UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

JEAN PHELAN,
Plaintiff-Appellant,

v.

SYNTHES (U.S.A.),
Defendant-Appellee.

No. 01-2045

Appeal from the United States District Court
for the District of South Carolina, at Florence.
Patrick Michael Duffy, District Judge.
(CA-99-3047-4-23)

Argued: February 27, 2002

Decided: May 28, 2002

Before WILKINSON, Chief Judge, and WILLIAMS and GREGORY, Circuit Judges.

Affirmed by unpublished per curiam opinion.

COUNSEL

ARGUED: Scott Bryn Umstead, SCOTT B. UMSTEAD, P.A., Myrtle Beach, South Carolina; Thomas Casey Brittain, HEARN, BRITTAIN & MARTIN, Myrtle Beach, South Carolina, for Appellant. Susan Pedrick McWilliams, NEXSEN, PRUET, JACOBS & POLLARD, L.L.C., Columbia, South Carolina, for Appellee.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

OPINION

PER CURIAM:

Jean Phelan appeals from the district court's orders excluding her proffered expert testimony and directing a verdict for Appellee Synthes, Inc., U.S.A. on Phelan's claims arising from injuries she suffered when a "tibial nail" manufactured by Synthes and implanted in Phelan's leg fractured, necessitating surgical removal of the nail. During the jury trial, the district court excluded the proffered testimony of Phelan's expert, Dr. Joseph Dyro, under Federal Rule of Evidence 702 as well as the standard of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and its progeny. The district court granted judgement as a matter of law for Synthes, finding that there was insufficient evidence for the jury to find for Phelan. We affirm.

I.

In September of 1996, Phelan was involved in a motorcycle accident in Myrtle Beach, South Carolina. She suffered, among other injuries, a fractured right tibia. The fracture was toward the distal (*i.e.*, lower) end of the bone. To align the fractured parts of her tibia as it healed, Phelan's doctor, Richard W. Ward, M.D., concluded that "internal fixation with an intramedullary nail,"[1] was appropriate. Ward performed a surgical procedure on Phelan's leg in September of 1996, implanting the nail in her tibia.

The Synthes nail selected by Ward was accompanied by a "Package Insert" addressed to the "operating surgeon." (J.A. at 214.) Generally, this Package Insert contained warnings about the stresses placed on a metallic surgical implant in the body, identified the various fac-

[1]An intramedullary nail is a metallic surgical implant used to align a fractured bone while it heals. The nail is inserted inside a bone and secured in place with screws that pass through both the bone and the nail.

tors that would affect the life and strength of the nail, and listed some general instructions and possible adverse effects of use of the nail.

In Phelan's case, several screws were used in the initial operation to secure the nail inside her tibia. One of the screws was placed approximately one centimeter from the fracture, at the distal end of the tibia. After the nail was inserted, Phelan was discharged from the hospital and instructed by Ward not to place any weight on her right leg. She was to use crutches or a walker to move around. In November 1996, Phelan returned for a follow-up visit. Ward instructed her at that time to begin placing approximately fifty percent of a normal load on the leg in order to stimulate healing. In January 1997, two of the screws were removed to allow some degree of motion of the fractured pieces of Phelan's tibia. According to Ward, this process, known as "dynamization," was intended to speed the healing process. Ward testified that dynamization reduced the stabilization of the bone and the nail, increasing the weight borne by both when Phelan placed weight upon her leg.

On February 5, 1997, Phelan again returned to Ward's office for an appointment. An x-ray of Phelan's leg on that date showed that the tibial nail had fractured at or very near the point where one of the screws not removed in January passed through it, leaving the nail in two pieces. In an attempt to facilitate healing in spite of the fracture, Ward placed a cast on Phelan's leg. Ward replaced the cast with a brace in May 1997. Finally, because of significant "angulation"[2] at the site of the fracture in the bone, Ward performed surgery to remove the nail.

II.

Phelan brought this action in state court in South Carolina, asserting liability against Synthes on three grounds: (1) breach of implied warranty of merchantability as to the tibial nail; (2) strict liability

[2]Ward testified that the angulation was severe enough that Phelan's ankle was not aligned with her hip and knee, as is normal. Rather, the lower part of her leg was bowed significantly, causing her foot to be behind the line of her hip and knee.

under South Carolina Code section 15-73-10;[3] and (3) negligence. Synthes removed the action to the District Court for the District of South Carolina pursuant to diversity of citizenship.

At trial Phelan proffered the testimony of Dr. Dyro, a "biomedical engineer."[4] (J.A. at 116.) After hearing Dr. Dyro's summary of his qualifications, his conclusions and the basis for those conclusions, the district court excluded Dr. Dyro's testimony on the ground that his conclusions were not sufficiently supported by reliable scientific methodology to satisfy the standard of Rule 702, *Daubert*, and its progeny. Phelan's challenge to the exclusion of Dr. Dyro's testimony is the first issue raised in this appeal.

Having excluded Dr. Dyro's testimony, the district court stated that

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[3]South Carolina Code section 15-73-10 provides that

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user or consumer, or to his property, if
>
> (a) The seller is engaged in the business of selling such a product, and
>
> (b) It is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in subsection (1) shall apply although
>
> (a) The seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) The user or consumer of the product has not bought the product from or entered into any contractual relation with the seller.

S.C. Code Ann. § 15-73-10 (Law Co-op. 1977).

[4]Dr. Dyro holds a Ph.D. in Biomedical Electronics Engineering from the University of Pennsylvania. He testified that "[b]iomedical engineering is the application of engineering principles to the study of biological systems," and that "a biomedical engineer is . . . skilled in the application of engineering principles to the solution of problems in . . . medicine and in biology . . . ." (J.A. at 118-19.)

it would consider granting judgement as a matter of law to Synthes and instructed the parties to prepare to argue the issue. After a recess, Phelan and Synthes argued the question of whether any issue remained for the jury to determine absent Dr. Dyro's testimony. Phelan contended that even without Dr. Dyro's testimony, the evidence was sufficient to create a question for the jury on the issue of whether Synthes was negligent in failing adequately to warn Phelan's doctor, Ward, in its Package Insert of the risks involved in using the nail in these circumstances. The district court, however, found that the evidence in support of Phelan's failure-to-warn theory did not present a legally sufficient basis for a jury verdict in her favor and granted judgement as a matter of law for Synthes. Phelan's challenge to the district court's grant of judgement as a matter of law to Synthes is the second issue raised in this appeal.

III.

We first address the question of whether the district court properly excluded Dr. Dyro's testimony. A district court's decision to admit or exclude expert testimony is reviewed for abuse of discretion. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001).

Under Rule 702 of the Federal Rules of Evidence, "trial judges act as gatekeepers to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Id.* at 199 (quoting *Daubert*, 509 U.S. at 588). Rule 702 provides that

> [i]f 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.

Fed. R. Evid. 702. Under this standard, it is the duty of a trial judge before whom expert scientific testimony is proffered to "conduct a preliminary assessment of whether the reasoning or methodology

underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Cooper*, 259 F.3d at 199 (internal quotation marks omitted). "'[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.'" *Id.*, 249 F.3d at 200 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Dr. Dyro's proposed testimony in this case included three opinions: (1) that the Synthes nail "is defective and unreasonably dangerous in this application"; (2) that the Package Insert included with the nail "is defective because it does not instruct the physician concerning the unreasonably dangerous application"; and (3) that pre-market testing performed on the nail "was deficient . . . and even misleading, in that it did not . . . employ a protocol which would have revealed this unreasonably dangerous situation." (J.A. at 137-38.) Each of these opinions was premised on Dr. Dyro's underlying conclusion that the nail is more likely to break when one or more of the screws securing it is placed very near the site of the bone fracture. It is in that "application" — when one or more of the screws is near the fracture site — that Phelan contended the nail is unreasonably dangerous.

The district court excluded Dr. Dyro's testimony despite finding that he was "a very accomplished man and . . . qualified to render expert opinions in a good many areas . . .," because he had not "brought his expertise to bear on the issues in this case except in a very general way." (J.A. at 165.) In other words, the district court found that the reasoning or methodology underlying Dr. Dyro's opinions was not sufficiently specific to the issues at hand to render those opinions admissible.

A district court determining whether to admit expert scientific testimony must determine, under Rule 702 and *Daubert*, whether the testimony has a sufficient foundation in valid scientific methodology to be reliable. The *Daubert* Court enumerated four factors relevant in this analysis: (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4)

whether the theory or technique enjoys general acceptance within a relevant scientific community. *Daubert*, 509 U.S. at 592-94.

In the instant case, Dr. Dyro proposed to testify to the three opinions listed above after a review and analysis of the literature dealing with tibial nail fractures, an examination of an FDA database cataloguing similar failures, and an application of "basic mechanical engineering analysis." (J.A. at 152-59.) He admitted that he had neither examined nor performed any tests on tibial nails in forming these opinions.

Dr. Dyro's first proffered opinion, that the Synthes nail is "defective and unreasonably dangerous in this application," refers to the "application where the fracture is very close to . . . the point of fixation . . . by the locking screw," and the "fracture is in the distal end of the tibia . . . ." (J.A. at 137.) This opinion, he stated, was based upon his review of literature dealing with tibial nail fractures and "upon biomechanical principles" with which he was familiar through his work. (J.A. at 138.) When asked by the district court whether there was "anything specific that you have used in applying [your] education or experience" to form this opinion, Dr. Dyro responded that he had referred to "[s]pecific things like the stress applied to a cantilever beam and the point of where that stress is applied."[5] In essence, then, Dr. Dyro's first proffered opinion was based on little more than the assertion that a tibial nail would be subject to the stress placed on a "cantilever beam" when it is secured to the bone only at the distal end, and the stress placed on the nail would make it "more likely" to break. (J.A. at 163-64.) Dr. Dyro did not identify or quantify the stresses that would be placed on the nail other than to say generally that the stresses would be those placed on "a cantilever beam." He proposed to testify, however, that this principle made the Synthes nail "defective and unreasonably dangerous," as used in Phelan's tibia, triggering liability under S.C. Code Ann. section 15-73-10.[6] The trial court did

[5]A "cantilever" is defined as "a projecting beam or member supported at only one end." Webster's Third New International Dictionary 329 (1986).

[6]The South Carolina Court of Appeals has stated the required elements of a claim of negligence or strict liability in a products liability action as follows:

not abuse its discretion in determining that this opinion was not supported by reliable methodology where Dr. Dyro's opinion was based largely on extrapolation from a simple principle of engineering without quantitative or otherwise specific examination of the properties of the Synthes nail itself. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (noting that the trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

Further, Dr. Dyro's first proffered opinion was to serve as the link between the unreasonably dangerous condition he identified and the failure of the nail in Phelan's case. He proposed to testify that the nail was unreasonably dangerous "in this particular case of Jean Phelan where the nail is inserted and locked at a point within a, very close to the fracture," and thus to suggest that the nail in Phelan's leg broke because of what he identified as its unreasonably dangerous condition. (J.A. at 155.) Missing from Dr. Dyro's proffer, however, was any basis for believing that this nail broke because of the stresses he suggested would have been placed on it in the position it was in, or for eliminating equally plausible causes for the nail's breaking — excessive loads placed on the nail by Phelan, for example. *See Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (holding that expert's testimony did not have sufficient indicia of reliability under *Daubert* where the expert's theory did not, "as a matter of logic, . . . eliminate other equally plausible causes" of the incident in question). Moreover, Dr. Dyro did not testify (nor did he identify

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> In a product liability action under both negligence and strict liability theories, the plaintiff must establish (1) that he was injured by the product; (2) that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant; and (3) that the injury occurred because the product was in a defective condition unreasonably dangerous to the user. Further, [l]iability for negligence requires, in addition to the above, proof that the manufacturer breached its duty to exercise reasonable care to adopt a safe design.

Allen v. Long Mfg. N.C., Inc., 505 S.E.2d 354, 356-57 (S.C. Ct. App. 1998) (internal quotation marks omitted, alteration in original, and emphasis omitted).

any basis on which he could testify) regarding *how* likely the nail was to fail in this application. Because he did not conduct any tests nor perform any calculations regarding the nail in question, Dr. Dyro could not even identify the extent of the stress or force that would be placed on a nail in the circumstances under which this nail was used.[7] The district court did not err, therefore, in concluding that Dr. Dyro's first proffered opinion was not demonstrably reliable enough to be admissible.

Dr. Dyro's second proffered opinion — that the Package Insert included with the nail "is defective because it does not instruct the physician concerning the unreasonably dangerous application" (J.A. at 137) — and his third — that pre-market testing performed on the nail "was deficient . . . and even misleading, in that it did not . . . employ a protocol which would have revealed this unreasonably dangerous situation," (J.A. at 137-38) both rest upon the same basic conclusion as his first — that the nail was defective and unreasonably dangerous in this application. Because Dr. Dyro had no reliable basis on which to assert that the nail was defective and unreasonably dangerous, these opinions were likewise not sufficiently supported by reliable methodology. In sum, then, the district court did not abuse its discretion in excluding Dr. Dyro's proffered expert testimony.[8]

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[7]Indeed, unlike Roger Dean Harris, an expert in metallurgy called by Phelan, Dr. Dyro could not identify specifically the extent of the forces that would have to have been placed on the nail to cause it to break.

[8]Phelan argues that the district court did not allow sufficient time for full explanation of the basis for Dr. Dyro's proffered opinions. Specifically, Phelan contends that the district court was "extraordinarily impatient and prevented any meaningful development of proffered expert testimony." (Br. of Appellant at 13.) Synthes contends that Phelan has waived any objection to the district court's handling of their proffer by failing to object to it at trial. Regardless of whether the issue has been waived, we find no merit in the contention that the district court abused its discretion in limiting the length of the proffer of expert testimony. Indeed, Phelan has not identified any basis for Dr. Dyro's conclusions that she was prevented from presenting as a result of the district court's claimed impatience, except to state very generally that more time would have allowed her to go into greater detail.

IV.

After excluding Dr. Dyro's proffered expert testimony, the district court granted judgment as a matter of law for Synthes, concluding that no reasonable jury could find for Phelan. We review de novo the district court's grant of judgment as a matter of law. *Anderson v. Russell*, 247 F.3d 125, 129 (4th Cir. 2001).

Phelan does not argue that her claims of strict liability and breach of implied warranty of merchantability should have been submitted to the jury absent Dr. Dyro's testimony. Rather, she argues only that "enough evidence had already been adduced to create a jury issue as to the adequacy of the warning in [Synthes'] product package insert." (Br. of Appellant at 26.)

The district court was correct to grant judgment as a matter of law to Synthes on the strict liability and warranty claims because those claims required Phelan to show that she was injured when the nail broke as a result of an unreasonably dangerous weakness when screws were placed through it near the fracture site, a conclusion for which Dr. Dyro's testimony was her only direct evidence. She contends, however, that even absent Dr. Dyro's testimony the evidence created a jury question regarding whether Synthes negligently failed to include in its Package Insert a warning that the nail was likely to fail if used in the circumstances it was used in here.

Specifically, Phelan asserts that she should have been allowed to present to the jury the claim that Synthes failed to warn in its Package Insert of the danger of the nail's breaking if "union"[9] did not occur within three to four months, and that Synthes' failure to warn rendered the nail unreasonably dangerous and caused her injuries. She argues that "[t]he record is replete with testimony from Dr. Ward which clearly shows there was substantial evidence from which a jury could reasonably infer that Appellant's injuries were *caused by Appellee's inadequate warning*." (Br. of Appellant at 27 (emphasis added).) Her contention is that because the Insert referred only to the

[9]"Union" is defined as "the renewal of continuity in a broken bone or between the edges of a wound." Dorland's Illustrated Medical Dictionary at 1911 (29th ed. 1994).

danger of the nail's breaking if "nonunion"[10] or delayed union were to occur, it did not warn of the danger of the nail's breaking *before* nonunion could technically be said to have occurred.

To prevail on her negligent failure-to-warn claim, Phelan was required to show that the Synthes nail was a defective product in a condition unreasonably dangerous to her and that Synthes breached its duty to exercise reasonable care to adopt a safe design. *Allen v. Long Mfg. N.C., Inc.*, 505 S.E.2d 354, 357 (S.C. Ct. App. 1998). It is well settled under South Carolina law that "a seller may prevent a product from being unreasonably dangerous if the seller places an adequate warning on the product regarding its use." *Id.* Phelan's argument that her failure-to-warn claim should have been submitted to the jury rests on the proposition that the nail was unreasonably dangerous *because* the Insert's warning did not reveal the danger that it could break before such time as "nonunion" or "delayed union" could be said to have occurred.[11] As her counsel clarified at oral argument, Phelan argues that the nail was unreasonably dangerous here because the Insert lulled her and her surgeon, Dr. Ward, into a false sense of security, believing that the nail would not fail for several months when in fact it was in danger of failing at any time and thus causing her injury, by inducing the assumption that the nail was not in danger of failing until approximately six months after it was implanted.

It is not clear whether a product may be shown to be unreasonably dangerous under the South Carolina negligence standard by proof that the product's warning suggests that it will not fail in a particular application and that the product did subsequently fail in that application. *Cf. Allen*, 505 S.E.2d at 537 (noting that "unreasonably dangerous condition" must be shown in a failure-to-warn negligence case, but not indicating whether a warning's suggestion that a product is

[10]"Nonunion" is defined as "failure of the ends of a fractured bone to unite." Dorland's Illustrated Medical Dictionary at 1232 (29th ed. 2000).

[11]The parties disagree as to when nonunion or delayed union may technically be said to have occurred. Phelan contends that until six months have elapsed since treatment, neither may be declared to have occurred. Synthes contends that either may generally occur between three months and six months after treatment. As we explain, it is not necessary to our holding to resolve this disagreement.

safe for use in a particular application may by itself render the product unreasonably dangerous); *id.* at 359 (noting that a product that is not unreasonably dangerous does not require a warning). Thus it is not clear whether Phelan has posited a cognizable legal theory here. We need not resolve this question, however, because even assuming that Phelan's failure-to-warn theory was a legally cognizable one, we conclude that the Insert warns against the danger that Phelan suggests it ignores and does not make the kind of "guarantee" she claims it does.

Phelan's argument rests largely on a portion of the Insert which reads "[i]f there is delayed union or nonunion of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue." (J.A. at 214.) This language and other references to delayed union and nonunion in the Insert, argues Phelan, essentially suggest that the nail will *not* break before "nonunion" or "delayed union" could be declared. Because "union" does not occur for some time after a bone begins the healing process, Phelan contends, the nail's breakage in the period before union or nonunion could be identified — *i.e.*, when it is too soon to declare either result — is not covered by the Insert's warning, and indeed, is impliedly declared not to be a danger.

Phelan's argument, however, is not supported by the text of the Insert itself. The Insert contains a general warning that

> [l]oads produced by weight bearing and activity levels will dictate the longevity of the implant. The patient should understand that stress on an implant can involve more than weight bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in failure of the implant.

(J.A. at 214.) This warning clearly spells out the danger that absent union, various stresses on the nail could cause it to break. Recognizing that the circumstances in which the nail may be used will vary, the insert cautions that *absent* union, not only in the event of nonunion or delayed union, the nail may fail under a certain amount of stress. This statement cannot be construed as an indication that the nail will not fail in the months after the nail is implanted but before

union occurs. Before union occurs, by definition, there is an "absence of solid bony union." It is in these circumstances that the warning specifically indicates the nail may break under any of a number of stresses. *Cf. Anderson v. Green Bull, Inc.*, 471 S.E.2d 708, 710 (S.C. Ct. App. 1996) (noting that "[a] product bearing a warning that the product is safe for use if the user follows the warning is neither defective nor unreasonably dangerous"). Thus, even assuming she posits a cognizable legal theory of unreasonable dangerousness and causation under South Carolina law, Phelan was unable to present evidence here of the inadequacy of the warning, and the judgment of the district court must be affirmed.

V.

For the foregoing reasons, the judgment of the district court is affirmed.

AFFIRMED