United States Court of Appeals
For the Eighth Circuit

No. 24-1874

Julie Sprafka

Plaintiff - Appellant

v.

Medical Device Business Services, Inc., an Indiana Corporation, formerly known as DePuy Orthopaedics, Inc.; DePuy Orthopaedics, Inc.

Defendants - Appellees

Appeal from United States District Court
for the District of Minnesota

Submitted: December 19, 2024
Filed: June 4, 2025

Before LOKEN, ERICKSON, and KOBES, Circuit Judges.

LOKEN, Circuit Judge.

Dr. Andrea Saterbak performed knee replacement surgery on Julie Sprafka in August 2016 using the "ATTUNE" knee replacement system designed and manufactured by DePuy Orthopaedics, Inc., now known as Medical Device Business Services, Inc. (collectively, "DePuy"). Four years later, Dr. Kristoffer Breien performed revision surgery on Sprafka's knee after the ATTUNE's tibial baseplate

debonded. Sprafka brought this diversity action against DePuy, asserting claims of strict liability, negligent products liability, and breach of express and implied warranties. Sprafka withdrew her breach of warranty claims and proceeded on two products liability theories: (1) the ATTUNE system was defectively designed, and (2) DePuy failed to adequately warn or instruct as to the risk of debonding.[1]

After the parties filed expert witness disclosures, DePuy moved to exclude the opinions of Sprafka's design defect expert, Dr. Mari S. Truman, and for summary judgment. After extensive briefing and argument, the district court[2] granted the motion to exclude Dr. Truman's opinions because she failed to satisfy the requirements of amended Rule 702 of the Federal Rules of Evidence and the standards of Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579, 593-94 (1993). The court then granted DePuy's motion for summary judgment because, under Minnesota law, Sprafka cannot prevail without an expert supporting her design defect claim. Sprafka appeals both rulings, arguing the district court erred in excluding Dr. Truman's expert opinions and erred in granting DePuy summary judgment because the design defect claim was supported by another expert, Dr. Breien. Concluding that the district court did not abuse its substantial discretion and properly applied Minnesota law, we affirm.

I. Background

Artificial knee replacement systems are generally comprised of a metallic femoral piece, a metallic tibial baseplate, a tibial insert, and a dome kneecap. DePuy

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[1]Under Minnesota law, negligence and strict liability theories merge into a single products liability claim in failure to warn and design defect cases. See Bilotta v. Kelley Co., 346 N.W.2d 616, 622-23 (Minn. 1984).

[2]The Honorable Donovan W. Frank, United States District Judge for the District of Minnesota.

has designed and manufactured several models of artificial knee replacement systems, including the SIGMA (introduced in 1996), the ATTUNE (introduced in 2013), and the ATTUNE S+ (introduced in 2017). Total knee replacement is considered one of the most successful surgical procedures, but every system model has some failures that often require revision surgery to reduce knee pain and improve functionality. Though rare, one of the more common failures is called tibial component loosening, where the tibial baseplate does not stay securely fixed to the tibia ("debonds").

Sprafka's right knee was replaced in August 2016 using the ATTUNE system. On October 29, 2018, Sprafka reported swelling and pain in her knee to Dr. Saterbak, whose evaluation revealed no loosening of the tibial baseplate or other significant issues. On June 10, 2020, Sprafka saw a new surgeon, Dr. Breien, who conducted an examination and concluded the tibial baseplate had loosened from her tibia, causing Sprafka's pain. Dr. Breien performed revision surgery in September 2020, replacing the ATTUNE with another implant. Dr. Breien observed that the ATTUNE's tibial baseplate came free from the tibia with little or no force. He concluded the baseplate had debonded from the bone.

Sprafka filed this products liability action in August 2021, asserting design defect and failure to warn claims. She alleges that when DePuy redesigned the SIGMA and started selling the ATTUNE it reduced the depth of "pockets" on the underside of the baseplate to make removal from the bone easier if revision surgery becomes necessary. Sprafka alleges the ATTUNE did not deliver on its promises of improved function, increased stability, and greater patient satisfaction because the redesign resulted in significantly higher failure rates than the SIGMA due to debonding of the tibial baseplate. By March 2016, months before her surgery, Sprafka alleges DePuy had identified deficiencies in the ATTUNE's tibial baseplate, but not until March 2017 did DePuy apply to the Food and Drug Administration for approval of a new tibial baseplate component that the FDA approved in June 2017 (the ATTUNE S+ system).

To support her design defect claim, Sprafka retained Dr. Truman, a biomedical engineer. Dr. Truman offered three preliminary opinions: (1) the ATTUNE system was defectively designed; (2) a safer alternative existed at the time it was developed; and (3) DePuy's testing prior to seeking FDA approval and release into the marketplace was inadequate. Sprafka disclosed that surgeon Saterbak would testify that she selected the ATTUNE knee replacement system based, in part, on representations made by DePuy, and that no information provided prior to Sprafka's surgery identified the risk of cement debonding from the tibial baseplate.

Sprafka also disclosed Dr. Breien as a treating physician and non-retained expert with relevant and material information regarding Sprafka's pre- and post-surgical care, reasonable medical costs, and the ATTUNE knee replacement system. Based on his revision surgery, Sprafka disclosed Dr. Breien will testify: (i) the failure of the cement to bond to the tibial baseplate caused mechanical loosening in the ATTUNE system; (ii) the tibial baseplate should not have debonded; (iii) tibial baseplate debonding was the sole cause of the ATTUNE knee replacement system's failure; (iv) Sprafka needed revision surgery because of the ATTUNE system failure; (v) his observations are consistent with reported findings of other surgeons who have replaced failed ATTUNE knee replacement systems; and (vi) the ATTUNE system implanted in Sprafka in 2016 was defective.

DePuy moved to exclude the opinions of Dr. Truman and for summary judgment. The district court found that Dr. Truman, while qualified, rendered unreliable and speculative opinions. The court granted summary judgment in favor of DePuy because, under Minnesota law, "[e]xpert testimony is necessary to get a product-liability claim past summary judgment when the product at issue and any of its relevant inner workings are beyond the ken of a lay jury." Markel v. Douglas Techs. Grp., Inc., 968 F.3d 888, 890 (8th Cir. 2020). Without Dr. Truman's expert testimony, the court explained, Sprafka is unable to prove her products liability design defect claim.

II. Discussion

A. Dr. Truman's Expert Opinions. Sprafka first argues that the district court erred in excluding Dr. Truman's expert opinion that the ATTUNE knee replacement system was defectively designed. The district court found that Dr. Truman's opinions were not based on independent research but were developed for the purpose of litigation. The court noted that Dr. Truman produced no reliable data to support her opinion that the ATTUNE knee replacement system has a higher failure rate because of debonding than other devices on the market. The court further noted that Dr. Truman did not identify what depth of pockets or level of roughness would have prevented debonding. Due to these deficiencies, among others, the district court concluded that Sprafka cannot show the existence of a design defect or that a safer alternative existed at the time of Sprafka's surgery.

We review the exclusion of expert opinions under the deferential abuse of discretion standard. Ackerman v. U-Park, Inc., 951 F.3d 929, 932 (8th Cir. 2020). To be admissible, expert opinions must be based upon sufficient facts or data and must be the product of reliable principles and methods that have been reliably applied to the facts of the case. Fed. R. Evid. 702. Reliability can be established by showing that the expert's theory or technique can be (or has been) tested, that the theory or technique has been subject to peer review and publication, that there is a known or potential rate of error, and that the theory or technique is generally accepted in the scientific community. Id., quoting Daubert, 509 U.S. at 593-94. "A district court has great latitude in determining whether expert testimony meets the reliability requisites of Rule 702." In re Wholesale Grocery Prods. Antitrust Lit., 946 F.3d 995, 1000 (8th Cir. 2019) (quotation omitted). We will not reverse a district court's Daubert ruling unless it is "manifestly erroneous." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142 (1997) (quotation omitted).

In 2023, Rule 702 was amended "to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule." Fed. R. Evid. 702, Advisory Committee notes to 2023 amendment.[3] Contrary to Sprafka's argument that the district court "went beyond its appropriate 'gatekeeping' function," after Rule 702's recent amendment courts continue to have a gatekeeping role to assure that evidence admitted in a case is both relevant and reliable. Academy Bank, N.A. v. AmGuard Ins. Co., 116 F.4th 768, 790 (8th Cir. 2024), citing Daubert, 509 U.S. at 588-89. "As the gatekeeper, the district court's role is to discern expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." Ackerman, 951 F.3d at 933 (quotation omitted).

We agree with the district court that Dr. Truman's opinions fail to satisfy the requirements of Rule 702 and the Daubert standards. Her opinions have not been subjected to typical scientific scrutiny through peer review and publication. Rather, they were prepared for litigation and based primarily on two published case studies with limited participants -- fifteen patients in one study and three in another study -- as well as Dr. Breien's testimony that he and his partners have observed an "unacceptably" high rate of revisions following implantation of the ATTUNE knee replacement system. In both case studies, the author examined the number of ATTUNE revisions due to debonding but did not consider the total number of ATTUNE systems implanted. Similarly, Dr. Breien acknowledged that he did not know the actual rate of debonding but that he and his partners had observed in their practice a higher rate than other systems. Other data relied on by Dr. Truman

[3]The Committee concluded this emphasis was necessary because many courts had incorrectly held "that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility."

included registry data, which appears to show the ATTUNE system may have a similar or lower revision rate than other systems on the market.

Evidence in the record indicates that aseptic loosening is an issue for knee replacement systems. The fact that a system loosens does not automatically demonstrate a product defect. Expert opinions that are merely legal conclusions about the case are properly disregarded, as they are nothing more than opinions intended to substitute for the judgment of the district court. Davis v. City of Little Rock, 122 F.4th 326, 332 (8th Cir. 2024). Further, Dr. Truman's recognition that the case studies do not establish the rate of debonding for the ATTUNE system reinforces the speculative nature of her opinion that the ATTUNE system has a higher failure rate than other systems. Without a scientific or reliable basis to establish the rate of debonding for the ATTUNE knee replacement system, or data showing how the ATTUNE system compares with other devices on the market, Dr. Truman's opinions lack reliability. The district court did not abuse its discretion in excluding Dr. Truman's opinions.

B. The Grant of Summary Judgment. In ruling on DePuy's motion for summary judgment after excluding Dr. Truman's expert opinions, the district court merged Sprafka's strict liability and negligence claims and held that Sprafka is unable to prove her design defect claim without expert testimony. See Bilotta, 346 N.W.2d at 622-23. Under Minnesota law, the elements of a strict product-liability claim are that "(1) a product was in a defective condition unreasonably dangerous for its intended use; (2) the defect existed at the time the product left the defendant's control; and (3) the defect proximately caused the plaintiff's injury." Duxbury v. Spex Feeds, Inc., 681 N.W.2d 380, 393 (Minn. App. 2004), citing Bilotta, 346 N.W.2d at 623 n.3; see Markel, 968 F.3d at 890.

On appeal, Sprafka does not dispute that expert testimony is required to support claims involving complex questions of medical devices and medical causation.

However, she argues, even if we uphold the district court's exclusion of Dr. Truman's expert opinions under Rule 702 and Daubert, the district court erred in granting summary judgment in favor of DePuy because Dr. Breien's expert opinion, as disclosed, "would enable the jury to find that DePuy's ATTUNE knee replacement system was defectively designed and caused Sprafka's injury." We conclude this argument was not properly preserved in the district court, and if it was, the summary judgment record on appeal does not support Sprafka's contention.

DePuy's motion to exclude expert opinions only challenged the opinions of Dr. Truman -- the expert whose opinions Sprafka expressly disclosed would support her claim of design defect. DePuy's Memorandum of Law in Support of Defendants' Motion for Summary Judgment argued that if the court excluded Dr. Truman's opinion testimony, then it would be entitled to summary judgment, as Sprafka would not have "expert testimony in support of her design defect theory." Sprafka's Memorandum of Law in Opposition to the Motion for Summary Judgment did not argue that Dr. Breien's expert opinion, standing alone, was sufficient support for the design defect claim. Rather, Sprafka asserted that "[t]he testimony of Dr. Breien *combined* with the testimony of Mari Truman is sufficient to create a genuine issue of material fact upon which the jury could find the lack of design features was a proximate cause of the tibial baseplate debonding in Julie Sprafka's leg" (emphasis added). At the summary judgment hearing, DePuy again argued that it would be entitled to summary judgment if Dr. Truman's opinions are excluded. The district court repeatedly asked if Sprafka could get past summary judgment if Dr. Truman's opinions were excluded. Sprafka's counsel never responded directly to this question. Nor did Sprafka move for reconsideration when the district court did not address whether Dr. Breien could provide sufficient expert testimony on the ATTUNE device's alleged design defect.

"[F]ailure to oppose a basis for summary judgment constitutes waiver of that argument." Satcher v. Univ. of Ark. at Pine Bluff Bd. of Trs., 558 F.3d 731, 735 (8th

Cir. 2009); see Hiland Partners GP Holdings, LLC v. Nat'l Union Fire Ins. Co., 847 F.3d 594, 598 (8th Cir. 2017) ("A party . . . cannot assert arguments that were not presented to the district court in opposing summary judgment in an appeal contesting an adverse grant of summary judgment."). Thus, this issue was not properly preserved for appeal. Moreover, Sprafka's argument on appeal is seriously flawed. She argues that Dr. Breien was adequately disclosed as a second design defect expert because she disclosed that Dr. Breien will testify that "the ATTUNE knee replacement system implanted in Julie Sprafka in 2016 was defective." But design defects are not the only type of defects that can establish strict product liability because the product was sold in a defective condition unreasonably dangerous for its intended use. "If something goes wrong in the manufacturing process, if a product has a part missing or malformed or is made of improper materials, clearly we have a 'defect' in the common sense of the term." Holm v. Sponco Mfg., Inc., 324 N.W.2d 207, 215 n.2 (Minn. 1982) (Simonett, J., concurring in part); see generally Restatement (Second) of Torts § 395 (1965). Here, Sprafka did not assert a manufacturing defect claim. Dr. Breien only observed her ATTUNE device years after it was implanted, and his report and opinions expressed no knowledge of the design issues on which Dr. Truman based her unreliable design defect opinions. The district court did not err, much less plainly err, in failing to take up the unasserted argument that Dr. Breien was an adequate, stand-alone design defect expert.

There is another issue lurking in this complex appeal that neither party even mentions. Sprafka's strict liability and negligence claims included a claim that DePuy failed to provide adequate warnings or instructions as to the risk of debonding. Failure to warn and design defect claims both require the manufacturer to owe a duty of care to the injured party, which "arises from the probability or foreseeability of injury to the plaintiff." Montemayor v. Sebright Prods., Inc., 898 N.W.2d 623, 629 (Minn. 2017) (quotation omitted); see Kallio v. Ford Motor Co., 407 N.W.2d 92, 99 (Minn. 1987). Even if causation is a complex issue outside the knowledge of a jury, rendering expert testimony necessary in a particular case, expert testimony may be

unnecessary to establish the standard of care. See SECURA Ins. Co. v. Deere & Co., 12 N.W.3d 103, 111 (Minn. App. 2024).

Dr. Breien opined that the failure of the cement to bond to the tibial base was the sole cause of Sprafka's revision surgery. That may have been sufficient expert testimony supporting Sprafka's claim of causation; DePuy did not move to exclude Dr. Breien's opinions. In addition, the record and reasonable inferences from the record may have been sufficient to show that, prior to Sprafka's revision surgery, DePuy was aware of deficiencies and risks in the ATTUNE system caused by its design change and did not provide warnings or instructions to fully inform consumers, doctors, or patients. If expert testimony is not needed to establish this standard of care, Sprafka's lack of expert testimony to support her design defect theory may not be sufficient to warrant summary judgment dismissing her failure to warn and instruct theory.

Although the failure to warn claim was discussed at the summary judgment argument hearing, the district court did not consider this issue or even separately discuss the grant of summary judgment on the failure to warn claims after Dr. Truman's design defect opinions were excluded. But again, for a good reason. Pre-sale negligent failure to warn was specifically alleged in the Second Claim for Relief in Sprafka's Complaint (post-sale failure to warn was not alleged), and it was argued in her opposition to the motion for summary judgment. But at the argument hearing, counsel only argued the Rule 702 and Daubert issues relating to Dr. Truman's opinions. The district court explicitly asked if the case would be over if Dr. Truman's opinions were excluded. DePuy's counsel responded affirmatively, stating that if the design defect claims fail for lack of expert testimony, there can be no claim for failure to warn of design defects. Sprafka's counsel did not respond to that argument. Thus, the court's failure to address the issue in its Order does not mean it was overlooked. Sprafka did not move for reconsideration of that claim.

Nor was this issue addressed in Sprafka's briefs on appeal. Rather, Sprafka argues the district court erred because Dr. Breien was not excluded and could provide the necessary expert testimony about the ATTUNE device, its inner workings, and its defective design. In her Statement of Issues on appeal, Sprafka explicitly limited her appeal to whether the district court erred "in granting summary judgment where Plaintiff's design defect claims were supported by another expert, Dr. Kristoffer Breien, whose testimony was not excluded." Thus, the distinct argument that the district court erred in granting DePuy's summary judgment motion on the failure to warn claim is waived. See Woodward v. Credit Serv. Int'l Corp., 132 F.4th 1047, 1057 (8th Cir. 2025) (issue waived if not meaningfully argued on appeal).

For the foregoing reasons, the judgment of the district court is affirmed. We grant the opposed motion of Lawyers for Civil Justice to file an *amicus* brief urging affirmance.

ERICKSON, Circuit Judge, concurring specially.

I concur specially in the opinion of the Court. I agree that the district court did not abuse its discretion when it excluded the expert opinions of Dr. Truman. As to the grant of summary judgment, as noted by the Court, the record also contains expert opinions from Dr. Breien, which DePuy did not seek to exclude, related to the ATTUNE knee replacement system and the cause of Sprafka's injury. Further, the district court did not analyze Sprafka's failure to warn claim when it dismissed her case. While the issue of whether summary judgment is appropriate is a close one for me on the record before us, I concur in the Court's conclusion that these issues were not preserved for our review.