16-2890-cv(L)
In Re: Mirena IUD Products Liability Litigation

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

Rulings by summary order do not have precedential effect. Citation to a summary order filed on or after January 1, 2007, is permitted and is governed by Federal Rule of Appellate Procedure 32.1 and this Court's Local Rule 32.1.1. When citing a summary order in a document filed with this Court, a party must cite either the Federal Appendix or an electronic database (with the notation "summary order"). A party citing a summary order must serve a copy of it on any party not represented by counsel.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 24th day of October, two thousand seventeen.

PRESENT: JOHN M. WALKER, JR.,
JOSÉ A. CABRANES,
REENA RAGGI,
Circuit Judges.

IN RE: MIRENA IUD PRODUCTS LIABILITY LITIGATION

MIRENA MDL PLAINTIFFS,

Plaintiffs-Appellants,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendant-Appellee.

16-2890-cv(L)
16-3012-cv(CON)

FOR PLAINTIFFS-APPELLANTS: JAY L.T. BREAKSTONE (Melanie H. Muhlstock & Jessica L. Richman, *on the brief*), Parker Waichman LLP, Port Washington, NY.

FOR DEFENDANT-APPELLEE: LISA S. BLATT (Sarah M. Harris & Said O. Saba, Jr., *on the brief*), Arnold & Porter Kaye Scholer LLP, Washington, DC.

Shayna S. Cook & Brian P. O'Donoghue, Goldman Ismail Tomaselli Brennan & Baum LLP, Chicago, IL.

Michael X. Imbroscio, Paul W. Schmidt, & Phyllis A. Jones, Covington & Burling LLP, Washington, DC.

William P. Harrington, Bleakley Platt & Schmidt, LLP, White Plains, NY.

E. James Shepherd, Shook Hardy & Bacon LLP, Houston, TX.

FOR *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLEE:

Brian D. Boone (David Venderbush, New York, NY, *on the brief*), Alston & Bird LLP, Charlotte, NC, *for* the Chamber of Commerce of the United States of America and Pharmaceutical Research and Manufacturers of America.

Appeal from a judgment of the United States District Court for the Southern District of New York (Cathy Seibel, *Judge*).

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the July 29, 2016 judgment of the District Court be and hereby is **AFFIRMED**.

Plaintiffs-appellants, women who were injured when the intrauterine device ("IUD") Mirena injured their uteruses ("Plaintiffs"), appeal the July 29, 2016 judgment of the District Court. On appeal, Plaintiffs argue that the District Court improperly excluded their expert witnesses on general causation in a March 8, 2016 Opinion and Order, and improperly granted summary judgment for defendant-appellee Bayer Pharmaceuticals Inc. ("Bayer") in a July 28, 2016 Opinion and Order, thereby terminating the multi-district litigation ("MDL"). We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal.

Mirena is a plastic, T-shaped, 1.26 by 1.26 inch IUD that delivers the hormone levonorgestrel ("LNG") into the uterus to prevent pregnancy. Plaintiffs are women from across the country who were injured when Mirena perforated, became embedded in, and/or migrated from their uteruses. Plaintiffs sued the manufacturer of Mirena, Bayer, alleging negligence, strict liability, manufacturing defect, design defect, failure to warn, breach of warranty (implied and express), negligent misrepresentation, fraud, and various state-specific statutory violations. In 2013, the nearly 1,300 cases were certified as part of this MDL. Several were chosen to be part of an Initial Disposition Pool and went through full discovery.

At bottom, the MDL is about *when* Mirena perforated Plaintiffs' uteruses. Both parties agree—and Bayer has always warned—that Mirena can injure a woman's uterus *during insertion* and afterward migrate outside the uterus (what is called "primary perforation"). But the parties disagree about whether, in the absence of an injury at the time of insertion, Mirena can *later* perforate and migrate from a uterus (what is called "secondary perforation"). Bayer did not warn about the possibility of post-insertion, secondary perforation, and thus is exposed to liability if secondary perforation in fact occurred.

The instant appeal concerns the evidence Plaintiffs proffered to establish general causation of secondary perforation by Mirena. General causation concerns whether the type of injury at issue can be caused by the product. Plaintiffs principally proffered three categories of evidence for general causation of secondary perforation: 1) statements from Bayer employees, including short excerpts from a handful of Bayer employee emails, a PowerPoint presentation slide, and a sentence in a deposition all appearing to say that secondary perforation can occur; 2) the 2014 change Bayer made to the Minera warning label; and 3) expert witnesses.

On March 8, 2016, the District Court issued an Opinion and Order excluding all of Plaintiffs' experts on general causation because, it found, their testimony was not reliable and thus not helpful to the trier of fact. The District Court emphasized that the expert opinions all assumed the existence of the very fact in dispute—the possibility of secondary perforation—and then "worked backwards to hypothesize a mechanism by which it might occur." Joint App'x at 349. The District Court also applied the *Daubert* factors to each witness, finding that none of their tests had known error rates, none was subject to peer review, none was generally accepted in the scientific community, all had been developed for the purpose of litigation, and most used tests that are not easily replicable.

Bayer then filed an omnibus motion for summary judgment in the MDL docket, arguing that expert witnesses were necessary to prove general causation and thus Plaintiffs, lacking any such witnesses, could not prove general causation. Plaintiffs responded that summary judgment was inappropriate because a reasonable jury could find general causation on the basis of the admissible evidence, in particular the employee statements and the 2014 label change.

On July 28, 2016, the District Court granted summary judgment to Bayer and terminated the entire MDL. The District Court found, first, that in all fifty states expert witness testimony is typically required to prove causation in complex medical device cases. Second, assuming *arguendo* that Federal Rule of Evidence 801(d)(2) admissions could substitute for expert testimony in some jurisdictions, the District Court found that the "admissions" here were too ambiguous to do so.

Judgment was entered on July 29, 2016. This appeal followed.

STANDARD OF REVIEW

This Court "review[s] the district court's decision to admit or exclude expert testimony under a highly deferential abuse of discretion standard." *Zuchowicz v. United States*, 140 F.3d 381, 386 (2d Cir. 1998). Accordingly, a district court Rule 702 ruling "will be reversed only for manifest error." *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004). "That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

This Court reviews a district court's award of summary judgment *de novo*, "construe[ing] the evidence in the light most favorable to the [losing party]" and "drawing all reasonable inferences and resolving all ambiguities in [its] favor." *Darnell v. Pineiro*, 849 F.3d 17, 22 (2d Cir. 2017) (internal quotation marks omitted). This Court "will affirm only when 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *In re 650 Fifth Ave. & Related Props.*, 830 F.3d 66, 86 (2d Cir. 2016) (quoting Fed. R. Civ. P. 56(a)).

DISCUSSION

I. The District Court Properly Excluded Plaintiffs' Expert Witnesses on General Causation under *Daubert*

We first consider whether, in its March 8, 2016 Opinion and Order, the District Court properly excluded three of Plaintiffs' expert witnesses on general causation: Dr. Young, Dr. Jarrell, and Dr. Wray. Upon review, we conclude that it did.

In *Daubert*, the Supreme Court provided a non-exhaustive list of factors for a district court to consider when determining whether an expert's specialized knowledge will assist the trier of fact. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). The *Daubert* factors include: "[1] the theory's testability, [2] the extent to which it has been subjected to peer review and publication, [3] the extent to which a technique is subject to standards controlling the technique's operation, [4] the known or potential rate of error, and [5] the degree of acceptance within the relevant scientific community." *United States v. Romano*, 794 F.3d 317, 330 (2d Cir. 2015) (internal quotation marks omitted). "These factors do not constitute . . . a definitive checklist or test," and the inquiry "will necessarily vary from case to case." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (internal quotation marks omitted).

In its careful and well-reasoned Opinion and Order, the District Court identified numerous problems with the Plaintiffs' experts, but three are particularly noteworthy.

First, the theories proffered by Plaintiffs' experts are not accepted in the wider obstetrics and gynecological scientific community. *See Romano*, 794 F.3d at 330. Not only do the experts fail to identify any authorities that directly support the existence of secondary perforation, but what scientific authority there is casts doubt on the phenomenon's existence.

Second, the experts lacked pre-litigation expertise in the phenomenon of secondary perforation and developed their theories for the purposes of this litigation. *See Washburn v. Merck & Co.*, 213 F.3d 627 (2d Cir. 2000) (summary order). For instance, Dr. Young had no specialized expertise in Mirena or uterine perforation before this litigation. Dr. Jarrell had no previous experience with IUDs or hormonal contraception. And Dr. Wray had not even heard of secondary perforation before consulting in the litigation.

Third, finding no direct support in the literature for secondary perforation and having conducted no prior research on the subject, the experts all assumed the existence of the very phenomenon in dispute and then hypothesized how it could occur. Plaintiffs argue that this is no different than "the engineering expert in *Kuhmo* [*Tire Co. v. Carmichael*, 526 U.S. 137 (1999) being] asked to determine the mechanism that caused the tire to blow." Plaintiffs' Opening Br. at 34 n.11. But in *Kuhmo* there was no dispute about *whether* the tire had blown, only how it happened. *See Kuhmo*, 526 U.S. at 142 ("On July 6, 1993, the right rear tire of a minivan driven by Patrick Carmichael blew out."). Here, by contrast, the parties dispute whether secondary perforation has ever occurred. The experts thus begged the very question they were trying to answer.

In short, we conclude that the District Court properly excluded Plaintiffs' expert testimony for substantially the reasons provided in its March 8, 2016 Opinion and Order.

II. The District Court Properly Granted Summary Judgment to Defendant Bayer

Having concluded that the District Court properly excluded Plaintiffs' witnesses on general causation, we next turn to whether the District Court correctly granted summary judgment in favor of Defendant Bayer. We conclude that it did.

As a preliminary matter, state law controls on the question of what evidence is necessary to prove an element of a state law claim, such as general causation. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002); *see also* 29 Charles Alan Wright & Victor James Gold, Federal Practice & Procedure: Evidence § 6263 (2d ed.) ("[S]tate law controls where it makes a precondition to recovery in a medical-malpractice action the proffer of expert testimony to prove an element of the substantive-law claim, such as standard of care or causation.").

The District Court determined that all fifty states typically require expert testimony to prove causation where the causal relationship is outside the common knowledge of lay jurors. *See In re Lipitor Mktg., Sales Practices & Prod. Liab. Litig.*, 227 F. Supp. 3d 452, 469–77 (D.S.C. 2017) (surveying all States and U.S. territories); *see also Barnes v. Anderson*, 202 F.3d 150, 159 (2d Cir. 1999) ("Expert medical opinion evidence is usually required to show the cause of an injury or disease because the medical effect on the human system of the infliction of injuries is generally not within the sphere of the common knowledge of the lay person." (internal alterations and quotation marks omitted)). And Plaintiffs have not identified any state that does not require expert testimony in the circumstances at issue here. Nevertheless, Plaintiffs identify dicta from several cases suggesting that party admissions

can sometimes substitute for expert testimony on general causation. *See* Plaintiffs' Opening Br. at 48–51.

We need not reach the question of whether party admissions could ever substitute for expert testimony. Assuming *arguendo* that they could, the putative admissions proffered by Plaintiffs are simply not enough to establish general causation. As the District Court correctly found, no reasonable juror could find general causation more likely than not based on the Plaintiffs' admissible evidence.

Employee emails. The Plaintiffs first proffer three short excerpts from emails authored by Bayer employees that purportedly "admit" that secondary perforation can occur. Plaintiffs' Opening Br. at 7–9. But as Bayer notes and Plaintiffs do not contest, these excerpts were from emails in which the employees reported, without necessarily endorsing, adverse event reports. Bayer Br. at 55. Moreover, adverse event reports are anecdotal, and thus of very limited probative value. *See Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989–90 (8th Cir. 2001); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 184 (S.D.N.Y. 2009). The District Court therefore properly concluded that a reasonable jury could not rely upon the email excerpts to find general causation.

PowerPoint Presentation. Plaintiffs also argue that one sentence from a 2008 Bayer lunchtime PowerPoint presentation slide proved general causation of secondary perforation. That sentence read: "Migration into the abdomen (spontaneous perforation unrelated to insertion) can occur." Plaintiffs' Opening Br. at 9. We do not know the context in which this slide was presented, let alone what was said at the meeting. Nor does the sentence supply the jury with knowledge of the causes of secondary perforation. As such, the District Court correctly found that it cannot be a substitute for expert testimony.

Costales Testimony. Plaintiffs further note that in 2013, Dr. Costales, Bayer's Global Medical Expert, Women's Healthcare, testified that "a perforation happening unrelated to insertion, rare as it may be, . . . could happen." Plaintiffs' Opening Br. at 9. However, acknowledgement of the possibility of causation does not establish that causation is more likely than not, as the District Court correctly found.

2014 Label Change. Finally, Plaintiffs contend that the 2014 changes Bayer made to the Mirena label constitute proof of general causation. In 2014, Bayer changed the Mirena label to read: "Perforation (total or partial, including penetration/embedment of Mirena in the uterine wall or cervix) may occur most often during insertion, although the perforation may not be detected until sometime later." As the District Court incisively observed, the grammatical structure of this label is cryptic at best, and at most suggests the hypothetical possibility of secondary performation. It therefore cannot substitute for expert testimony.

In sum, we conclude that the District Court properly granted Defendant's motion for summary judgment for substantially the reasons provided in its July 28, 2016 Opinion and Order.

CONCLUSION

We have reviewed all of the arguments raised by Plaintiffs on appeal and find them to be without merit. For the foregoing reasons, we **AFFIRM** the July 29, 2016 judgment of the District Court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk