[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
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No. 10-12578

D.C. Docket No. 7:08-cv-00114-HL

WANDA WILLIAMS,

Plaintiff-Appellant,

versus

MAST BIOSURGERY USA, INC.,
a wholly owned subsidiary of Mast
Biosurgery AG, the parent company,

Defendant-Appellee.

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

(June 30, 2011)

Before TJOFLAT, WILSON and RIPPLE,[*] Circuit Judges.

[*] Honorable Kenneth F. Ripple, United States Circuit Judge for the Seventh Circuit, sitting by designation.

RIPPLE, Circuit Judge:

Wanda Williams brought this diversity action in the United States District Court for the Middle District of Georgia against Mast Biosurgery USA, Inc. ("Mast"), a medical device manufacturer. She sought relief under Georgia products liability law. After barring certain testimony that Ms. Williams had attempted to offer in order to establish an element of her claim, the district court entered summary judgment for Mast. We conclude that the district court did not err in its evidentiary rulings and that Ms. Williams has failed to introduce evidence sufficient to establish the manufacturing defect that she alleged. Accordingly, we affirm the judgment of the district court.

I

BACKGROUND

A. Facts

In 2006, Ms. Williams sought treatment for a painful, undiagnosed gynecological condition that was suspected to contribute to infertility. An ultrasound revealed a large ovarian cyst. Ms. Williams underwent a laproscopic procedure to drain the cyst. During the procedure, Dr. Adcock, her gynecologist, observed within Ms. Williams's abdomen significant dense adhesions that had

resulted from a prior surgery some years before. He further observed that these adhesions "were suspicious for malignancy or something to that effect." R.37, Ex. 1 at 48.

To address further these observations, Dr. Adcock performed an exploratory laparotomy on August 22, 2006. During this second procedure, he biopsied Ms. Williams's peritoneum and both ovaries and removed "extensive adhesions of [the] sigmoid and rectum to the posterior uterine fundus." Id. at 49 (internal quotation marks omitted). To prevent new adhesions from forming, Dr. Adcock placed four pieces of SurgiWrap in Ms. Williams's abdomen. SurgiWrap is a product designed and produced by Mast. It is marketed as a bioresorbable barrier used to prevent post-surgical adhesions. Dr. Adcock believed that preventing further adhesions between Ms. Williams's organs could have a positive effect on her fertility.

One month after the August 22 procedure, Ms. Williams returned to Dr. Adcock's office. She presented a number of symptoms, including persistent diarrhea, fever and pain in the lower left quadrant of her abdomen. Observing that she "looked really sick," Dr. Adcock admitted her to the hospital and ordered tests to ascertain the reason for her distress. Id. at 81. After ruling out various causes of her symptoms, he referred her to Dr. George Yared, a gastroenterologist, for a

colonoscopy. During the colonoscopy, Dr. Yared observed what he described as several stiff, hard and brittle pieces of plastic in Ms. Williams's colon, some as large as fourteen to eighteen millimeters. He removed two large pieces, but was unable to remove other pieces embedded in the wall of the colon. He suspected the material was the SurgiWrap used by Dr. Adcock during the August 22 procedure. The day following the colonoscopy, Ms. Williams underwent, at Dr. Yared's recommendation, a further exploratory procedure by Dr. Robert Brown, a general surgeon. In addition to cleaning out the significant infection in her pelvis, Dr. Brown performed a partial sigmoid colectomy to remove a damaged section of her colon, an appendectomy and a colostomy formation. He found and removed multiple small pieces that he believed were a foreign, clear, plastic-like substance. A pathologist, Dr. Robert Nelms, Jr., examined the specimens and described the material as stiff and thick.

The foreign bodies removed from Ms. Williams were not subjected to any chemical or other testing to determine their identity or composition.

B. District Court Proceedings

Ms. Williams filed a complaint against Mast seeking damages for her injuries on a strict products liability claim. She contended that the SurgiWrap

used in her procedure had a manufacturing defect that caused it to perform in a manner other than as intended.

1. Evidentiary Matters

During discovery, Mast moved to exclude certain testimony offered by Ms. Williams's treating physicians. It contended that they could not serve as experts. Preferring to wait until the depositions of the treating physicians had been taken, the court declined to rule on the motion. Mast therefore renewed its motion after the depositions were taken. It argued both that Ms. Williams had failed to abide by the procedural rules regarding expert designation and that the testimony failed to meet the standards established in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). Finally, Mast filed a motion for summary judgment, contending that Ms. Williams had not produced any admissible evidence that the SurgiWrap suffered from any manufacturing defect or that SurgiWrap was the cause of any injury to her.

The district court first granted in part and denied in part the motion to exclude testimony. The court evaluated the deposition of each physician independently, first to determine whether the testimony was lay or expert and then, if expert, to determine whether it was admissible under Daubert.

As to Dr. Adcock, the court ruled that he had offered admissible lay testimony regarding Ms. Williams's condition and his treatment of her. It then concluded that Dr. Adcock's further statements that, in his opinion, SurgiWrap had not dissolved as it was supposed to do and had instead become hardened shards of plastic were expert opinions. The court explained that it had "serious doubts," R.52 at 5, regarding whether Dr. Adcock was qualified to offer an opinion on this matter, given his limited experience with the product, his admissions that he had not reviewed medical literature about it or conducted any tests, and his lack of expertise in plastics generally. Nevertheless, the court considered whether his testimony would be reliable and concluded that it would not. The court, therefore, barred Dr. Adcock's proffered testimony that SurgiWrap did not perform as intended and instead had hardened. It also refused to allow his testimony that the material removed from Ms. Williams was SurgiWrap.

Turning to the testimony of Dr. Yared, the district court concluded that he too would offer a mix of lay and expert testimony. However, the court ruled that Dr. Yared's expert opinion that Ms. Williams's injuries were caused by the foreign bodies he had removed was admissible. Unlike Dr. Adcock, Dr. Yared had followed an established methodology, differential diagnosis, to arrive at his conclusion about causation. Using this method, he had considered numerous

potential causes of the fistula, ruled out all but the foreign body and "ruled in" the foreign body as a potential cause. Id. at 11. Accordingly, Dr. Yared was permitted to testify not only about his observations, but also about causation. He was barred, however, from testifying that the foreign body was SurgiWrap "as he has no basis for that testimony." Id.

With respect to Dr. Brown's testimony, the court determined that it was lay testimony and noted that he had admitted that "he did not know what caused the perforation" in Ms. Williams's colon. Id. at 12.

Finally, as to Dr. Nelms's testimony, the court observed that he had produced a report indicating that the foreign materials removed from Ms. Williams were SurgiWrap. The court noted that his deposition testimony clarified that this statement in his report was based solely on the label on the sample provided to him; he had done nothing to verify the composition of the foreign body. The court determined that he would not be permitted to testify that the material he had inspected was SurgiWrap because any such opinion would not be reliable.

The court ruled therefore that only Dr. Yared would be permitted to give opinion testimony. It further declined to bar that testimony on the basis of the procedural challenges raised by Mast. It ruled that, because Dr. Yared was a treating physician who had been deposed extensively on the subjects in question,

exclusion was not warranted, despite the failure of the plaintiffs to abide by the designation requirements of Federal Rule of Civil Procedure 26. See id. at 11 n.6.[1]

2. Ruling on Summary Judgment

In a separate order, the court granted summary judgment to Mast. The court noted that, under Georgia law, a plaintiff bringing a strict products liability claim based on a manufacturing defect was required to produce evidence from which a jury could conclude: (1) that the product was defective and (2) that the defect caused the plaintiff's injury.

The court reviewed the deposition testimony and concluded that Ms. Williams had produced no admissible evidence of a defect. Specifically, the court noted that only Dr. Adcock had testified that the product was defective and that his

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[1] Federal Rule of Civil Procedure 26(a)(2) provides that a party must disclose any witness who is expected to provide expert testimony under the Federal Rules of Evidence. The rule further requires that, when an expert has been "retained or specially employed to provide expert testimony in the case," the witness must provide an expert report detailing all opinions the expert will express and the basis for them. Fed. R. Civ. P. 26(a)(2)(B). Mast urged that Ms. Williams should be barred from presenting the testimony of her physicians because she failed to comply with the designation and report requirements of Rule 26(a)(2) within the time prescribed by the district court. The district court initially rejected the procedural challenge, stating that it would be appropriate to consider after depositions had been taken and the content of the physician testimony was clear.

In its final evidentiary order, the court concluded that it would not exclude the only expert testimony admissible in substance, that of Dr. Yared, on the basis of failure to comply with the rule. The court found that there was no surprise in the use of Dr. Yared and that Mast had had an opportunity to depose him fully on the relevant subjects. See R.52 at 11 n.6.

testimony on that issue had been barred. Accordingly, summary judgment was entered for Mast. The court did not reach Mast's alternative arguments that Ms. Williams had failed to produce evidence of causation.

Ms. Williams now appeals.

II

DISCUSSION

Ms. Williams raises two contentions in this appeal. First, she submits that the district court erred in limiting the testimony of her physicians. Second, she contends that she presented sufficient evidence under Georgia products liability law to create triable issues of fact and therefore withstand summary judgment.

A. The Evidentiary Ruling

We review questions regarding the district court's admission of evidence for abuse of discretion. Mann v. Taser Int'l, Inc., 588 F.3d 1291, 1310 (11th Cir. 2009) (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141-42, 118 S. Ct. 512, 517, 139 L. Ed. 2d 508, 516 (1997)). Of course, premising an evidentiary ruling on an erroneous view of the law is considered an abuse of discretion. Goodman-Gable-Gould Co. v. Tiara Condo. Ass'n, 595 F.3d 1203, 1210 (11th Cir. 2010).

Ms. Williams contends that the district court erred in limiting the testimony of her treating physicians. In her view, the testimony of all four physicians involved in her care and treatment should have been admitted in full as lay testimony. More precisely, she believes that the district court erred when it refused to admit the physicians' testimony on the question of whether the SurgiWrap was defective. She believes that the district court erred in applying the Supreme Court's analysis under Daubert to the physicians' testimony because that rule applies only to expert opinions.

The testimony of treating physicians presents special evidentiary problems that require great care and circumspection by the trial court. Much of the testimony proffered by treating physicians is an account of their experience in the course of providing care to their patients. Often, however, their proffered testimony can go beyond that sphere and purport to provide explanations of scientific and technical information not grounded in their own observations and technical experience. When such a situation presents itself, the trial court must determine whether testimony not grounded in the physician's own experience meets the standard for admission as expert testimony. As we pointed out in United

States v. Henderson, 409 F.3d 1293 (11th Cir. 2005), distinguishing between lay[2] and expert testimony is an important one; arriving at an appropriate conclusion requires that trial courts be vigilant in ensuring that the reliability requirements set forth in Rule 702[3] not "'be evaded through the simple expedient of proffering an expert in lay witness clothing.'" Id. at 1300 (quoting Fed. R. Evid. 701 advisory committee's note to the 2000 amendment).

In Henderson, we did not apply the governing principles in this area but instead relied upon a harmless error analysis. Nevertheless, our discussion in the course of that decision sheds substantial light on the distinction between lay and expert testimony in the context of physician testimony.[4] We cited with approval

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[2] Under Federal Rule of Evidence 701, lay witnesses may offer opinions

> which are (a) rationally based on the perception of the witness, and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

[3] Federal Rule of Evidence 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[4] In United States v. Henderson, 409 F.3d 1293 (11th Cir. 2005), an oral surgeon offered testimony about the jaw fracture of a patient under her care. She described not only the patient's

(continued...)

the decision of our colleagues in the Tenth Circuit in Davoll v. Webb, 194 F.3d 1116 (10th Cir. 1999). In Davoll, the Tenth Circuit wrote that "[a] treating physician is not considered an expert witness if he or she testifies about observations based on personal knowledge, including the treatment of the party." Id. at 1138; see also Henderson, 409 F.3d at 1300 (citing Davoll). We also noted with approval the Tenth Circuit's decision in Weese v. Schukman, 98 F.3d 542 (10th Cir. 1996), that a physician may offer lay opinion testimony, consistent with Rule 701, when the opinion is "based on his experience as a physician and [is] clearly helpful to an understanding of his decision making process in the situation." Id. at 550; see also Henderson, 409 F.3d at 1300 (citing Weese with approval). These cases make clear that, when a treating physician's testimony is based on a hypothesis, not the experience of treating the patient, it crosses the line from lay to expert testimony, and it must comply with the requirements of Rule 702 and the strictures of Daubert.

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[4](...continued)
physical condition and her treatment of it, but also opined that it had resulted from a blow to the patient's face. We noted that it was "arguable" that the trial court erred in admitting the opinion testimony under Rule 701: "[A]lthough [the surgeon] was the treating physician, her opinion regarding the cause of [the patient's] injuries was not helpful to a clear understanding of her decision making process, nor did it pertain to [the patient's] treatment." Id. at 1300. Her testimony as to cause was, she admitted, "a hypothesis," which we noted was "[t]he essential difference between expert and lay" testimony. Id. (modification in original) (internal quotation marks omitted).

The next question, therefore, is whether any of the proffered testimony should have been considered lay as opposed to expert testimony and should have been admitted on that basis. Ms. Williams asks that, in answering this question, we focus on the physician statements that the foreign substance removed from her abdominal cavity was SurgiWrap. In her view, the physician's conclusion that the substance was SurgiWrap was necessary to treat her, and, therefore, under the approach outlined in Henderson, the testimony is admissible as the conclusion of a treating physician. Upon examination of the record, however, we cannot accept this argument. The record establishes that her treating physicians were concerned with the presence of foreign material and with its effect on her physical condition. The exact identity of the substance was not critical to the decision to remove it. Indeed, the fact that none of the physicians found it necessary to identify definitively the removed pieces--instead allowing them to be discarded--demonstrates that conclusive findings about its identity were not necessary to her treatment.

Although Ms. Williams does not raise it specifically, one other piece of testimony merits our consideration. Dr. Adcock provided the only direct testimony that SurgiWrap had failed to perform as intended and thus was defective. We agree with the district court that such a conclusion requires some

knowledge of how SurgiWrap should have performed, a question outside the ken of a lay witness because it must be premised on scientific or other specialized knowledge. The district court was therefore correct to apply the Daubert analysis to this testimony.[5]

B. Summary Judgment

Ms. Williams further submits that the district court erred in granting summary judgment to Mast. She disagrees with the district court's view that she presented no admissible evidence that the SurgiWrap was defective. We review a district court's entry of summary judgment de novo. Am. Fed'n of Labor & Cong. of Indus. Orgs. v. City of Miami, 637 F.3d 1178, 1186 (11th Cir. 2011). Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "No genuine issue of material fact exists if a party has failed to 'make a showing sufficient to establish the existence of an element . . . on which that party will bear the burden of proof at trial.'" Am. Fed'n of Labor, 637 F.3d at

[5] We do not understand Ms. Williams to argue that the district court misapplied Daubert on this or any other issue, only that it was inapplicable because the physician testimony she intended to offer was all lay testimony. We therefore do not review the district court's Daubert analysis itself.

1186-87 (modification in original) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265, 273 (1986)).

Because the district court's jurisdiction was based on diversity of citizenship, see 28 U.S.C. § 1332, the merits of the dispute are governed by state law. See Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78, 58 S. Ct. 817, 822, 82 L. Ed. 1188, 1194 (1938); Pendergast v. Sprint Nextel Corp., 592 F.3d 1119, 1132 (11th Cir. 2010).

At the outset, we believe it important to state with precision the nature of the claim presented by Ms. Williams. As the case comes to us, she brings a single claim for a manufacturing defect against Mast. With respect to such claims, Georgia law provides:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

Ga. Code Ann. § 51-1-11(b)(1). The Court of Apppeals of Georgia described these elements succinctly when it stated:

> To establish defendant's strict liability, plaintiffs must prove that defendant is the manufacturer of the property, that the property when

> sold by the manufacturer was not merchantable and reasonably suited to the use intended (i.e., defective), and that its condition when sold was the proximate cause of the injury sustained.

Chicago Hardware & Fixture Co. v. Letterman, 236 Ga. App. 21, 510 S.E.2d 875, 877-78 (1999) (footnote omitted); see also Center Chem. Co. v. Parzini, 234 Ga. 868, 218 S.E.2d 580, 582 (1975). Mast contends that Ms. Williams cannot proceed to a jury under the circumstances of this case without expert testimony to establish these elements. Ms. Williams counters that Georgia law is not so restrictive.

The district court took the view that Mast ought to be accorded summary judgment because there was no evidence of record to establish that it had sold a product that was defective at the time it was sold. The court noted that the only evidence on this issue was the testimony of Dr. Adcock and that his testimony had been excluded on the ground that he was not qualified to render an opinion as to whether the product was defective. The district court ruled that, without that testimony, Ms. Williams was without any testimony, expert or otherwise, on the issue of the product's defectiveness.

We believe that the district court was correct in its evaluation of the situation. As Mast quite correctly concedes, there was evidence, through the testimony of Dr. Yared, that there was a foreign substance in Ms. Williams's

abdominal cavity and evidence, through the admissible portion of Dr. Adcock's testimony, that the only foreign substance that had been left in the abdominal cavity was the SurgiWrap. However, the simple presence of the material in her body does not establish that the product was defective when it was sold by Mast. There was no admissible evidence as to how the material was supposed to break down after placement, whether the condition observed was within the range of expected consequences of its placement or whether it was the unexpected consequences of the placement that caused the injury observed by Dr. Yared.

It is important to note that, under Georgia law, it is not always necessary to have expert testimony on the question of whether there is a manufacturing defect in a product. Georgia courts have held that, in some situations, lay testimony can provide sufficient evidence of defect. Two cases are particularly instructive. In McDonald v. Mazda Motors of America, Inc., 269 Ga. App. 62, 603 S.E.2d 456, 461 (2004), the Court of Appeals of Georgia examined a claim under the related theory of breach of implied warranty, which also requires demonstration of a defect. The plaintiff claimed that, almost immediately after purchase, a new vehicle began operating with a loud rattling noise and that the dealer was unable to repair it. The defendant produced an expert, who testified that the vehicle had no defect, and the trial court granted summary judgment to the defendant on that

basis. The Court of Appeals of Georgia reversed. It first stated that expert testimony on the question of defect was unnecessary. In the case before it, the lay testimony about the operation of the vehicle was direct evidence "that gave rise to reasonable inferences that a jury could draw of the presence of defects and that such defects existed from the time of sale." Id. The choice between the expert and lay testimony on this matter, said the court, was one for the jury. Id.; see also Owens v. Gen. Motors Corp., 272 Ga. App. 842, 613 S.E.2d 651, 655 (2005) (concluding that a factual issue precluded summary judgment where the plaintiff had presented lay testimony that seatbelts had not functioned as intended, because issue was a "matter[] not of science but of skill and experience" (internal quotation marks omitted)).

The most instructive case for our present purposes is Williams v. American Medical Systems, 248 Ga. App. 682, 548 S.E.2d 371, 374 (2001). There, even a seemingly more technical claim involving a medical product survived summary judgment without expert testimony to establish a defect. In Williams, the plaintiff underwent a procedure to insert an inflatable penile implant. At the time of the procedure, the device appeared to be functioning normally; one month later, however, the plaintiff reported a variety of symptoms to the surgeon. Following a subsequent corrective procedure, the surgeon described the problem: an abnormal

disconnection between two parts of the implant, which had caused fluid leakage and infection. The appellate court determined that the treating physician's testimony was sufficient "evidence that the device did not operate as intended" for the strict liability claim to survive summary judgment. Id. at 374.[6]

McDonald and Williams illustrate that a plaintiff need not always rely upon expert testimony to establish that the device did not "operate as intended," Williams, 548 S.E.2d at 374. The nature of the product, the complexity of the facts and the nature of the purported product malfunction will determine the nature of the evidence necessary to establish this statutory prerequisite to liability. The claim in McDonald was that the new car's engine was "running rough." McDonald, 603 S.E.2d at 458 (internal quotation marks omitted). Such a condition undoubtedly is within the common experience of a jury; expert testimony is unnecessary. Williams, although a medical case, involved a particularly obvious type of defect; because of his experience with the device and his observation of the device in the patient, the surgeon could see a clear break in the implant where the product should have remained together.

[6] On the negligence-based claims, however, the court went on to hold that there was a lack of evidence that the defect could be attributed to any negligence on the part of the manufacturer. See Williams v. Am. Med. Sys., 248 Ga. App. 682, 548 S.E.2d 371, 374 (2001).

By contrast, in the present case, the issue of defect was significantly more complicated. To establish that the SurgiWrap implanted in her abdominal cavity was defective, Ms. Williams needed to demonstrate that it did not perform as intended, which required her also to establish how the product was intended to function. This issue presented an unremarkable task in McDonald and in Williams. In McDonald, testimony about direct observations sufficed to establish that the motor was running roughly; similarly, in Williams, testimony that the implant was in pieces allowed a jury to conclude that it was not operating as intended. In Ms. Williams's case, however, the issue of whether there was a defect concerned a bioresorbable plastic product with which even the treating physicians, let alone the lay jurors, had little to no experience. Under these circumstances, where those who had observed the patient and her condition could not assess accurately what they had observed and its significance, we do not believe that Georgia law would have permitted Ms. Williams to proceed to a jury without testimony about the nature of the product, its properties or its expected functioning when implanted in the human body.

Finally, the record does not contain other admissible evidence of defect. Although circumstantial evidence can suffice in some situations, see Firestone Tire & Rubber Co. v. King, 145 Ga. App. 840, 244 S.E.2d 905, 908-09 (1978), the

only such evidence in the record is Dr. Yared's expert testimony that the foreign body produced an abscess, which led to the other injuries Ms. Williams sustained. This testimony does not demonstrate that SurgiWrap itself performed other than as expected. More precisely, it does not strengthen the inference that it was a manufacturing defect in SurgiWrap that created these conditions, rather than any number of other potential explanations that were also consistent with a foreign body creating an abscess: The product may have been mishandled; the product may have been inserted in a negligent manner; the product may be contraindicated for patients with particular sensitivities, and Ms. Williams may have been within that group. We do not require Ms. Williams to provide evidence capable of disproving all other potential causes to survive summary judgment; however, she must provide evidence that would permit a jury to select her explanation, that of a manufacturing defect, as the most likely. Dr. Yared's testimony does not fulfill that function.

In sum, Ms. Williams did not produce evidence, expert or otherwise, from which a reasonable jury could conclude that the SurgiWrap implanted in her abdomen contained a manufacturing defect. Accordingly, the district court correctly entered summary judgment for Mast.

Conclusion

The district court did not abuse its discretion in limiting Ms. Williams's treating physicians' testimony. Further, because Ms. Williams failed to produce sufficient evidence of a defect in the SurgiWrap used in her procedure, the district court correctly entered summary judgment for Mast. We therefore affirm the judgment of the district court.

AFFIRMED