16-2890-cv(L)

16-3012-cv(CON)

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

IN RE: MIRENA IUD PRODUCTS LIABILITY LITIGATION

MIRENA MDL PLAINTIFFS,

Plaintiff-Appellant,

v.

BAYER HEALTHCARE PHARMACEUTICALS INCORPORATED,

Defendant-Appellee.

On Appeal from the United States District Court
for the Southern District of New York (White Plains)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES, URGING AFFIRMANCE

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent company, and no publicly held company holds ten percent or greater ownership in the organization.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has no parent corporation and no publicly traded company owns 10 percent or more of its stock.

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INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America is the world's largest business federation. Boasting over 300,000 members, the Chamber represents the interests of more than three million companies and professional organizations of every size, in every sector, and from every region of the country.

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA members are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. To that end, PhRMA supports public policies and legal outcomes that foster, reward, and protect innovation.

The Chamber and PhRMA regularly file *amicus curiae* briefs in cases of concern to the nation's business community. Those cases often involve questions about the admissibility of scientific or other expert evidence.

With increasing frequency, the Chamber's and PhRMA's members must defend themselves in lawsuits where the theory of causation rests on novel and untested scientific theories. The Chamber's and PhRMA's members thus have a strong interest in ensuring that district courts properly "fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 148-49 (1997) (Breyer, J., concurring).

The District Court below fulfilled its gatekeeping duty. After analyzing lengthy briefing and numerous scientific studies, it concluded that the proposed expert testimony on causation failed Rule 702's standards. And without an expert to establish causation, the District Court continued, Bayer was entitled to summary judgment on all claims. In ruling as it did, the District Court also rejected plaintiffs' Plan B—which was to prove causation through ambiguous company documents—because state substantive law requires expert testimony in complex medical cases. This Court should affirm the District Court's Rule 702 holdings under the deferential abuse-of-discretion standard. Clear evidentiary rules and appellate-review standards promote the certainty and predictability that the business community depends on to navigate the landscape of high-stakes tort litigation.[1]

[1] In accordance with Federal Rule of Appellate Procedure Rule 29(c)(5), the Chamber certifies that no party or party's counsel authored this brief in whole or in part and that no person except the Chamber, its members or its counsel funded the preparation or submission of this brief. Appellees have consented to this filing, and Appellants take no position.

INTRODUCTION

Cases like this one have become all too common. A plaintiff files a product-liability suit based on a novel and untested causation theory. The plaintiff then supports that new theory with only its expert-for-hire's *ipse dixit*. The good news is that, like the District Court below, courts in this Circuit and across the country have a demonstrated track record of rejecting expert testimony touting a new causation theory based on unproven and unreliable methods. *See, e.g.*, *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 269 (2d Cir. 2002).

When those cases percolate up on appeal, the arguments are typically the same. As the Appellants do in this case, plaintiffs who fail to proffer testimony meeting Rule 702's standards resort to arguing that Rule 702 is essentially meaningless, that the court "usurped the jury's function," and that the defects in the expert's testimony go "to its weight, not its admissibility." *Amorgianos*, 303 F.3d at 268. Or they might argue that "expert testimony was not necessary to satisfy [the] burden to prove causation." *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 46 (2d Cir. 2004). This Court has rejected those arguments in the past and should reject them again here.

In trying to sidestep Rule 702, Appellants ignore this Court's many decisions explaining what it takes to establish the admissibility of expert testimony on general causation. *See Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249 (2d Cir. 2005); *Wills*, 379 F.3d 32; *Amorgianos*, 303 F.3d 256. They also make mincemeat of the Supreme Court's *Joiner* decision, which not only compelled the

result below but also established the boundaries for this Court's review. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997). Instead of grappling with those precedents, Appellants try to distort the Rule 702 standard by invoking outdated pre-*Joiner* decisions.

Alternatively, Appellants argue that they don't need expert testimony to establish general causation. In advancing that position, Appellants ignore that every State requires expert testimony to prove a complex medical-causation theory like the one offered here. As this Court well knows, the *Erie* doctrine does not give federal courts sitting in diversity the option of ignoring state substantive law.

This appeal does not require the Court to break new ground, engage in fact-finding, or otherwise dive back into the science that the District Court reviewed. Under *Joiner*'s abuse-of-discretion standard and controlling state law, the result is not in doubt. This appeal is really about Appellants' efforts to undermine the governing standards that businesses rely on to prevent expensive and frivolous litigation.

ARGUMENT

Appellants try to turn this appeal into a referendum on (1) Rule 702 and (2) the *Erie* doctrine. Both are settled in this Circuit and compelled the outcome below.

I. THE COURT SHOULD REJECT APPELLANTS' ATTEMPT TO NULLIFY RULE 702.

Appellants cannot reasonably defend their proposed experts' methodologies—indeed, the methodologies were so unscientific that they satisfied *none* of Rule 702's requirements—so they resort to the familiar strategy of trying to nullify Rule 702's "exacting standards of reliability." *Weisgram v. Marley Co.*, 528 U.S. 440, 442 (2000). Appellants claim, for instance, that the deficiencies in their experts' testimony "went to its weight, rather than its admissibility." Appellants' Br. at 3. They also accuse the District Court of "adopting the mantle of amateur scientist and usurping the role of the trial jury." *Id.* at 13.

This Court has heard it all before—and rejected it out of hand. Appellants ignore the many Second Circuit decisions that countermand their arguments and, more importantly, establish that the District Court acted well within its broad gatekeeping authority. First and most glaring, Appellants barely mention *Amorgianos*, in which this Court "elaborate[d] on the nature of the district court's role as the gatekeeper for scientific and expert testimony" and directed "how the district court is to perform this critical function." 303 F.3d at 259. The case involved the exclusion of general-causation expert testimony to the effect that short-term exposure to paint solvents could cause nervous-system injuries. *Amorgianos*, 303 F.3d at 261. The plaintiffs' arguments were remarkably similar to the Appellants' arguments here:

- "[T]he district court overstepped its role in evaluating the expert's evidence." *Id.* at 264;

- "[T]he district court imposed standards more stringent than those contemplated by the Supreme Court in *Daubert*." *Id.*;
- The judge "traded in a judicial robe for a white lab coat." *Id.*;
- The judge "usurped the jury's function." *Id.* at 268; and
- The "defects" in the "expert testimony went to its weight, not its admissibility." *Id.*

This Court disagreed with and rejected all of those arguments.

Amorgianos confirmed that "the district court has broad discretion in determining what method is appropriate for evaluating reliability under the circumstances of each case." 303 F. 3d at 265. The Court repeatedly praised the district court's "rigorous examination," "extremely thorough review," and "rigorous analysis." *Id.* at 267, 269, 270. And the Court confirmed that "district courts may carefully review the studies on which proffered experts rely in forming their opinions," calling that "precisely" the "undertaking that assures that an expert, when formulating an opinion for use in the courtroom, will employ the same level of intellectual rigor as would be expected in the scientific community." *Id.* at 269. *Amorgianos* on its own requires affirmance of the District Court's ruling.

But other precedents also require affirmance. The Supreme Court's *Joiner* is one of them—which is perhaps why Appellants cite it only once and then parenthetically. Appellants' Br. at 15. Appellants also overlook this Court's decision in *Wills v. Amerada Hess*. There, the Court approved the district court's rejection of an expert's general-causation theory because (just like here) "it failed to comport with any of the relevant *Daubert* factors for reliability of expert

testimony." 379 F.3d at 48; *see also id.* at 49 ("the district court considered the oncogene theory in light of *Daubert*'s four factors for reliability and concluded that the oncogene theory failed to satisfy *any* of the relevant factors."). The Court explained that the "district court's assessment was entirely appropriate for discharging its duty to determine whether the reasoning or methodology underlying the proposed expert testimony is scientifically reliable." *Id.* at 49 (internal quotation marks and citation omitted); *see also Ruggiero*, 424 F.3d at 254 (approving the exclusion of expert testimony on general causation because the district court "applied the *Daubert* factors and concluded that there was no reliable basis for" the expert's opinion).

Instead of dealing with those controlling cases, Appellants repeatedly invoke outdated cases. Almost all of the cases that they cite pre-date *Joiner*, which clarified the general-causation analysis and altered this Court's Rule 702 jurisprudence. *See Ruggiero*, 424 F.3d at 255. Some even pre-date *Daubert*. Appellants' Br. at 20. Appellants rely heavily on *In re Joint Eastern & Southern District Asbestos Litigation*, but that "case is about sufficiency, not admissibility." 52 F.3d 1124, 1132 (2d Cir. 1995). Indeed, the whole point of that decision was to correct a district court that had imported the then-new *Daubert* standards into its sufficiency analysis. Appellants here make the reverse mistake of importing the *In re Joint Asbestos* sufficiency analysis into the now-old *Daubert* standards. *See, e.g.,* Appellants' Br. at 17-18. But as the Court explained, "[t]he 'admissibility' and 'sufficiency' of scientific evidence necessitates different inquiries and involve

different stakes." *In re Joint Asbestos*, 52 F.3d at 1132. *In re Joint Asbestos* is of no help to Appellants.

When (as here) a district court shows great care and thought in excluding expert testimony, an appellate court doesn't need to wring its hands over the decision. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 68 F. App'x 356, 357 (3d Cir. 2003) ("Given the District Court's careful analysis, no purpose will be served by this court undertaking a redundant discussion simply to reach the same result."). This Court can affirm the District Court's thorough review here in fairly short order, as it has in the past. *See Ruggiero*, 424 F.3d at 254 ("We see no error."); *Russo v. Keough's Turn of the River Hardware, LLC*, 529 F. App'x 50, 52 (2d Cir. 2013) ("We cannot conclude that the district court abused its discretion, much less that the district court reached a "manifestly erroneous" decision in precluding the testimony of [plaintiff's] expert); *Lynch v. Trek Bicycle Corp.*, 374 F. App'x 204, 207 (2d Cir. 2010) ("Given the Rule 702 factors and the *Daubert* factors bearing on reliability, the district court did not abuse its discretion in excluding [the expert's] testimony.").

The Court should reject Appellants' invitation to return to the pre-*Daubert* world in which district courts admitted unreliable expert testimony for cross-examination, confused juries rendered scientifically unsupportable verdicts, and appellate courts invented methods of *de novo* review to correct obvious injustices. *See, e.g., Brock v. Merrell Dow Pharm., Inc.*, 874 F.2d 307, *modified* 884 F.2d 166 (5th Cir. 1989) (cited in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)). In Rule 702, we have a better, more rationale regime—one that the Chamber's

and PhRMA's members rely on to keep the channels of commerce clear of frivolous (but often innovation-chilling) litigation. Under that regime, districts courts play the essential "gatekeeping role" to screen expert testimony. *Daubert*, 509 U.S. at 597. Juries reach better verdicts because they do not hear unreliable "[e]xpert evidence [that] can be both powerful and quite misleading because of the difficulty in evaluating it." *Id.* at 595. And appellate courts do not re-adjudicate expert issues from a cold record; instead, they "give the trial court the deference that is the hallmark of abuse-of-discretion review." *Joiner*, 522 U.S. at 143; *accord United States v. Mitchell*, 365 F.3d 215, 233–34 (3d Cir. 2004) ("deferential review is used when the matter under review was decided by someone who is thought to have a better vantage point than we on the Court of Appeals to assess the matter").

Under Rule 702, this is an easy case. The Court should affirm the exclusion of Appellants' proposed expert testimony. Far from manifestly erroneous, the District Court's decision tracks controlling precedent.

II. THE *ERIE* DOCTRINE BARS APPELLANTS' ATTEMPT TO PROVE GENERAL CAUSATION WITHOUT COMPLYING WITH STATE LAW.

The Court should also reject Appellants' invitation to commit an *Erie* mistake. "A federal court sitting in a diversity case will apply the substantive law of the forum state on outcome determinative issues." *McCarthy v. Olin Corp.*, 119 F.3d 148, 153 (2d Cir. 1997). Every U.S. State and Territory requires expert testimony to prove general causation in complex medical cases like these. Yet Appellants ask this Court to excuse their failure to proffer admissible expert

testimony by letting them prove general causation with no expert testimony and only ambiguous documents. Appellants' Br. at 7-12. Put another way, Appellants ask this Court to disregard the *Erie* doctrine.

Appellants are wrong. The Lipitor MDL judge recently confirmed that *Erie* is the right analysis and that *Erie* principles prevent drug-liability plaintiffs from proving causation with only alleged admissions. *See In re Lipitor Marketing, Sales Practices and Prod. Liab. Litig.*, --- F. Supp. 3d ---, 2017 WL 87067, *13 (D.S.C. Jan. 3, 2017) ("*In re Lipitor*").[2] This Court should do the same.

As both the District Court below and the *In re Lipitor* court recognized, state substantive law controls whether expert evidence of causation is needed to survive summary judgment. *See id.*, 2017 WL 87067 at *11 (quoting *Mirena* District Court opinion).[3] Appellants acknowledge that *Erie* required the District Court to apply state substantive law. Appellants' Br. at 46-47 (noting that "a rule that affects a party's burden of proof" is "a substantive law under Erie analysis, and federal courts operating under diversity jurisdiction must apply state law on that issue."). And Appellants do not dispute that all 50 States, the District of Columbia, and Puerto Rico "require" plaintiffs to establish causation with expert testimony "where the issues are medically complex and outside common

[2] The Lipitor MDL plaintiffs appealed that decision to the Fourth Circuit on February 10, 2017.

[3] *In re Lipitor* recognized that because the States' expert-evidence "rule defines and limits the primary rights and obligations of the parties, it 'must be applied under the *Erie* doctrine.'" (2017 WL 87067 at *12 (quoting *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95, 109 (4th Cir. 1991)).

knowledge and lay experience." *Id.*, 2017 WL 87067 at *13 (cataloguing all U.S. jurisdictions).[4] Yet they nevertheless argue that they can substitute party-opponent admissions for expert testimony. Appellants cite no authority for their attempt to displace established law in every State and Territory. Indeed, after reviewing all of cases cited below, the District Court concluded that there is no support for Appellants' view. *In re Mirena IUD Prod. Liab. Litig.*, No. 13-MD-2434, --- F. Supp. 3d --, 2016 WL 4059224, at *12 (S.D.N.Y. July, 28, 2016).

For good reason. "A federal court in a diversity case is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." *Day & Zimmermann, Inc. v. Challoner*, 423 U.S. 3, 4 (1975) *see also Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88, 97–98 (4th Cir. 2011) (holding that "a federal court in the exercise of its diversity jurisdiction should act conservatively when asked to predict how a state court would proceed on a novel issue of state law"). This Court cannot ignore state substantive law requiring expert testimony on general causation any more than it can write a new state law in the first instance.[5]

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[4] This Court has applied state law to affirm summary judgment "[i]n the absence of any expert evidence as to general causation." *Amorgianos*, 303 F.3d at 271 (applying New York state law to hold that "defendant was entitled to summary judgment").

[5] Even if federal law applied (which Appellants do not argue), the claims here would still fail. "Ample federal precedent" establishes "that expert testimony is required when medical causation is outside the common knowledge of lay jurors." *In re Lipitor*, 2017 WL 87067, at *13 n.14 (citing *Amorgianos*, 303 F.3d

Appellants' discussion of party-admission admissibility under Federal Rule of Evidence 801(d)(2) is irrelevant. There is a difference between "a procedural rule governing admissibility" of expert testimony and "substantive state rules on the sufficiency of evidence." *Bryte ex rel. Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005). The dispute here is not whether the documents are admissible but rather whether they alone can establish a complex issue of general medical causation in the absence of admissible expert testimony. Under *Erie*, they cannot because no State law would allow it.

* * *

State (and territorial) law uniformly requires admissible expert testimony to prove general causation. That consistency allows the Chamber's and PhRMA's members to carry on business without having to worry that they will face meritless causation theories or, worse, liability divorced from the science based only on company communications. In many cases, innovation is an iterative process involving round after round of testing and review. If companies thought that they could face product liability for statements made during that iterative process when the science refuted the plaintiff's claim, then they might discourage the kind of the free-flowing communication that often leads to the best new ideas. Businesses and consumers would suffer as a result

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at 268); *see also Wills*, 379 F.3d at 50 (holding that, "[a]bsent admissible expert testimony on the issue of causation, Wills was unable to sustain her burden to prove causation" under the Jones Act).

CONCLUSION

This Court should affirm the District Court's exclusion of Appellants' general-causation testimony and grant of summary judgment to Bayer.

Dated: March 10, 2017

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CERTIFICATE OF SERVICE

I certify that, on March 10, 2017, I electronically filed this brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit. I filed the brief using the CM/ECF filing system, which will send notification of the filing to counsel of record in the case, all of whom are registered on the CM/ECF system.

/s/ Brian D. Boone
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