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[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT No. 14-12603

Non-Argument Calendar

D.C. Docket No. 6:11-cv-01582-RBD-GJK

ANTHONY PAYNE, JOHNITA PAYNE, his wife,

Plaintiffs - Appellants,

versus

C.R. BARD, INC., BARD PERIPHERAL VASCULAR, INC.,

Defendants - Appellees.

Appeal from the United States District Court for the Middle District of Florida

(March 31, 2015)

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Before JULIE CARNES, FAY, and EDMONDSON, Circuit Judges.

PER CURIAM:

In this products liability case, Plaintiffs Anthony and Johnita Payne appeal the district court's exclusion of the testimony of their expert witness, Fredrick Hetzel, Ph.D., and the consequent grant of summary judgment in favor of Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. ("Bard"). No reversible error has been shown; we affirm.

Bard manufactures a medical device -- called the Bard G2 inferior vena cava filter ("G2 Filter") -- that is designed to be placed inside a person's inferior vena cava ("IVC") to prevent pulmonary embolisms. The device, which consists of a central shaft with twelve protruding "struts," anchors into the walls of the IVC and serves as a mechanical barrier to prevent clots from reaching the heart or lungs.

In 2007, Anthony Payne ("Payne") suffered from recurrent bilateral lower-extremity deep-vein thrombosis, putting him at increased risk of suffering a pulmonary embolism. In September 2007, Payne's doctor implanted a G2 Filter into Payne's IVC. In January 2008, scans showed that the struts of the G2 Filter had perforated Payne's IVC. In February 2009, more scans showed that Payne had

suffered a pulmonary embolism. Scans also showed that the G2 Filter had fractured and that one of the struts had detached. Doctors have been unable to remove the G2 Filter or the fractured strut. Payne continues to suffer chest pain and shortness of breath.

Plaintiffs filed this civil action against Defendants, asserting four claims: (1) strict liability based on defective design; (2) strict liability based on defective manufacturing; (3) negligence; and (4) loss of consortium. Plaintiffs seek compensatory and punitive damages.

Daubert¹ Motion

In support of their claims, Plaintiffs sought to introduce the testimony of expert witness Dr. Hetzel. Dr. Hetzel's testimony was proffered mainly to establish that the G2 Filter implanted in Payne was defective and that Defendants' warnings and labels were inadequate.

Following a <u>Daubert</u> hearing, the district court concluded that Dr. Hetzel was unqualified to testify competently about matters in the case and that Dr. Hetzel's methodologies were not sufficiently reliable or helpful. As a result, the

¹ <u>Daubert v. Merrell Dow Pharm. Inc.</u>, 113 S.Ct. 2786 (1993).

district court -- with a reasoned written opinion -- granted Defendants' motion to exclude Dr. Hetzel's testimony. ²

We review a district court's ruling on the admissibility of expert testimony for abuse of discretion. <u>United States v. Frazier</u>, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc). "[T]he deference that is the hallmark of abuse-of-discretion review requires that we not reverse an evidentiary decision of a district court unless the ruling is manifestly erroneous. Thus, it is by now axiomatic that a district court enjoys 'considerable leeway' in making these determinations." <u>Id</u>. (citations and quotation marks omitted). Even when a ruling on the admissibility of expert testimony may be "outcome determinative," resulting in summary judgment, "we do not apply a stricter standard." <u>McDowell v. Brown</u>, 392 F.3d 1283, 1294 (11th Cir. 2004).

Expert testimony is admissible under Fed.R.Evid. 702 if (1) "the expert is qualified to testify competently" about the subject of the testimony; (2) the expert's methodology "is sufficiently reliable as determined by the sort of inquiry mandated in <u>Daubert;</u>" and (3) the expert's testimony will "assist[] the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." Frazier, 387 F.3d at 1260. The party

² At the <u>Daubert</u> hearing, Plaintiffs presented no live testimony and relied solely on excerpts from Dr. Hetzel's video deposition.

offering the expert testimony bears the burden of establishing, by a preponderance of the evidence, the expert's qualification, reliability, and helpfulness. <u>Id.</u>; <u>Kilpatrick v. Breg, Inc.</u>, 613 F.3d 1329, 1335 (11th Cir. 2010).

On appeal, Plaintiffs contend that Dr. Hetzel is qualified to testify based on his experience.³ Plaintiffs point mainly to Dr. Hetzel's experience analyzing medical devices, including his participation in one project involving an IVC filter. When an expert witness relies mainly on experience to show he is qualified to testify, "the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliable applied to the facts." <u>Frazier</u>, 387 F.3d at 1261.

The district court noted that Dr. Hetzel's sole experience working with an IVC filter "occurred more than twenty years ago, lasted only three to six months, and was only 'conceptual." In addition, Dr. Hetzel has never designed, tested, or manufactured an IVC filter and has taught no seminars and published no articles about IVC filters. Because Plaintiffs failed to establish a sufficient nexus between Dr. Hetzel's "limited and dated" experience with IVC filters and the opinions he offered in this case, the district court concluded that Dr. Hetzel was unqualified to testify. The district court did not abuse its discretion.

³ Plaintiffs do not assert on appeal that Dr. Hetzel (who holds a Ph.D. in organic chemistry), is qualified to testify based only upon his educational training.

The opinions contained in Dr. Hetzel's Supplemental Report can be broken into four main categories: (1) medical opinions about the in vivo forces inside the IVC and the migration of Payne's G2 Filter and fractured strut; (2) opinions about the design and testing of the G2 Filter; (3) opinions about metallurgy, including the properties of Nitinol (the metal used to construct the G2 Filter); and (4) opinions about the adequacy of the warning labels on the G2 Filter.

Plaintiffs failed to satisfy their burden of proof; the district court committed no manifest error in concluding that Dr. Hetzel was unqualified to testify. First, because Dr. Hetzel lacks medical training or experience, he is unqualified to testify as an expert on medical issues. Plaintiffs have also failed to show how Dr. Hetzel's limited experience working with a "conceptual" IVC filter over 20 years ago led to, or is pertinent to, the opinions he has reached in this case about the design, testing, or labeling of the G2 Filter. Dr. Hetzel also lacks the necessary training and experience to testify as an expert in metallurgy.⁴

Under the deferential standard of review applicable to the district court's exclusion of expert testimony, we see no reversible error. The district court analyzed carefully and thoroughly Dr. Hetzel's proffered testimony, qualifications and methodologies. Nothing evidences that the district court committed manifest

⁴ For example, the record shows that, during a 2010 deposition in an unrelated case, Dr. Hetzel testified that he lacked sufficient expertise to testify as an expert about medical devices that have a metallurgical failure.

error in determining that Dr. Hetzel's expert testimony -- in its entirety⁵ -- was inadmissible.

Motion to Reopen

After the district court excluded Dr. Hetzel's testimony, Plaintiffs moved to reopen the deadline for expert disclosures so they could identify a replacement expert witness. The district court granted the motion, but only for the limited purpose of allowing Plaintiffs to disclose, as an expert witness, Murray Asch, M.D. (whom Plaintiffs had already identified as a "rebuttal" witness). The district court explained that "it appears that Dr. Asch -- who is well-known to Defendants -- might be used as an expert in Plaintiffs' case-in-chief without undue delay of the proceedings or prejudice to Defendants." Plaintiffs were given five days from the

⁵ Contrary to Plaintiffs' assertions, the district court considered expressly Dr. Hetzel's qualifications to render an opinion about Defendants' filings with the Food and Drug Administration ("FDA") at the <u>Daubert</u> hearing. The district court acknowledged that Dr. Hetzel had some experience preparing FDA applications, but concluded that he was unqualified -- by education or experience -- to testify about Defendants' FDA filings in this case.

On the record before us, we also reject Plaintiffs' contention that the district court had an improper "inherent mistrust for Dr. Hetzel." And we also reject the contention that such alleged distrust colored improperly the court's determination that Dr. Hetzel was unqualified to testify about the adequacy of Defendants' warning labels.

⁶ The district court noted that its ruling was consistent with an earlier order by the magistrate judge, granting Plaintiffs additional time to disclose properly Dr. Asch as a rebuttal witness.

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date of the district court's order to complete their disclosure and to notify the court about whether Dr. Asch would testify during Plaintiffs' case-in-chief.

We review a district court's ruling on a motion to extend a deadline for an abuse of discretion. Oravec v. Sunny Isles Luxury Ventures, L.C., 527 F.3d 1218, 1231 (11th Cir. 2008). A party seeking the extension of an already-expired scheduling order deadline must show both good cause <u>and</u> excusable neglect. Fed.R.Civ.P. 6(b)(1), 16(b)(4). To establish "good cause" a party must show that "the schedule cannot be met despite the diligence of the party seeking the extension." Oravec, 527 F.3d at 1232. In determining whether a party has shown "excusable neglect" warranting an extension, a court must consider all pertinent circumstances, including "the danger of prejudice to the nonmovant, the length of the delay and its potential impact on judicial proceedings, the reason for the delay, including whether it was within the reasonable control of the movant, and whether the movant acted in good faith." Advanced Estimating Sys. v. Riney, 77 F.3d 1322, 1325 (11th Cir. 1996) (alteration omitted).

The district court abused no discretion in granting Plaintiffs an extension that was limited both in time and in scope. The district court had already extended several of its scheduling deadlines, including granting the parties a 60-day extension for the disclosure of expert reports. Allowing Plaintiffs to identify and

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to disclose an entirely new expert so late in the proceedings would have likely resulted in substantial delay to the judicial proceedings and in prejudice to Defendants. And, having an expert witness stricken under <u>Daubert</u>, in and of itself, is insufficient to warrant an extension. <u>Cf. Rink v. Cheminova</u>, 400 F.3d 1286, 1296 (11th Cir. 2005) (concluding that the district court abused no discretion in denying a continuance to allow for the replacement of an expert witness stricken under <u>Daubert</u>). Plaintiffs failed to demonstrate good cause or excusable neglect justifying an extension greater than the one granted by the district court.

Summary Judgment

Under Florida law, a plaintiff asserting a product liability claim against a product manufacturer must show, among other things, that the product was defective and that the defect proximately caused plaintiff's injuries. See West v. Caterpillar Tractor Co., 336 So. 2d 80, 86-87 (Fla. 1976). "[E]xpert testimony is often required to establish defective design of a product." Worsham v. A.H. Robins Co., 734 F.2d 676, 685 n.8 (11th Cir. 1984).

After the district court properly excluded Dr. Hetzel's testimony and granted Plaintiffs' motion to reopen, Plaintiffs notified the district court that Dr. Asch

would <u>not</u> testify as an expert in their case-in-chief. Thus, Plaintiffs had no expert testimony establishing that the G2 Filter implanted in Payne was defective.

Because Plaintiffs failed to present admissible evidence establishing a necessary element of their claims against Defendants, Defendants were entitled to summary judgment.⁷

AFFIRMED.

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After the exclusion of Dr. Hetzel's testimony, Plaintiffs sought, among other things, to postpone consideration of Defendants' motion for summary judgment until after a final ruling on the Lehmann Report. The district court did not rule expressly on Plaintiffs' motion. Instead, the district court said it would reserve ruling on Defendants' motion for summary judgment <u>if</u> Plaintiffs timely filed a complete expert disclosure about Dr. Asch.

The district court abused no discretion in granting Defendants' summary judgment motion before a final ruling on the Lehmann Report in the <u>Tillman</u> case. First, Plaintiffs failed to satisfy the district court's stated precondition for postponing a ruling on summary judgment. Second, the ruling on the Lehmann Report would not have changed the outcome of this case. The Lehmann Report (prepared before the G2 Filter was on the market) discusses a different Bard filter and says nothing about the G2 Filter. Thus, even if ruled admissible, the Lehmann Report could not, by itself, have established the defect element of Plaintiffs' case.

⁷ Plaintiffs argue that the district court abused its discretion by ruling on Defendants' summary judgment motion without first waiting for a final ruling on a discovery issue. Defendants had filed a motion for a protective order, asserting that an internal report prepared by Defendants' litigation consultant (the "Lehmann Report") was inadmissible. Meanwhile, Defendants had filed a similar motion for a protective order about the Lehmann Report in a related case against Defendants that was pending before the Middle District of Florida's Jacksonville Division (the "<u>Tillman</u> Case"). In the interest of judicial economy, the district court in this case referred Defendants' motion to the magistrate judge assigned to the Tillman case.