

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT**

United States Court of Appeals
Fifth Circuit

FILED

August 2, 2012

No. 11-60624

Lyle W. Cayce
Clerk

DEBORAH SMITH, MICHAEL SMITH

Plaintiffs - Appellants

v.

JOHNSON & JOHNSON, INC., ETHICON, INC.

Defendants - Appellees

Appeal from the United States District Court
for the Southern District of Mississippi
3:08-CV-245

Before DAVIS, OWEN, and SOUTHWICK, Circuit Judges.

PER CURIAM:*

In this products liability action arising from injuries sustained during surgery using Mersilene mesh, appellants Deborah and Michael Smith appeal the district court's order striking certain expert reports from their opposition to defendants' motion for summary judgment and granting summary judgment in favor of Johnson & Johnson and Ethicon. The appellants also appeal the district court's order granting costs to the appellees as discovery sanctions. Because we find that the district court's evidentiary rulings were not an abuse of discretion,

* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

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and that the plaintiffs did not raise a material issue of fact as to the adequacy of the Mersilene mesh warning, we affirm.

I.

As a complication resulting from a total abdominal hysterectomy performed in 2001, Deborah Smith (“Smith”) experienced vaginal vault prolapse and required further surgery. Smith consulted with Dr. Phillip Barksdale of the Women’s Hospital in Baton Rouge, Louisiana, who determined that she required an abdominal sarcoplexy¹, a procedure which Dr. Barksdale would perform with Mersilene mesh.

At that time, the Mersilene mesh package included the following statement under the heading “Adverse Reactions”:

No significant adverse clinical reactions to MERSILENE mesh have been reported. The use of nonabsorbable MERSILENE mesh in a wound that is contaminated or infected could lead to fistula formation and/or extrusion of the mesh.

Dr. Barksdale later testified that he read the warning, and that he had performed hundreds of surgeries using Mersilene mesh and was aware of the risks involved. He concluded that because of the severity of Smith’s prolapse, surgery was the best option for her. On April 2, 2002, Dr. Barksdale performed the surgery, using Mersilene mesh to repair the vaginal vault prolapse.

After the surgery, Smith experienced gradually worsening pain and vaginal discharge. In July of 2006, she presented with those symptoms at Northside Hospital in Atlanta, Georgia, where she was diagnosed with vaginal mesh erosion, persistent sinus tract, failure of mesh reversion, left and right lower quadrant pain, history of adhesions, frequent urination, and rectocele.

¹ A procedure in which the vaginal vault is supported by affixing it to a membrane in the pelvis.

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Smith was admitted to the hospital, where she underwent two surgical procedures designed to remove the eroded mesh and attempt to close the persistent sinus tract formation. Smith stayed in the hospital for five weeks, during which time she developed sepsis, hypobunemia, renal insufficiency, pneumonia and respiratory failure.

The Smiths filed this action in 2007 in the United States District Court for the Eastern District of New York. The court transferred the action to the Southern District of Mississippi. After a number of delays and extensions, the magistrate judge held a hearing in 2009 setting firm deadlines for both parties to designate experts.

On September 11, 2009, the day of the Smiths' deadline, the Smiths sent defense counsel a letter containing the names and CVs of three experts. The defendant moved to strike those expert designations based on the letter's failure to comply with the federal rules, which require "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(B)(2). The Smiths did not submit expert reports until November of 2009. In December, the defendants moved for summary judgment, and the Smiths responded in January. Attached to that response was an affidavit from Dr. William Hyman, who had not to that point been designated as an expert. Throughout this time period, the defendants continued to submit motions to strike the Smiths' submitted expert designations and expert reports for lack of timeliness.

On March 16, 2010, the magistrate judge issued an order denying the defendants' motions to strike. The magistrate judge found that the plaintiffs had failed to timely designate their experts, but that the importance of the expert testimony weighed heavily in favor of permitting the late designation. Finding that the defendants had incurred unnecessary expenses due to the

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plaintiffs' lateness, the magistrate judge ordered the plaintiffs to pay costs to the defendants.

The Smiths appealed the magistrate judge's order, and the district court after hearing argument on the appeal issued a memorandum opinion and order granting the defendants' motion to strike the designation of Dr. Hyman as an expert as well as the reports of Dr. Wohlrab and Dr. Hart. The district court also granted the defendants' motion for summary judgment, finding that the Smiths had not established a genuine issue of material fact as to whether an adequate warning would have prevented Dr. Barksdale from using Mersilene mesh in performing Smith's abdominal surgery.

II.

We review the district court's evidentiary rulings for abuse of discretion. *Jowers v. Lincoln Elec. Co.*, 617 F.3d 346, 355 (5th Cir. 2010). "A trial court abuses its discretion when its ruling is based on an erroneous view of the law or a clearly erroneous assessment of the evidence." *Bocanegra v. Vicmar Servs.*, 320 F.3d 581, 584 (5th Cir. 2003).

We review a grant of summary judgment *de novo*, applying the same standard as the district court. *Int'l Fid. Ins. Co. v. Sweet Little Mexico Corp.*, 665 F.3d 671, 679 (5th Cir. 2011).

III.

A.

We turn first to the district court's evidentiary rulings concerning the plaintiffs' experts. The district court struck the expert testimony of Drs. Hart and Wohlrab from the plaintiffs' opposition to summary judgment, and denied the plaintiffs' motion to designate Dr. Hyman as an expert.

The appellants argue that striking the Hart and Wohlrab reports improperly reversed the magistrate judge's order of March 16, 2010, which gave the appellants additional time to properly designate their experts. But the

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district court's order makes clear that the court struck those reports for reasons unrelated to timeliness, stating that "the problem of untimeliness was cured by the March 16, 2010 order." The district court struck the reports of Drs. Wohlrab and Hart based on its finding that their reports were conclusory and provided no factual support or reasons for their conclusions.

Dr. Hart's report discussed his medical credentials and stated his "opinion that there is a causal relationship between the use of the Mersilene mesh and erosion and sinus tract formation." It then stated that his opinion was based on his "training and experience as a medical doctor" and review of "Volumes of Deborah Smith's medical records." According to Dr. Hart's report, he did not consult any of the medical literature concerning Mersilene mesh or any of the documentation about the product. He also gave no reasons or explanation for his conclusions. "It is a well established rule that without more than his credentials and subjective opinion, an expert's testimony that a medical condition simply 'is so' is not admissible." *Boyd v. State Farm Ins. Co.*, 158 F.3d 326 (5th Cir. 1998). Furthermore, Dr. Hart's medical report did not address the actual question at issue in this case, which is not whether the Mersilene mesh caused Smith's injuries, but rather whether the warning provided by the manufacturer in the Mersilene mesh documentation was sufficient and whether any inadequate warning caused Smith's injuries.

Dr. Wohlrab submitted a similar report. He listed his credentials and then stated his "opinion with a reasonable degree of medical certainty, that the Mersilene mesh . . . caused vaginal erosion." Like Dr. Hart, Dr. Wohlrab stated that he did not review medical studies or literature relating to Mersilene mesh or any of the documentation about the product. And like Dr. Hart's report, Dr. Wohlrab's focused on the role of the mesh in Smith's injury rather than on the adequacy of the Mersilene mesh warning.

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Because the reports submitted by Dr. Wohlrab and Dr. Hart stated conclusory opinions only tangentially related to the issue in this case, the district court did not abuse its discretion in striking them from the plaintiffs' opposition to summary judgment.

The district court denied the plaintiffs' motion to designate Dr. William Hyman as an expert based on lack of timeliness. The plaintiffs filed a motion to designate Dr. Hyman three days after the magistrate judge's order permitting the late designation of Drs. Wohlrab, Hart and Goldstein, months after their original deadline for filing expert reports.

In determining whether to permit the late designation of an expert, district courts apply the four-factor test established in *Betzels v. State Farm Lloyds*, 480 F.3d 704 (5th Cir. 2007), considering 1) the explanation given for the failure to identify the witness, 2) the importance of the witness's testimony, 3) potential prejudice to the opposing party in allowing the witness's testimony, and 4) the possibility that a continuance would cure such prejudices. The plaintiffs stated that they were unable to timely designate Dr. Hyman because the defendants were withholding necessary documentation, but the documents upon which Dr. Hyman relied were available prior to the original September deadline for designation of experts. As to the second factor, the plaintiffs themselves stated that every one of Dr. Hyman's opinions could be elicited from their other expert witnesses. As to prejudice and cure, the defendants had already been found to be prejudiced by the months of delay in expert designations, and a continuance would not have cured that prejudice due to the long history of delays in the case. Denying the plaintiffs' motion to designate Dr. Hyman as an expert was not an abuse of discretion.

The district court affirmed the magistrate's order awarding costs to the defendants as a sanction for the plaintiffs' lateness in designating experts. The district court has authority, in its discretion, to impose sanctions against a party

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who fails to cooperate in discovery. Fed. R. Civ. P. 37. The imposition of sanctions is reviewed for an abuse of discretion. *Brown v. Oil States Skagit Smatco*, 664 F.3d 71, 76 (5th Cir. 2011). The appellants argue that the amount of costs awarded in this case was unreasonable. The district court awarded \$23,376.00 in costs to the defendants, which is a substantial sanction. The plaintiffs do not identify any specific charges that are improper, but argue that the total size of the amount awarded was excessive. But the amount awarded was carefully documented by the defendants, who clearly delineated the specific costs that they had incurred as a result of the plaintiffs' late designation of experts. The amount took into account the fact that discovery was delayed for months because of the plaintiffs' failure to comply with deadlines. The district court did not abuse its discretion in awarding those costs to the defendants.

B.

We turn now to the appellants' argument that the district court improperly granted summary judgment in favor of the defendants. The plaintiffs' claims stem from defendants' alleged failure to warn of risks associated with the use of Mersilene mesh. Under the learned intermediary doctrine, which is codified in the Mississippi Products Liability Act, a manufacturer of a prescription drug has no duty to warn the end user of the drug's possible adverse effects. *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688 (Miss. 1988). The manufacturer's duty to warn runs only to the prescribing physician, who acts as an intermediary between the manufacturer and the patient. *Id.* The learned intermediary doctrine applies to medical devices as well as prescription drugs. *Moore v. Memorial Hosp. of Gulfport*, 825 So. 2d 658, 662 n.6 (Miss. 2002).

In order to make out a case for failure to warn under the learned intermediary doctrine, the plaintiff must establish that the treating physician, or a reasonable physician in the treating physician's position, would not have used the product had he received an adequate warning. *Thomas v. Hoffman-*

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LaRoche, Inc., 949 F.2d 806, 812 (5th Cir. 1992). To satisfy the burden of establishing warning causation, the plaintiff may establish either how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded. *Id.* Under Mississippi law, an adequate warning is one that neither understates nor overstates the known risks associated with the use of a particular product. *Id.* at 815. The plaintiff must demonstrate that there was a risk that was not disclosed in the warning, and that the undisclosed risk was high enough that, if disclosed, would have changed the treating physician's decision to prescribe the product for the plaintiff. *Id.* at 814.

At the time of Deborah Smith's surgery in 2002, the Mersilene mesh package stated that "No significant adverse clinical reactions to Mersilene mesh [had] been reported." The plaintiffs submitted evidence from an FDA database showing that there were eight adverse event reports submitted prior to 2002 detailing injuries incurred as a result of the use of Mersilene mesh, three of which are associated with tears in the mesh. The plaintiffs contend that if the warning on the package had contained that information, Smith's surgeon Dr. Barksdale would not have used Mersilene mesh in performing the abdominal sarcoplexy.

The defendants submitted testimony by Dr. Barksdale directly contradicting that argument. Dr. Barksdale testified that he was aware of the risks inherent in using Mersilene mesh, and stated that he was personally aware of the possibility of adverse events including extrusion and erosion. Dr. Barksdale had performed a number of surgeries using Mersilene mesh, and some of those patients had reported to him with erosions and tears. Dr. Barksdale also testified that he read the "Contraindications" section of the Mersilene package insert, which advised that Mersilene mesh "in contaminated wounds should be used with the understanding that subsequent infection may require removal of

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the material.” Dr. Barksdale saw infection as a very serious potential issue and took that possibility into account in deciding whether surgery with Mersilene mesh was the best option for Smith.

Dr. Barksdale’s testimony makes clear that he was aware of the potential dangers in using Mersilene mesh and chose to use the mesh in Smith’s surgery despite those risks. When Dr. Barksdale examined Smith, she was in extreme pain and was experiencing Stage III vaginal prolapse. Dr. Barksdale concluded that surgery with Mersilene mesh was the best possible treatment option, despite his awareness of the possibility of erosion or tearing in the mesh.

As this court has held, in an opinion upholding a grant of summary judgment based on the learned intermediary doctrine, “If . . . the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury and the plaintiff’s recovery must be denied.” *Ebel v. Eli Lilly & Co.*, 321 Fed. Appx. 350, 356 (5th Cir. 2009) (quoting *Ackerman v. Wyeth Pharm.*, 462 F.3d 203, 208 (5th Cir. 2008)). Because the plaintiffs have provided no evidence showing that there were risks of which Dr. Barksdale was unaware, they have not raised an issue of material fact as to whether a more detailed warning would have prevented Dr. Barksdale from using Mersilene mesh.

IV.

The district court did not abuse its discretion in excluding the plaintiffs’ expert reports and denying their motion to designate an additional expert months after the established deadline, nor did it abuse its discretion in sanctioning the plaintiffs for their failure to comply with discovery orders.

The plaintiffs failed to raise a material fact as to whether Deborah Smith’s injuries would have been prevented had the defendants provided a different or more detailed warning to their treating physician. We therefore AFFIRM the district court’s judgment in all respects.

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AFFIRMED.