

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 22-1399

JUDITH A. SHEARS; GARY F. SHEARS, JR.,

Plaintiffs – Appellants,

v.

ETHICON, INC.; JOHNSON & JOHNSON,

Defendants – Appellees,

and

ETHICON, L.L.C.,

Defendant.

Appeal from the United States District Court for the Northern District of West Virginia, at Clarksburg. Irene M. Keeley, Senior District Judge. (1:20-cv-00264-IMK)

Argued: January 24, 2023

Decided: July 22, 2024

Before KING, AGEE, and HEYTENS, Circuit Judges.

Vacated and remanded by published opinion. Judge King wrote the opinion, in which Judge Agee and Judge Heytens joined.

ARGUED: Jason Patrick Foster, THE SEGAL LAW FIRM, Charleston, West Virginia, for Appellants. Amy M. Pepke, BUTLER SNOW LLP, Memphis, Tennessee, for

Appellees. **ON BRIEF:** Scott S. Segal, Robin Jean Davis, THE SEGAL LAW FIRM, Charleston, West Virginia, for Appellants. Natalie Rose Atkinson, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia, for Appellees.

KING, Circuit Judge:

In this “pelvic mesh” products liability action on appeal from the Northern District of West Virginia, the federal trial court entered judgment against the plaintiffs following a March 2022 jury trial. Pursuant to an Order of Certification of April 2023, we certified a question of law to the Supreme Court of Appeals of West Virginia regarding the plaintiffs’ strict liability design defect claim. *See Shears v. Ethicon, Inc.*, 64 F.4th 556 (4th Cir. 2023) (the “Certification Order”). As explained herein, having now received the state supreme court’s answer to our certified question, we vacate the trial court’s judgment and remand for further proceedings.

I.

A.

1.

In our April 2023 Certification Order, we outlined the facts and procedural history of this civil action, including the following:

Beginning in October 2008, plaintiff Judith Shears — a resident of Monongalia County, West Virginia — presented to her physician with complaints of stress urinary incontinence and a host of other abdominal complications. Mrs. Shears was eventually referred to a urogynecologist, who treated her conditions by placing a synthetic surgical mesh sling called “Tension-Free Vaginal Tape” (hereinafter “TVT” or the “TVT mesh”) beneath her urethra. Mrs. Shears’s symptoms at first abated, but in the years following the TVT implantation, she began experiencing renewed incontinence, urinary tract infections, and pelvic pain, along with urinary frequency and urgency. In October 2013, a urologist discovered that the TVT mesh had partially eroded into Mrs. Shears’s bladder, and an operation was performed to remove the eroded mesh and an attached bladder stone. Additional eroded mesh was discovered in Mrs. Shears’s bladder in 2014,

and she has since experienced recurrent bladder stones and severe associated bladder and urinary difficulties.

Along with her husband Gary Shears, Mrs. Shears initiated this civil action in July 2013 against Ethicon, Inc. — the manufacturer and seller of the TVT mesh and its parent company Johnson & Johnson.¹ The Shearses filed their lawsuit in the Southern District of West Virginia as part of a multidistrict litigation captioned *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, No. 2:12-md-02327 (the “MDL”), which was assigned by the federal judicial system’s Judicial Panel on Multidistrict Litigation to the Honorable Joseph R. Goodwin.² Contending that the TVT’s erosion was to blame for Mrs. Shears’s injuries, the Shearses pursued numerous claims for relief, including — as relevant to this appeal — a strict product liability claim alleging a design defect in the TVT, as well as a claim for negligent design thereof. Mr. Shears, for his part, joined in the lawsuit by suing for loss of consortium.

See Shears, 64 F.4th at 558-59 (footnotes in original). After several years of extensive pretrial proceedings before the MDL court, more fully described in our Certification Order, the Shearses’ lawsuit was transferred to the Northern District of West Virginia in December 2020. *See id.* at 559-61.

2.

Upon transfer, the federal trial court in northern West Virginia began addressing pretrial motions, including *Daubert* motions regarding expert witnesses for both the Shearses and Ethicon. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)

¹ We refer to defendants Ethicon and Johnson & Johnson collectively as “Ethicon.”

² The Shearses’ lawsuit was filed as part of the specific Ethicon MDL, which comprised nearly 28,000 cases filed against Ethicon relating to the company’s TVT mesh. Six other pelvic mesh-related product liability MDLs were also assigned to Judge Goodwin, and at the time of the proceedings described herein, the seven MDLs together encompassed some 58,000 cases.

(establishing standard for admissibility of expert testimony under Federal Rule of Evidence

702). Critically, as highlighted in our Certification Order:

One of Ethicon’s *Daubert* motions sought to limit the testimony of Dr. Uwe Klinge, the Shearses’ design and materials expert. Dr. Klinge’s expert report spoke to two possible alternatives to the design of Ethicon’s TVT mesh — specifically, polyvinylidene fluoride and “Ultrapro.” Dr. Klinge expressed that, in his professional opinion, those materials posed a far lower risk of erosion in pelvic tissue than the TVT mesh and represented “safer alternative mesh materials for treatment of stress urinary incontinence than Ethicon’s TVT Prolene mesh.”

See Shears, 64 F.4th at 561-62 (alteration and citations omitted).

During a hearing on the *Daubert* motions on February 11, 2022, the federal trial court questioned the Shearses’ lawyer regarding Section 411 of the Supreme Court of Appeals of West Virginia’s recently published *West Virginia Pattern Jury Instructions for Civil Cases* (the “PJI”). Section 411, entitled “Design Defect — Necessity of an Alternative, Feasible Design,” provides as follows:

There are many designs which, although they may eliminate a particular risk, are not practicable to produce. To prove that a design is defective, [*name of plaintiff*] must prove that there was an alternative, feasible design that eliminated the risk that injured [*him/her*].

See J.A. 69.³ The language of Section 411 reflects a so-called “Elimination Mandate,” that is, a requirement that an identified alternative, feasible product design “eliminate the risk” of harm suffered by the plaintiff.

³ Citations herein to “J.A. ___” refer to the contents of the Joint Appendix filed by the parties in this appeal.

Focusing on the Elimination Mandate, the federal trial court expressed its concern “about the requirement under West Virginia products liability law . . . that the alternative feasible design must eliminate the risk of which the plaintiff complains that caused the injuries.” *See* J.A. 5464. The court accepted the legal soundness of Section 411’s requirements, observing that it “saw [in Dr. Klinge’s expert report] fulsome discussions about this is better, this is safer,” but Dr. Klinge “never said [the alternative mesh designs] eliminated the risk but rather reduced the risk.” *Id.* at 5465. Ultimately, because Dr. Klinge’s expert testimony would not have aided the Shearses in satisfying the Section 411 Elimination Mandate — that is, because his proposed testimony simply did “not meet the standard under West Virginia law” — the court granted Ethicon’s *Daubert* motion and barred Dr. Klinge from testifying about his proffered alternative mesh designs. *Id.* at 5569.

3.

In March 2022, the Shearses proceeded to a jury trial against Ethicon in Clarksburg — continuing to press their strict liability design defect claim, as well as a claim alleging negligent design of the TVT mesh. Critically, the federal trial court’s *Daubert* ruling required the Shearses to alter their trial strategy. That is, “[r]ecognizing . . . that the trial court’s restraint of Dr. Klinge’s testimony essentially foreclosed their ability to establish a defective product design under the standard of Section 411, the Shearses pursued their design defect claim under an alternative, so-called ‘malfunction theory’ of liability.” *See Shears*, 64 F.4th at 562. As we further explained in our Certification Order:

Under West Virginia law, the malfunction theory permits success on a strict product liability claim using only circumstantial evidence, so long as the plaintiff “shows that a malfunction in the product occurred that would not

ordinarily happen in the absence of a defect.” *See Anderson v. Chrysler Corp.*, 403 S.E.2d 189, 194 (W. Va. 1991). The trial court promptly ended the Shearses’ reliance on the malfunction theory, however, granting Ethicon’s motion for judgment as a matter of law on the design defect claim at the close of the Shearses’ case-in-chief. . . . Following the presentation of Ethicon’s evidence, the court instructed the jury on the Shearses’ sole remaining negligent design claim, and the jury returned a verdict for Ethicon on that claim later the same day.

Id. at 562-63. After the entry of a final judgment on the verdict, the Shearses timely noticed this appeal, and we possess jurisdiction pursuant to 28 U.S.C. § 1291.

B.

On April 5, 2023, after obtaining briefing from the parties and conducting oral argument, this Court *sua sponte* availed itself of the privilege afforded by the State of West Virginia through the Uniform Certification of Questions of Law Act, *see* W. Va. Code §§ 51-1A-1 to 51-1A-13, and requested that the Supreme Court of Appeals of West Virginia resolve a certified question of law. Focusing on Section 411 and the elements of a strict liability design defect claim under West Virginia law, we certified the following question:

Whether Section 411 of the *West Virginia Pattern Jury Instructions for Civil Cases*, entitled “Design Defect — Necessity of an Alternative, Feasible Design,” correctly specifies the plaintiff’s burden of proof for a strict liability design defect claim pursued under West Virginia law.

More specifically, whether a plaintiff alleging a West Virginia strict liability design defect claim is required to prove the existence of an alternative, feasible product design — existing at the time of the subject product’s manufacture — in order to establish that the product was not reasonably safe for its intended use. And if so, whether the alternative, feasible product design must eliminate the risk of the harm suffered by the plaintiff, or whether a reduction of that risk is sufficient.

See Shears, 64 F.4th at 558.

In a unanimous June 2024 Opinion delivered by Justice C. Haley Bunn, the Supreme Court of Appeals of West Virginia exercised its discretion to accept and rephrase our certified question of law. *See Shears v. Ethicon, Inc.*, No. 23-192, slip op. at 1 (W. Va. June 11, 2024) (the “Opinion”). Justice Bunn explained:

The United States Court of Appeals for the Fourth Circuit certified questions asking this Court to clarify certain elements of proof required to establish a *prima facie* case in a strict liability claim based upon a design defect. We answer as follows:

Whether Section 411 of the *West Virginia Pattern Jury Instructions for Civil Cases*, entitled “Design Defect — Necessity of an Alternative, Feasible Design,” correctly specifies the plaintiff’s burden of proof for a strict liability design defect claim pursued under West Virginia law.

Answer: No.

More specifically, whether a plaintiff alleging a West Virginia strict liability design defect claim is required to prove the existence of an alternative, feasible product design — existing at the time of the subject product’s manufacture — in order to establish that the product was not reasonably safe for its intended use.

Answer: Yes

If so, whether the alternative, feasible product design must eliminate the risk of the harm suffered by the plaintiff, or whether a reduction of that risk is sufficient.

Answer: As part of a *prima facie* case of strict product liability based upon a design defect, a plaintiff is required to prove that an alternative, feasible design existing at the time the subject product was made would have substantially reduced the risk of the specific injury suffered by the plaintiff.

Id. at 1 (footnote and alteration omitted).

Significantly, the Opinion contains two original syllabus points concerning Section 411 and the elements of a strict liability design defect claim. *See State v. McKinley*, 764 S.E.2d 303, 309 (W. Va. 2014) (explaining that “[o]riginal syllabus points announce an important new point of law decided in the case”). Those syllabus points — Syllabus Points 1 and 5 — provide as follows:

1. *West Virginia Pattern Jury Instructions for Civil Cases* § 411 (2017) does not correctly specify a plaintiff’s burden of proof in a strict liability claim based upon a design defect.

* * *

5. As part of a prima facie case of strict product liability based upon a design defect, a plaintiff is required to prove that an alternative, feasible design existing at the time the subject product was made would have substantially reduced the risk of the specific injury suffered by the plaintiff.

See Syl. Pts. 1 & 5, Opinion at i-ii.

II.

In view of, and having hereby adopted the Opinion of the Supreme Court of Appeals of West Virginia, we now resolve this appeal. The Shearses challenge the federal trial court’s embrace of Section 411 of the PJI, insisting that Section 411’s framing of the standard of proof for a strict liability design defect claim lacks support in controlling West Virginia law. Specifically, the Shearses assert that the trial court’s *Daubert* ruling is legally unsound, because it restricted Dr. Klinge’s expert testimony based on a requirement that does not exist in West Virginia law — the Elimination Mandate.

It is settled that we review a trial court's decision on the admissibility of expert testimony for abuse of discretion. *See United States v. Campbell*, 963 F.3d 309, 313 (4th Cir. 2020). A court abuses its discretion when its conclusions are "guided by erroneous legal principles." *See In re Jemsek Clinic. P.A.*, 850 F.3d 150, 156 (4th Cir. 2017) (internal quotation marks omitted). Even when the trial court has committed an error in ruling on the admission or exclusion of evidence, that error is subject to harmless error review. *See* Fed. R. Civ. P. 61; *see also Wickersham v. Ford Motor Co.*, 997 F.3d 526, 531 (4th Cir. 2021). And an error is harmless when this Court is satisfied "with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the errors." *See Wickersham*, 997 F.3d at 531 (internal quotation marks omitted).

Here, by its *Daubert* ruling, the federal trial court excluded the proposed testimony of Dr. Klinge regarding two mesh designs that posed a lower risk of erosion in pelvic tissue. *See* J.A. 3011-14. In ruling that Dr. Klinge's testimony "does not meet the standard under West Virginia law," the court relied on Section 411, and its Elimination Mandate. *Id.* at 5569.

The Opinion of the Supreme Court of Appeals of West Virginia in response to our Certification Order establishes that the federal trial court abused its discretion by relying on an erroneous legal principle. That is, there is "no support in West Virginia law for PJI [Section] 411's requirement for an alternative feasible design that 'eliminated the risk' that injured the plaintiff." *See* Opinion at 14. Rather, a plaintiff asserting a strict product liability claim based upon a design defect — although required to "prove that an alternative,

feasible design was available to the manufacturer at the time the product in question was manufactured” — need only show that such design “substantially reduces the risk of the specific injury suffered.” *Id.* at 17-18.

We are also satisfied that the federal trial court’s exclusion of Dr. Klinge’s testimony readily satisfies harmless error review. The *Daubert* ruling essentially required the Shearses to pursue their strict product liability claim by using only circumstantial evidence under the alternative “malfunction theory” of liability. *See Shears*, 64 F.4th at 562. And proceeding under the malfunction theory was not fruitful for the Shearses, resulting in judgment as a matter of law in favor of Ethicon on their strict product liability claim.

III.

Pursuant to the foregoing, we vacate the judgment of the federal trial court and remand for such other and further proceedings as may be appropriate.⁴

VACATED AND REMANDED

⁴ We acknowledge that the Shearses also maintain in this appeal that the trial court (1) improperly granted Ethicon judgment as a matter of law on their strict liability design defect claim under the malfunction theory and (2) incorrectly instructed the jury on their negligence-based product liability claim. We express no view on either contention, recognizing that further proceedings on remand may render review of those issues unnecessary.