No. 14-958

IN THE
Supreme Court of the United States

MARIANNE CHAPMAN AND DANIEL CHAPMAN,
Petitioners,

v.

THE PROCTER & GAMBLE DISTRIBUTING LLC AND THE PROCTER & GAMBLE MANUFACTURING COMPANY,
Respondents.

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

REPLY BRIEF FOR PETITIONERS

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The decision below expressly requires epidemiological evidence as a precondition to the admissibility of general causation in toxic tort cases. That rule deepens a longstanding and well-recognized conflict between the Fifth Circuit and five other circuits. The circuit split warrants prompt review, especially because mass tort cases are frequently conducted through multi-district litigation, which subjects plaintiffs from across the country to the pre-trial evidentiary standards of the circuit in which the transferee court is located. Moreover, resolution of the circuit split would directly affect the disposition of this case, because application of the rule adopted by the other five circuits would have permitted petitioners to proceed to trial. Respondents' brief implausibly denies the existence of the entrenched circuit split and erroneously contends that this case does not implicate that conflict. Neither argument is persuasive. This Court should grant certiorari to review the important and recurring issue presented by the petition.

ARGUMENT

I. THE DECISION BELOW DEEPENS A RECOGNIZED CIRCUIT SPLIT ON THE QUESTION PRESENTED

A well-defined and recognized circuit conflict exists as to whether epidemiological evidence is necessary for the admissibility of expert evidence on general causation. Indeed, the Restatement (Third) of Torts: Liability for Physical and Emotional Harm (2010) recognizes a split between those circuits that have adopted an "epidemiological threshold" requirement for general causation and the "substantial body of case law and commentary [that] rejects an epidemiologic threshold" requirement. Restatement § 28

reporters' note cmt. c(3), at 442-43. The decision below puts the Eleventh Circuit firmly in the former camp, and thus deepens the already-existing circuit conflict.

A. The Decision Below Adopts An Epidemiological Threshold Test For Admissibility Of General-Causation Expert Testimony

Respondents deny that the Eleventh Circuit has adopted an epidemiological threshold requirement. But the key paragraph of the decision below is clear: the Eleventh Circuit's affirmance was based on the inability of plaintiffs' experts to provide epidemiological evidence that "this circuit has recognized as *indispensable* to proving the effect of an ingested substance." App. 18a-19a (emphasis added). "Indispensable" means "absolutely necessary" or "required." *Webster's New World College Dictionary* 727 (4th ed. 2010). Having held epidemiological evidence "indispensable," the court proceeded to hold that the other evidence supporting plaintiffs' expert opinions "insufficient" and their opinions thus inadmissible under Rule 702. App. 18a-19a. Consistent with its traditional practice, this Court should "take the Court of Appeals at its word," rather than adopt respondents' "wishful interpretation of the Court of Appeals' opinion." *Erica P. John Fund, Inc. v. Halliburton Co.*, 131 S. Ct. 2179, 2187 (2011).

Respondents' brief consists largely of efforts to avoid the clear import of the Eleventh Circuit's decision. First, they assert (at 22-23) that the appeals court affirmed the entirety of the district court's reasoning, which respondents claim did not adopt a strict epidemiological evidence requirement. But respondents' argument is unpersuasive. Although the district court did not state that epidemiological

evidence is always essential, it repeatedly focused on the absence of such evidence as a "serious weakness" in plaintiffs' expert methodologies. Resp. App. 16a-17a, 21a. Moreover, even if the district court did not expressly adopt an epidemiological threshold test, the appeals court clearly did. Of the district court's many reasons for excluding plaintiffs' experts, the Eleventh Circuit singled out plaintiffs' lack of epidemiological evidence as the basis for affirmance. App. 18a-19a.

The appeals court's holding was not lost on the district court itself. In its subsequent *Daubert* ruling in the other denture-cream products-liability cases pending in the Multi-District Litigation ("MDL"), the district court interpreted the decision below to require epidemiological evidence. *See In re Denture Cream Prods. Liab. Litig.*, No. 09-2051-MD, 2015 WL 392021, at *34 (S.D. Fla. Jan. 28, 2015) (holding that "Plaintiffs have not presented sufficient proof of general causation using the indispensable primary methodologies identified by the Eleventh Circuit") (citing the decision below).

Respondents also argue (at 19-21) that prior Eleventh Circuit decisions have held that epidemiological evidence is not required. But respondents misread those prior cases. Although they paid lip service to the possibility of admitting general-causation opinions unsupported by epidemiological evidence, they proceeded without exception to exclude plaintiffs' evidence for failing to satisfy epidemiological standards. It thus was not a leap for the court below to acknowledge that those prior cases had made epidemiological evidence "indispensable." The court

below correctly understood itself as following prior circuit case law, not repudiating it.[1]

Specifically, in *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194 (11th Cir. 2002), the court affirmed the exclusion of the plaintiffs' experts because the case studies they relied on merely "report[ed] symptoms observed in a single patient *in an uncontrolled context*." *Id.* at 1199 (emphasis added); *see also id.* at 1200 (holding challenge/dechallenge studies inadequate because they "are still case reports and do not purport to offer definitive conclusions as to causation"). The court concluded that the case reports were unreliable precisely because they were not controlled epidemiological studies and thus could not provide "definitive conclusions." *Id.*

Likewise, in *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329 (11th Cir. 2010), the court acknowledged *Rider*'s statement that "[t]he absence of [epidemiological] evidence is not fatal," but then held that the main study relied on by the plaintiffs' experts "was unreliable" because it "was merely a compilation of case reports without any statistical context" and "'thus [did] not provide as much information as controlled epidemiological studies do.'" *Id.* at 1336-38 (quoting *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) (following *Rider*'s reasoning)); *see also id.* at 1338-39 (holding other case reports unreliable for the same reason).[2] Again, the court's

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[1] Respondents' invocation (at 21, 25-26) of the "law of the Eleventh Circuit" is inapt because the decision below did not create an "intra-circuit" conflict.

[2] Respondents' two remaining cases are inapposite. In *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741 (11th Cir. 1986), the district court resolved a battle between experts who relied

application of Rule 702 functionally required the plaintiffs' experts to adduce epidemiological evidence to support their opinions.

The epidemiological evidence requirement adopted by the court below does not "depart from well-established Eleventh Circuit precedent." Opp. 21. Rather, in announcing that requirement, the court below merely confirmed the principle that prior cases had long applied in practice: without epidemiological evidence, general-causation opinions are inadmissible in toxic tort cases in the Eleventh Circuit.

B. The Fifth Circuit Also Has Adopted An Epidemiological Evidence Requirement

Contrary to respondents' contention, the Fifth Circuit also has adopted an "epidemiological threshold" test. The holding in *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified on reh'g*, 884 F.2d 166 (5th Cir. 1989) (per curiam), that the plaintiffs' "failure to present statistically significant epidemiological proof" was "fatal" to general causation, 884 F.2d at 167, is fully consistent with the Eleventh Circuit's statement in this case that the epidemiological evidence is "indispensable" to the admissibility of plaintiffs' experts. The decision below thus joins the Eleventh and Fifth Circuits as the two circuits that have adopted an epidemiological threshold requirement.

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on competing epidemiological studies, and the appeals court affirmed. *See id.* at 743-45 & n.6. In *Hendrix v. Evenflo Co.,* 609 F.3d 1183 (11th Cir. 2010), the plaintiff's experts relied on published epidemiological studies, but the Eleventh Circuit found them inadequate because they did not examine the causal relationship between the alleged cause (trauma) and the plaintiff's condition (autism spectrum disorder). *See id.* at 1199-1201. The court did not resolve whether other non-epidemiological evidence would have been sufficient.

It is true that *Brock* (unlike the court below in this case) hedged by stating that "we do not hold that epidemiologic proof is a necessary element in all toxic tort cases." 874 F.2d at 313. But, despite that caveat, the court clearly required epidemiological evidence. "[I]n the very next sentence, the court denigrated animal studies, which would be the primary alternative source of evidence of causation." Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U.L. Rev. 643, 668 (1992). Commentators thus correctly recognize that *Brock* was the "first case to employ" an epidemiological threshold requirement. Restatement § 28 reporters' note cmt. c(3), at 442; *accord* Green, 86 Nw. U.L. Rev. at 667-68; Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Context-Sensitive Science in Toxic Torts After* Daubert v. Merrell Dow Pharmaceuticals, Inc., 16 Va. Envtl. L.J. 1, 31 n.125 (1996).

Respondents also have no answer to the Fifth Circuit's decision in *Christophersen v. Allied-Signal Corp.*, 902 F.2d 362 (1990), *opinion superseded on reh'g en banc*, 939 F.2d 1106 (5th Cir. 1991) (*en banc*) (per curiam). Relying on *Brock*'s *dicta*, the panel in *Christophersen* reversed the district court's exclusion of an expert's opinion due to the absence of epidemiological evidence. *See* 902 F.2d at 367. The *en banc* court, however, vacated the panel's opinion and affirmed the district court's conclusion that the lack of epidemiological evidence made the expert's opinions unreliable. *See* 939 F.2d at 1115-16.

Christophersen put to rest any doubt about the Fifth Circuit's stance. District courts in that circuit thus have consistently interpreted circuit law

as requiring epidemiological evidence. *See*, *e.g.*, *Chambers v. Exxon Corp.*, 81 F. Supp. 2d 661, 665 (M.D. La. 2000) ("The reports submitted by plaintiffs' experts fail to present a single peer-reviewed, controlled epidemiological study that supports their causation theories. . . . [A]s the Fifth Circuit stated in *Brock*, theories of toxic causation 'unconfirmed by epidemiological proof cannot form the basis for causation in a court of law.'") (quoting 874 F.2d at 315), *aff'd*, 247 F.3d 240 (5th Cir. 2001) (per curiam); *LeBlanc v. Merrell Dow Pharms., Inc.*, 932 F. Supp. 782, 783 (E.D. La. 1996) (quoting *Brock*'s conclusion that the absence of epidemiological evidence is "fatal").

C. The Rule In The Fifth And Eleventh Circuits Conflicts With That Of The First, Third, Fourth, Ninth, And D.C. Circuits

Respondents agree (at 27-29) that, in the First, Third, Fourth, Ninth, and D.C. Circuits, epidemiological evidence is not "indispensable" to the admissibility of expert testimony. As set forth in the petition (and as respondents do not dispute), those circuits hold that the absence of epidemiological evidence is not alone a basis to exclude expert testimony on general causation. The law in those circuits thus squarely conflicts with the decision below and the law of the Fifth Circuit.[3]

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[3] Respondents (at 27-28) dispute how "lenien[t]" the law of these circuits is, but the key undisputed point is that these circuits do not view epidemiological evidence as a necessary precondition to the admissibility of expert general-causation testimony.

II. THE QUESTION PRESENTED WARRANTS THIS COURT'S REVIEW

Respondents do not seriously dispute the importance of the standard for admissibility of general-causation expert testimony. Nor could they. As explained in the petition, the admissibility of plaintiffs' expert testimony on causation is frequently the critical, dispositive issue in mass tort cases. Pet. 31-32. A plaintiff who is unable to introduce expert testimony on causation will be unable to establish an essential element of her claim. *See* Pet. 31; *see also*, *e.g.*, *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1244 (E.D.N.Y. 1985) (Weinstein, J.) ("[I]n the mass toxic tort context . . . presentation to the trier of causation depends almost entirely on expert testimony."), *aff'd*, 818 F.2d 187 (2d Cir. 1987). This Court should grant review to ensure uniformity in the federal courts on this issue of critical importance to mass tort cases nationwide.

Respondents also do not dispute the nationwide significance of the question whether epidemiological evidence is necessary. "There are thousands upon thousands of synthetic agents being used in the United States that might pose toxic risks, yet only a tiny fraction have been the subject of any epidemiologic inquiry." Green, 86 Nw. U.L. Rev. at 680 (footnote omitted). Epidemiological studies are extremely difficult and expensive to design. Ethical considerations often make them infeasible. Even when they are possible, they often take years to conduct and are not available until long after the statute of limitations for victims' claims has run. The Fifth and Eleventh Circuits' rigid epidemiological evidence test warrants urgent review because it imposes severe burdens that functionally will make it impossible for

many tort victims in those circuits to obtain relief for their serious injuries. *See id*. ("Imposing a burden of production that includes an epidemiologic threshold will screen out all of these cases, but at a cost of precluding more refined attempts, based on animal studies, structure analysis, available knowledge about biological mechanisms and related evidence, to make an assessment of whether there exists a causal relationship.").

III. THIS CASE IS AN IDEAL VEHICLE FOR RESOLVING THE QUESTION PRESENTED

This case presents an excellent opportunity for the Court to resolve the division among the circuits and clarify a recurring and important question of expert admissibility law. This case is a compelling vehicle for two main reasons. First, the facts of this case vividly illustrate the inappropriateness of the Eleventh Circuit's *per se* epidemiological requirement. The district court deemed unreliable expert opinions on causation that are so well-accepted as to be canonical in the field of medicine. Leading neurology textbooks published by Harvard and Columbia medical schools that are used to train medical students across the country teach that zinc excess can cause CDM. *See* Pet. 30-31. The National Institutes of Health publishes on its website that there is a reliable scientific basis to connect zinc excess to CDM. *See* Pet. 30. And the Food and Drug Administration found the scientific evidence persuasive enough to issue an advisory notice recommending that denture-cream manufacturers, including respondents, remove zinc from their products. *See* FDA, Notice and Recommended Action (Feb. 23, 2011).

This case thus presents an ideal vehicle for clarifying the proper scope of a district court's "gatekeep-

ing" function under Rule 702. As this Court held in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), Rule 702's benchmark for experts in the courtroom is "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152. Here, plaintiffs' experts were themselves the leading experts in the field. They relied on the same analyses and arrived at the same conclusions that the medical profession widely recognizes as received wisdom. The district court's nay-saying of that medical consensus based on its own perceptions of scientific reliability clearly contravenes Rule 702 and this Court's precedents, and calls for this Court's review.

Second, the case's procedural posture – an appeal from a final judgment that was predicated on the district court's erroneous evidentiary ruling – makes it well-suited for review. This Court need not address any threshold question regarding the review of an interlocutory order. The district court's exclusion of plaintiffs' general-causation experts left petitioners with no causation evidence with which to oppose summary judgment. Reversal of the Eleventh Circuit's evidentiary ruling would require reversal of the court's grant of summary judgment to respondents, and permit petitioners to proceed to trial.

That this case is part of an MDL makes it particularly suitable for this Court's review. Under the MDL statute, the Eleventh Circuit's epidemiological threshold requirement governs all federal denture-cream cases nationwide. *See* 28 U.S.C. § 1407(a). For cases originally filed in district courts in the First, Third, Fourth, Ninth, and D.C. Circuits, the MDL transfer is effectively case-dispositive, because it subjects them to the Eleventh Circuit's far more

restrictive admissibility test. That result is contrary to the purpose of the MDL statute to promote efficiency without altering the rights of the parties. Indeed, because the question presented arises commonly in mass tort cases that are transferred to a single court pursuant to the MDL process, the entrenched circuit split produces especially pernicious and anomalous results: the case might have been filed in a jurisdiction that does not impose a *per se* epidemiological requirement but be transferred to one that does. The MDL posture of the case (and similar ones like it) thus heightens the need for this Court to ensure uniformity in the circuits on this important question.

Contrary to respondents' argument (at 29-32), the district court's exclusion of plaintiffs' specific-causation expert, Dr. Greenberg, does not render the question presented "academic." Rather, the court's exclusion of Dr. Greenberg was dependent on its erroneous answer to the question presented. Relying on its exclusion of plaintiffs' general-causation experts, the district court held that "Dr. Greenberg's differential diagnosis is not reliable as a matter of law in the Eleventh Circuit because he ruled-in and considered an etiology – Fixodent-induced copper-deficiency myelopathy – that has not been established to cause Ms. Chapman's disease." Resp. App. 43a (quoted at App. 25a). Overturning the Eleventh Circuit's epidemiological evidence requirement would also undercut the court's exclusion of Dr. Greenberg.

The district court also criticized Dr. Greenberg for failing to rule in (and then rule out) several other potential causes of Ms. Chapman's disease. *Id.* at 43a-45a. But neither the district court nor the Eleventh Circuit suggested that that alleged failure

would be independently sufficient to exclude his testimony. *See id.* at 46a; App. 25a. Indeed, as the Eleventh Circuit itself has recognized, such failures "speak to the weight to be afforded [the expert's] testimony, not its admissibility." *Southern States Coop., Inc. v. Melick Aquafeeds, Inc.*, 476 F. App'x 185, 189 (11th Cir. 2012) (per curiam); *see* Pet. 34 n.11 (citing other circuit cases). Thus, if this Court were to reverse the Eleventh Circuit's exclusion of plaintiffs' general-causation experts, the judgment below would have to be vacated, and it is likely that, on remand, the exclusion of Dr. Greenberg's testimony would also be reversed. Because the district court's exclusion of Dr. Greenberg's testimony is intertwined with and will be affected by the Court's resolution of the question presented, it poses no impediment to this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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