctly recognized that it is not “*per se* unreliable for an expert to draw an inference of causation” from a published and peer-reviewed epidemiologic study. App. 15–16. The Eighth Circuit further concluded that the district court overlooked other evidence in the record—including “a number of published studies”—that plausibly supported the medical experts' opinions. App. 25; *see generally* App. 25–33 (discussing studies and reports). Though these studies had “limitations,” the Eighth Circuit still determined that “findings in these studies provide empirical support bridging the analytical gap from simulated operating-room conditions to real-world operating-room conditions”—thus making the gap that

the district court identified “at least partially illusory.” App. 27.

This garden-variety application of Rule 702’s reliability standard to the facts of this case warrants no further review. And the same is true with respect to the plaintiffs’ engineering expert, Dr. Elghobashi. The district court excluded Dr. Elghobashi’s opinion about effects his model did not measure “because (1) his conclusion about the Bair Hugger’s effects in real-world operating rooms relied on an unproven and untested premise, (2) there was too great an analytical gap between the results of his CFD and his conclusion about the Bair Hugger’s effects in real-world operating rooms, and (3) the CFD model was developed for litigation.” App. 9. Critically, the Eighth Circuit *agreed* with the district court about the first problem, holding that Dr. Elghobashi did not provide “support for [his] assertion” that introducing “additional real-world conditions” into his model would “exaggerate[]” “Bair Hugger’s effect on the dispersion of squames” in the operating room. App. 22. The Eighth Circuit therefore affirmed this aspect of the district court’s exclusion decision and limited the scope of Dr. Elghobashi’s opinion.⁷

⁷ Having limited his opinion, the Eighth Circuit reversed the “categorical exclusion of Dr. Elghobashi and his model,” finding that the results of the CFD model supported his remaining conclusions, eliminating the “problematic analytical gap” identified by the district court. App. 22–23. It also properly rejected the district court’s emphasis on the fact that Dr. Elghobashi’s testimony and model was “developed for litigation.” App. 23. That Dr. Elghobashi’s report was published in a peer-reviewed journal, the Eighth Circuit held, made any “lingering questions of reliability and objectivity go to weight rather than admissibility.” App. 23; *see also Daubert*, 509 U.S. at 593

This partial affirmance, standing alone, undermines 3M's repeated claims that the Eighth Circuit has "reduce[d] evidentiary reliability to mere relevance." Pet. 2. Dr. Elghobashi's opinion about real-world operating rooms was indisputably relevant to the plaintiffs' claims. Still, the Eighth Circuit excluded it solely because it was *unreliable*; this aspect of his opinion was "based on [his] knowledge," not on any scientific evidence. App. 22. And it did so by expressly citing *Joiner*—only highlighting that the decision below merely applied this Court's settled reliability standard to the record evidence. *See id.*

For reasons of its own, 3M is understandably dissatisfied with the Eighth Circuit's conclusions and would prefer a do-over. But that does not justify this Court stepping in to reassess the scientific evidence in this particular case.

C. Review is further unwarranted because there is no conflict in the lower courts over the standard of admissibility for expert evidence. 3M selectively quotes from other circuits' decisions to suggest that some circuits employ a more demanding reliability standard than others. Pet. 26–28. But these varying linguistic formulations of the *Daubert*/Rule 702 standard does not mean that different circuits are actually using different standards—let alone that the differing formulations are somehow outcome determinative.

Perhaps recognizing this, 3M never even attempts to argue that any other court would have reached a different conclusion in this case—the sine qua non of a circuit split.

(explaining that the reliability inquiry considers "whether the theory or technique has been subjected to peer review and publication").

And for good reason. To take just a single example: 3M identifies the Third Circuit as a court that applies a “demanding reliability standard.” Pet. 26, 28. But 3M fails to mention that the Third Circuit has *also* repeatedly held that “[t]he standard for [determining] reliability is not that high.” *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 81 (3d Cir. 2017); *United States v. Schiff*, 602 F.3d 152, 173–74 (3d Cir. 2010); *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999). Indeed, in one of the very cases that 3M cites, the Third Circuit suggested that the “ultimate touchstone” of Rule 702’s “reliability requirement” is mere “helpfulness to the trier of fact.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994).⁸

All this goes to show that, under *Daubert*, the reliability inquiry is a “flexible one,” on which “[m]any factors will bear.” 509 U.S. at 593–94. It is therefore unsurprising that different courts evaluating different expert evidence will reach different outcomes based on the specific facts before them. That does not mean there is a conflict over the proper standard—let alone a certworthy conflict. This Court should deny 3M’s petition.

⁸ Applying these precedents, the Third Circuit has held, for example, that a district court erred in applying a “merits standard of correctness” and a “bright-line exclusionary rule” in excluding an expert’s testimony due to statistical flaws, without evaluating whether the expert’s opinion and explanations otherwise rested on good grounds. *See Karlo*, 849 F.3d at 83. As the Third Circuit emphasized, “[t]he question of whether a study’s results were properly calculated *or interpreted* ordinarily goes to the weight of the evidence, not its admissibility.” *Id.* (emphasis added).

II. The Eighth Circuit, like all other circuits, reviews district-court decisions to exclude expert evidence for abuse of discretion.

This Court should also deny review of 3M's second question presented, which it tacks on near the end of its petition. Initially, 3M is simply wrong when it claims that the Eighth Circuit has adopted an "insufficiently deferential standard of appellate review" for decisions excluding expert evidence. Pet. 28. The decision below expressly identified and applied the abuse-of-discretion standard that this Court held was required in *Joiner*. Regardless, because the second question presented fails to satisfy any of the traditional criteria for certiorari, review is unwarranted.

A. 3M's entire argument on the second question presented turns on two stray passages in the Eighth Circuit's 35-page opinion below. First, the Eighth Circuit "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. Then, a couple paragraphs later, the Eighth Circuit identified another "intriguing juxtaposition"—specifically, the tension between the "significant deference" owed to district-court exclusion decisions and the "general rule" that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." App. 12.

Based solely on these two remarks, 3M contends (at 28) that the Eighth Circuit has adopted a novel and "insufficiently deferential standard of appellate review." Quite the opposite: In reviewing the expert testimony and record evidence, not once did the Eighth Circuit mention the "intriguing juxtaposition[s]" it had observed earlier.

Instead, as 3M admits, the decision below expressly recognized the district court’s “gatekeeping function” and identified the governing abuse-of-discretion standard. App. 10. And that is the *only* standard of review that the Eighth Circuit applied throughout its analysis of the district court’s exclusion decision.

Specifically, the Eighth Circuit held that the district court “abused its discretion in excluding [the medical] experts’ general-causation opinions on the basis of excessive analytical gaps” because the district court had overlooked or improperly discounted substantial empirical support in the record for those opinions. App. 35. Likewise, it held that the “court abused its discretion insofar as it excluded *all* of Dr. Elghobashi’s testimony,” because, “properly limited,” his testimony was “admissible.” App. 24 (emphasis added); *see also* App. 22.

The Eighth Circuit’s application of the abuse-of-discretion standard was entirely consistent with this Court’s precedent. *See, e.g., Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990) (explaining that “[a] district court would necessarily abuse its discretion if it based its ruling on . . . a clearly erroneous assessment of the evidence”). Indeed, in *Joiner* itself, this Court reviewed in detail the underlying studies in the record to determine whether they reliably supported the experts’ opinions and whether the court abused its discretion in excluding their testimony. *See* 522 U.S. at 144–46. The Eighth Circuit here did the same. No review of its application of settled law to the facts of this case is necessary.

B. In any event, the second question presented is plainly unworthy of certiorari. 3M never even tries to suggest that there is any conflict in the lower courts over the appropriate standard of appellate review of district-

court decisions to exclude expert evidence. And rightly so—because there is none. This Court was crystal clear in *Joiner*: “[T]he question of admissibility of expert testimony . . . is reviewable under the abuse-of-discretion standard,” and that same standard applies whether the district court admits or excludes the testimony. 522 U.S. at 142–43.

Nor does 3M make any effort to show that this Court’s review is necessary to resolve an “*important* question of federal law.” S. Ct. R. 10 (emphasis added). Even if it were true that the Eighth Circuit applied the incorrect standard of review (and it is not), 3M identifies only *one* other decision in which the Eighth Circuit—or any other court—has remarked on the “juxtaposition” between the abuse-of-discretion standard and Rule 702’s “liberal thrust.” Pet. 29 (discussing *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557 (8th Cir. 2014)). Indeed, the various Eighth Circuit decisions that 3M critiques in its argument on the first question presented (at 24–26) expressly applied only an abuse-of-discretion standard.⁹ And numerous Eighth Circuit decisions upholding the exclusion of expert testimony (*see supra*, n.4) did so based

⁹ *See, e.g., Klingenberg v. Vulcan Ladder USA, LLC*, 936 F.3d 824, 828 (8th Cir. 2019); *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011); *First Union Nat. Bank v. Benham*, 423 F.3d 855, 861 (8th Cir. 2005); *Smith v. BMW N. Am., Inc.*, 308 F.3d 913, 918 (8th Cir. 2002); *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 928 (8th Cir. 2001); *McKnight By & Through Ludwig v. Johnson Controls, Inc.*, 36 F.3d 1396, 1401 (8th Cir. 1994).

on a determination that the district court abused its discretion.¹⁰

So, even accepting 3M's characterization of the decision below, this Court's review of the second question presented would possibly affect only rare "outlier" decisions in a single circuit—decisions that no one, not even 3M, contend implicate a conflict in the lower courts. This Court should thus deny review of the second question.

III. 3M's overblown policy arguments about "junk" science are not presented by this case and best directed to the advisory committee currently considering possible changes to Rule 702.

Central to 3M's and its amici's strident pleas for review is their purported concern that an insufficiently demanding admissibility standard will allow "dubious" expert evidence and so-called "junk" science to proliferate. Pet. 2, 17, 31–32; *see, e.g.*, Atlantic Legal Foundation et al. Amicus Br. 3–4 (critiquing "purveyors of pseudo-science" and "professional expert witnesses who, for a price, peddle junk science testimony").

But this policy concern, which has little empirical support, actually demonstrates why 3M's petition should be denied. *First*, the expert testimony in this case was not based on "dubious" or "junk" science—the experts are well-renowned in their fields and relied on reams of

¹⁰ *See, e.g.*, *Weisgram*, 169 F.3d at 521; *J.B. Hunt Transport, Inc.*, 243 F.3d at 444; *Glastetter*, 252 F.3d at 991–92; *Pro Service Auto., LLC*, 469 F.3d at 1214; *Smith*, 462 F.3d at 925; *Marmo*, 457 F.3d at 758; *Menz*, 507 F.3d at 1114–15; *Bland*, 538 F.3d at 899; *Pol-ski*, 538 F.3d at 840–41; *Barrett*, 606 F.3d at 980–81; *In re Wholesale Grocery Prods. Antitrust Litig.*, 946 F.3d at 1002.

published and peer-reviewed materials. So 3M’s concern is not even presented here. *Second*, the rulemaking process, not this Court, is the proper forum for these policy arguments. In fact, industry groups—including some of 3M’s amici here—*have* raised these very concerns with the advisory committee currently considering amendments to Rule 702. It would make no sense for this Court to grant review only for the advisory committee to change (and perhaps even moot) the questions presented.

A. To start, there is considerable basis to question the validity of 3M’s (obviously self-interested) concern about so-called “junk” science. But, to the extent that 3M presents this concern in good faith, it is a reason to deny this petition, not grant it—because the expert evidence here was decidedly *not* “junk” science.

As the Eighth Circuit detailed, the experts here relied on peer-reviewed and published epidemiological and experimental studies that investigated the relationship between Bair Hugger and PJI, as well as Bair Hugger’s effect on contamination and spread of bacteria-laden particles in operating rooms. App. 14–19, 25–32. Dr. Elghobashi’s own study—which 3M and the district court denigrated as being “developed for litigation”—was published in a peer-reviewed biomedical-engineering journal. App. 20. And 3M itself conceded that Dr. Elghobashi is a world-renowned expert in computational fluid dynamics and that his CFD model was reliable. *See* App. 48, 54.

In fact, although 3M asserts (at 36) that the plaintiffs’ expert evidence “complete[ly] deviat[es] from consensus medical opinion,” several of 3M’s own key pieces of evidence—for example, the 2018 International Consensus Meeting on Periprosthetic Joint Infection—recognize the

“theoretical risk” posed by forced-air warming. App. 36; *see also* App. 37 (observing that even the “authorities 3M calls to our attention as showing a lack of general acceptance acknowledge that ‘concerns exist’ about a link between forced-air warming and surgical-site infections”). And the scientific evidence supporting the plaintiffs’ claims continues to accumulate. Just last year, experimental research presented to the American Society of Anesthesiologists found that forced-air warming devices, including Bair Hugger, “could be significant sources of . . . air contamination” of operating-room air. John G. Brock-Utne, Justin T. Ward & Richard A. Jaffe, *Potential Sources of Operating Room Air Contamination: A Preliminary Study*, *J. Hosp. Infection* (2021), available at <https://perma.cc/SZ9X-CP9C> (study collecting air samples from Bair Hugger and other forced-air warming devices and identifying bacterial colony counts in each sample). One of the lead researchers and chief resident at Stanford University’s Department of Anesthesiology concluded “with certainty that the Bair Hugger is contributing airborne microbes into the air.” Michael Vlessides, *Warming Devices May Be Source of Airborne Microbial Contamination, but Fix Is Possible*, *Anesthesiology News* (March 11, 2021), <https://perma.cc/5BQN-SL2A>.

Even if the plaintiffs’ expert opinions in this case may not be generally accepted, that does not mean that they are “junk” or “dubious” science. *See, e.g., Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (*Daubert II*) (explaining that “methods accepted by a minority in the scientific community may well be sufficient” to demonstrate reliability); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153 (1999) (defining parameters of reliable testimony as “the range where

experts might reasonably differ, and where the jury must decide among the conflicting views of different experts, even though the evidence is ‘shaky’”). It is clear that “*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.” *Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 85 (1st Cir. 1998); see Fed. R. Evid. 702, advisory committee note (explaining that the amended rule “is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise”). Indeed, “[t]he rejection of a simple dichotomy between ‘good’ and ‘bad’ science facilitates discussion in a number of areas otherwise precluded.” Edmond & Mercer, *supra*, at 14.

This case illustrates why the often-invoked “junk science” slogan does not reflect reality. The only independent scientific commission tasked with studying the role of science in litigation concluded three decades ago that, as for the “alleg[ations] that ‘junk science’ is flooding the courtroom,” “many of the concerns are greatly exaggerated” and “it does not appear that federal courts are being inundated with fringe science.” Carnegie Commission on Science, Technology, and Government, *Science and Technology in Judicial Decision Making* 13 (1993); see also, e.g., Brie D. Sherwin, *Anatomy of A Conspiracy Theory: Law, Politics, and Science Denialism in the Era of Covid-19*, 8 Tex. A&M L. Rev. 537, 575 (2021). Others have also found that “there is no evidence that at any point in time the federal court system has been flooded with charlatan experts.” Sean Ryan, *Backfire: Abandoning the Abuse of Discretion Standard of Review for Daubert Rulings Shoots Trial Courts in the Foot*, 47 U. Tol. L. Rev. 349, 357 (2016) (arguing that “the junk science problem was largely manufactured on

anecdotal information and inflated rhetoric, made at the insistence of defendant-friendly think tanks”). Instead, the label of “[j]unk science is a convenient scapegoat for deeper law-science conflicts because it plays on public fears of science and technology being out of control, while providing a rallying point for legal reform.” Gary Edmond & David Mercer, *Trashing “Junk Science”*, 1998 Stan. Tech. L. Rev. 3, 4 (1998).

B. In the end, 3M and its amici are pressing a policy argument based on a faulty premise: Rule 702, as applied by the lower courts, does not sufficiently keep out allegedly unreliable expert evidence. But “[i]t is hardly this Court’s place to pick and choose among competing policy arguments.” *Pereida v. Wilkinson*, 141 S. Ct. 754, 766 (2021). Rather, such arguments should be directed to the institution that *is* responsible for addressing such policy-based concerns—here, the Judicial Conference Committee on Rules of Practice and Procedure.

All the more so here because the Advisory Committee on Evidence Rules is *currently* considering amendments to Rule 702—changes that might obviate 3M’s and its amici’s concerns. Last summer, the advisory committee announced its proposed amendments to Rule 702 and requested public comment. *See* 86 Fed. Reg. 41087, 41088 (July 30, 2021). And in a few weeks, the advisory committee will hold a meeting to determine “whether to give final approval to the amendment[s].” Advisory Committee on Evidence Rules, Agenda for May 6, 2022 Committee Meeting, U.S. Courts, (May 6, 2022) at 2, <https://perma.cc/5VVB-8275>; *see also* 86 Fed. Reg. 8039, 8039 (Feb. 11, 2022).

Notably, numerous industry groups—including many amici in this case—recently filed public comments

supporting the proposed amendments. These comments make clear that the advisory committee is best positioned to effectively address the broader concerns about Rule 702. For example, one of the amici here told the committee that the proposed amendments “will help to exclude junk science” by “reinforc[ing] federal district judges’ gatekeeper role and further clarify[ing] that admissibility of expert testimony must be based on proper methodology and valid factual bases.” Atlantic Legal Foundation Comment to Advisory Committee on Evidence Rules at 2–3 (Feb. 11, 2022), <https://perma.cc/NS3Q-HQPN>. Another argued that “Rule 702, as applied by many courts, is broken” and pointed explicitly to the Eighth Circuit’s decision below; the best way to “fix it,” the amicus continued, was by “[a]n amendment and a strong accompanying note.” Product Liability Advisory Council Comment to Advisory Committee on Evidence Rules at 14, 16, 32, 47–48 (Feb. 3, 2022), <https://perma.cc/B7PB-6VWV>; *see also, e.g.*, Washington Legal Foundation Comment to Advisory Committee on Evidence Rules at 3 (Dec. 14, 2021), <https://perma.cc/GS7R-XH6Y> (acknowledging that Rule 702 is “ambiguous”); Lawyers for Civil Justice Comment to Advisory Committee on Evidence Rules (Sept. 1, 2021), <https://perma.cc/9FV7-EEKR>.

These public comments only highlight why it would be unwise for this Court to step in to attempt to address issues that are currently under consideration by the relevant committee. The reliability inquiry that courts use to assess expert evidence might change if the proposed amendments to Rule 702 are ultimately adopted. Or it might not. But this Court should not short-circuit the rulemaking process by granting the petition *now*—only for its eventual decision to be possibly rendered moot by

the advisory committee's final decision.

As of now, what *Daubert* and Rule 702 require is that an expert's opinion be grounded on reliable scientific methods and that such inquiry be undertaken in light of the facts and evidence in a particular case. Because the Eighth Circuit applied that well-established standard to the facts here, this Court's review is unwarranted.

CONCLUSION

This Court should deny 3M's petition for a writ of certiorari.

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