

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.

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: April 5, 2023

Before KING, AGEE, and HEYTENS, Circuit Judges.

Order of Certification to the Supreme Court of Appeals of West Virginia. Judge King prepared and entered the Order of Certification, with the concurrence of Judge Agee and Judge Heytens.

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.

**ORDER OF CERTIFICATION
TO THE SUPREME COURT OF APPEALS OF WEST VIRGINIA**

KING, Circuit Judge:

This Court, availing itself of the privilege afforded by the State of West Virginia through the Uniform Certification of Questions of Law Act, W. Va. Code §§ 51-1A-1 to 51-1A-13, hereby requests that the Supreme Court of Appeals of West Virginia exercise its discretion to resolve the following certified question of law:

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.

We acknowledge that the Supreme Court of Appeals may reformulate the foregoing certified question. *See* W. Va. Code §§ 51-1A-4, -6(a)(3). In our view, there is no controlling appellate decision, constitutional provision, or statute of the State of West Virginia that definitively answers the certified question, and the answer thereto will be “determinative of an issue” in this pending cause. *Id.* § 51-1A-3. In particular, we discern an absence of West Virginia authorities supportive of what we refer to herein as the “Section 411 Elimination Mandate” — that being Section 411’s requirement that an

identified alternative, feasible product design “eliminate the risk of harm suffered by the plaintiff.”¹ Accordingly, we conclude that the question is appropriate for certification. To fully illustrate the nature of the controversy out of which the certified question arises, we next recite the relevant facts.

I.

A.

1.

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.

¹ The full text of Section 411 of the *West Virginia Pattern Jury Instructions* is set forth, *in haec verba, infra* at pages 6 and 13.

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.² 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.³ 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.

In June 2015, the MDL court consolidated 37 of the West Virginia-based actions pending against Ethicon in the MDL — including the Shearses' — for trial on the issue of the TVT's purported defective design. Ethicon objected to the MDL court's West Virginia consolidation, contending in pertinent part that, pursuant to West Virginia law, product

² We refer to defendants Ethicon and Johnson & Johnson collectively as “Ethicon.”

³ 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.

liability plaintiffs alleging a design defect are obliged to identify a “safer alternative design” which “would have *materially reduced* the plaintiff’s injuries.” *See Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, at 3 (S.D.W. Va. July 1, 2015), ECF No. 27 (emphasis added). More specifically, Ethicon asserted that proving a defective design requires “plaintiff-specific evidence” — thereby rendering any consolidated trial inappropriate. *Id.*

In an August 2015 order clarifying the scope of the consolidated trial, the MDL court overruled Ethicon’s objections, principally explaining that the Supreme Court of Appeals of West Virginia “has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product.” *See Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, at 17 (S.D.W. Va. Aug. 4, 2015), ECF No. 38 (the “Clarification Ruling”) (quoting *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547-48 (S.D.W. Va. 2011)).⁴ The MDL court acknowledged that “evidence on the existence of a safer alternative is certainly relevant” to “determining whether a product is ‘unsafe,’” but its Clarification Ruling resolved that “there is no West Virginia authority requiring plaintiffs to prove, as part of their *prima facie* case, that [a] proposed safer alternative design would have reduced an individual plaintiff’s specific injuries.” *Id.*

2.

In June 2016, as discovery proceedings were yet ongoing in the MDL court, the Supreme Court of Appeals of West Virginia published its *West Virginia Pattern Jury*

⁴ The Clarification Ruling is published and can be found at 117 F. Supp. 3d 810 (S.D.W. Va. 2015).

Instructions for Civil Cases (hereinafter the “PJI”). The PJI are a set of jury instructions made commercially available by the West Virginia high court, and their drafting and assembly were overseen by Justice Ketchum and Fourteenth Judicial Circuit Judge Alsop. The Preface to the PJI explains that the instructions “were written to help trial judges and lawyers instruct the jury in a civil case.” *See* J.A. 68.⁵ The Preface also makes clear, however, that the instructions are “not binding,” and specifies that “lawyers have an obligation to object and point out any errors in any pattern instruction.” *Id.*

Especially relevant to these proceedings, Section 400 of the PJI sets forth pattern jury instructions for various product liability claims. Contained within Section 400 is Section 411, an instruction entitled “Design Defect — Necessity of an Alternative, Feasible Design.” *See* J.A. 69. Section 411 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*].

Id.

Just weeks after the publication of the PJI, Ethicon used that development to seek reconsideration of the MDL court’s Clarification Ruling. In its motion, Ethicon maintained that Section 411’s requirement for a design defect plaintiff to prove an alternative, feasible product design that would eliminate the risk of harm to the plaintiff revealed error in the MDL court’s earlier characterization of the applicable burden of proof. Importantly,

⁵ Citations herein to “J.A. ___” refer to the contents of the Joint Appendix filed in this Court by the parties to this appeal.

Ethicon insisted that Section 411 did not reflect a new pronouncement of West Virginia law, but was instead rooted in extant authority from the Supreme Court of Appeals, given that the Section’s “Notes and Sources” provision referenced two decisions from the West Virginia high court — *Morningstar v. Black & Decker Manufacturing Co.*, 253 S.E.2d 666 (W. Va. 1979), and *Church v. Wesson*, 385 S.E.2d 393 (W. Va. 1989). *See* J.A. 69.⁶

By an unpublished order of December 2016, the MDL court granted Ethicon’s reconsideration motion, explaining that — in light of Section 411 of the PJI — its “inescapable conclusion” was that “in a West Virginia strict liability design defect products liability case, a plaintiff must prove that there was an alternative, feasible design — existing at the time of the product’s manufacture — that would have eliminated the risk that injured the plaintiff.” *See Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, at 11 (S.D.W. Va. Dec. 9, 2016), ECF No. 1525 (the “Reconsideration Ruling”). In its Reconsideration Ruling, the court recognized that “the PJI [are] optional and not binding on courts,” making note that the PJI’s Preface “emphatically state[s]” that the instructions “ARE NOT BINDING ON

⁶ We observe that, as an alternative to its request for the MDL court to reconsider its Clarification Ruling, Ethicon sought to have the following question certified by the MDL court to the Supreme Court of Appeals of West Virginia:

In order to prove that a design is defective in a product liability case, does West Virginia law require the plaintiff to prove that there was an alternative, feasible design that eliminated the risk that injured him or her?

See J.A. 62. The MDL court ultimately denied Ethicon’s alternative motion to certify as moot after granting the reconsideration motion. As explained herein, however, we now resolve that certification is the appropriate course for determining whether Section 411 is a complete and accurate statement of West Virginia law.

THE TRIAL JUDGE” and that “[o]n appeal, the Supreme Court is not bound by the correctness of these pattern instructions.” *Id.* at 5. Nevertheless, the Reconsideration Ruling went on to resolve that the PJI “have gone through multiple edits and revisions after extensive research and editing by the reporters, the review committees, Judge Alsop, and Justice Ketchum,” and that, at the end of the day, the instructions were “backed by the blessing of the West Virginia Supreme Court.” *Id.* at 5-6. After taking stock of Section 411’s reliance on the Supreme Court of Appeals’ *Morningstar* and *Church* decisions, the MDL court rested on “the persuasive force behind the PJI in helping me predict how the West Virginia Supreme Court would rule on this issue,” concluding that Section 411 supplies the correct burden of proof for a strict liability design defect claim pursued under West Virginia law. *Id.* at 6.⁷

B.

1.

In November 2020, following the entry of the MDL court’s Reconsideration Ruling, the close of discovery in the consolidated West Virginia cases, and summary judgment

⁷ As the Shearses note in their opening appellate brief, a supplemented version of the PJI was published in 2017, and — although the text of Section 411 remained unchanged therein — the Section’s “Notes and Sources” provision was updated to include a citation to the MDL court’s 2016 Reconsideration Ruling. *See* Br. of Appellants 21 n.4. That alteration does not resolve our uncertainty as to whether Section 411 provides a correct statement of West Virginia law. On the one hand, the Reconsideration Ruling is an unpublished decision rendered by a federal court — not a binding pronouncement of state law handed down by an arm of the West Virginia judiciary. And that matter aside, the Reconsideration Ruling is not some pre-existing edict that Section 411 can purport to be grounded in. It was instead rendered subsequent to Section 411’s formulation, accepting the “persuasive force behind” the Section’s characterization of design defect claims.

dispositions having been made as to several of the individual West Virginia plaintiffs, the MDL court entered a transfer order and ruled that, of the 79 cases remaining in the full Ethicon MDL, nine of those cases — including the Shearses’ — “would be more expeditiously concluded in the venues from which they arise.” *See In re: Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02327, at 1 (S.D.W. Va. Nov. 20, 2020), ECF No. 9186. In its transfer order, the court urged that, given the “[e]xtensive development of these cases over a period of years,” the receiving district courts should “immediately set the[] cases for trial without reopening discovery.” *Id.* at 1-2. On December 4, 2020, the Shearses’ case was officially transferred to the Northern District of West Virginia (hereinafter the “trial court”). *See Shears v. Ethicon, Inc.*, No. 1:20-cv-00264 (N.D.W. Va. Dec. 4, 2020), ECF No. 29.

At a hearing conducted on February 11, 2022, the trial court took up several pending *Daubert* motions regarding expert witnesses for both the Shearses and Ethicon.⁸ 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.” *See* J.A. 3011. 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

⁸ The Supreme Court’s decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), established the standard for the admissibility of expert testimony under Federal Rule of Evidence 702. Broadly, *Daubert* requires a district court to “ensur[e] that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” *See* 509 U.S. at 597.

represented “safer alternative mesh material[s] for treatment of stress urinary incontinence than Ethicon’s TVT Prolene mesh.” *Id.* at 3014.⁹ In other words, Dr. Klinge did identify alternative mesh designs — evidently in keeping with the demands of Section 411 of the PJI — but his expert report framed and qualified those designs as simply reducing the risk of harm that would stem from the product, thereby falling short of the Section 411 Elimination Mandate. Seizing on that distinction, Ethicon asserted that Dr. Klinge’s testimony was inadmissible.

The trial court questioned the Shearses’ lawyer regarding the Section 411 Elimination Mandate from the outset of the *Daubert* hearing, noting its concern “about the requirement under West Virginia products liability law, as found by Judge Goodwin and as established by the pattern jury instructions, that the alternative feasible design must eliminate the risk of which the plaintiff complains that caused the injuries.” *See* J.A. 5464. Accepting the legal soundness of Section 411’s requirements as the MDL court had, the trial court explained that, in Dr. Klinge’s expert report, it “saw 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 testimony simply “does 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 5569-70.

⁹ “Prolene” is one of several brand names used by Ethicon to market the TVT mesh.

2.

The Shearses proceeded to a seven-day jury trial against Ethicon in Clarksburg in March 2022, continuing to press their strict liability design defect claim as well as their claim alleging negligent design of the TVT mesh. Recognizing, however, 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.

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. The court ruled that, because the Shearses' experts had conceded in their testimony that erosion is a known risk of any pelvic surgery involving an artificial mesh implant like TVT, no reasonable jury could conclude that the mesh erosion experienced by Mrs. Shears was a "malfunction" that would not have occurred but for some unexpected flaw in the mesh's design. 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.

The Shearses timely noticed this appeal on April 12, 2022, and we possess jurisdiction pursuant to 28 U.S.C. § 1291.

II.

A.

In their appeal to this Court, the Shearses primarily challenge the trial court's (and, by extension, the MDL 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 is fatally flawed, lacking any support in controlling West Virginia law. The Shearses take particular issue with the Section 411 Elimination Mandate, asserting that the trial court erroneously restricted Dr. Klinge's expert testimony because of his inability to meet that high bar. Separately, the Shearses contest the trial court's ruling on the "malfunction theory" of liability and its ensuing award of judgment to Ethicon on the design defect claim, as well the court's formulation of the jury instruction regarding the negligent design claim.

As explained below, we are satisfied that "there is no controlling appellate decision, Constitutional provision or statute" of the State of West Virginia that resolves the question of whether Section 411 sets forth a correct statement of law — nor is there sufficient authority that would permit us to reasonably guess how the Supreme Court of Appeals of West Virginia might resolve that question. *See* W. Va. Code § 51-1A-3. The precedent that Ethicon relies on in defending Section 411 — that being the West Virginia high court's rulings in *Morningstar* and *Church*, and this Court's 2017 *Nease v. Ford Motor Co.* decision — simply does not carry the day. In so concluding, we are mindful that the parties to this appeal have not requested that any questions be certified to the Supreme Court of Appeals. Indeed, the parties agreed at oral argument that certification is not necessary, albeit only because each side is now assured that West Virginia law tips in their favor.

Nevertheless, a decision to certify an issue to a state high court “rests in the sound discretion of the federal court,” *see Lehman Bros. v. Schein*, 416 U.S. 386, 390-91 (1974), and we are entitled to *sua sponte* certify a state law question, *see Elkins v. Moreno*, 435 U.S. 647, 662 (1978).

Considering the sparsity of governing state law, we hereby certify the issue of Section 411’s validity to the Supreme Court of Appeals, confident that the Court’s answer — if it elects to furnish one — will “be determinative of an issue in [this] pending cause.” *See* W. Va. Code § 51-1A-3.¹⁰ We are of opinion that, once that certified question is resolved, existing West Virginia authority will provide us with adequate guidance to resolve the Shearses’ remaining appellate contentions.

B.

Once more, Section 411 of the PJI — as published in 2016 by the Supreme Court of Appeals of West Virginia — 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*].

¹⁰ We are confident that resolving the certified question will enable the Supreme Court of Appeals to reach the correct result as to the legal propriety of Section 411. That Section — and the balance of the PJI — was apparently adopted by a committee of reviewers and reporters, under the auspices of Justice Ketchum and Judge Alsop. By accepting the certified question and engaging skilled lawyers in adversary proceedings that include briefing and argument of the competing views, the Court will fully test the legal weight and import of the PJI in the context of an ongoing active controversy.

See J.A. 69. To be perfectly clear, we readily agree with the MDL court that the PJI should carry substantial weight in ascertaining the correct burden of proof that a plaintiff must bear in proving a claim pursued under West Virginia law. The PJI are owned and published by — indeed “backed by the blessing of” — the Supreme Court of Appeals, and by all accounts “have gone through multiple edits and revisions after extensive research and editing.” *See* Reconsideration Ruling 5-6. They may even constitute a “recent pronouncement[] of general rules or policies by [a] state’s highest court,” which, under this Court’s precedent, may be used in predicting a decision of a state high court in a diversity matter such as this one. *See Liberty Mut. Ins. Co. v. Triangle Indus., Inc.*, 957 F.2d 1153, 1156 (4th Cir. 1992).

Yet the PJI go out of their way to stress that they do not directly carry the force and effect of law — they are “not binding” on either trial or appellate courts in West Virginia, and they invite “lawyers . . . to object and point out any errors in any pattern instruction that is offered by a party or which a trial judge indicates will be read to the jury.” *See* J.A. 68. And as the Shearses have aptly explained in their objections to Section 411 of the PJI, no portion of that Section’s recitation of the standard of proof for a strict liability design defect claim finds direct support in controlling West Virginia law. That is especially so with respect to the Section 411 Elimination Mandate. Thus, wedged between the “persuasive force” of the PJI and the scarcity of West Virginia legal authorities backing Section 411’s framing, we find ourselves unable to determine whether the trial court rightly relied on Section 411 in limiting the testimony of the Shearses’ expert witness. That being so, we respectfully request the considered advisement of the Supreme Court of Appeals.

1.

For background, in *Morningstar v. Black & Decker Manufacturing Co.* — the Supreme Court of Appeals’ seminal decision regarding strict product liability claims — the Court recognized that a “defective product” “may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness.” *See* 253 S.E.2d 666, 682 (W. Va. 1979). *Morningstar* established a “general test” for “defectiveness” that looks to “whether the involved product . . . is not reasonably safe for its intended use.” *Id.* at 683. Once a plaintiff demonstrates that “the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff’s injury” while the product was being used in “a reasonably intended manner,” “a recovery is warranted.” *Id.* at 680, 682.

Elaborating on its “defectiveness” and “reasonable safety” standard, the 1979 *Morningstar* decision goes on to state that

[t]he standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer’s standards should have been at the time the product was made. . . . The term “unsafe” imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

See 253 S.E.2d at 682-83. The foregoing language reflects West Virginia’s formulation of the so-called “risk-utility test,” under which product defectiveness may be determined by balancing a given product’s risk of causing harm against the costs of reducing that risk. *Id.*

at 682 (“We believe that a risk/utility analysis does have a place in a tort product liability case.”).

Doubtlessly, the Supreme Court of Appeals has offered some measure of support for Section 411’s preliminary requirement that a strict liability design defect plaintiff is obliged to establish the existence of an “alternative, feasible design.” *Morningstar*’s construction of the risk-utility test looks in part to the “reasonably prudent manufacturer’s” consideration of “the general state of the art of the manufacturing process, including design.” *See* 253 S.E.2d at 682-83. And *Morningstar* also explained that expert testimony bearing on the risk-utility analysis will aid a jury in “evaluat[ing] the complex technical problems relating to product failure, safety devices, [and] design alternatives.” *Id.* at 682. Other courts applying West Virginia law, meanwhile, have resolved that proof of a “safer alternative” may serve as “at least *one* method of showing that a product is ‘not reasonably safe for its intended use.’” *See Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547-48 (S.D.W. Va. 2011) (emphasis added); *see also* Clarification Ruling 17 (“[W]hether required or not, evidence on the existence of a safer alternative is certainly relevant.”). It is of importance to us, however, that at no point has the Supreme Court of Appeals definitively stated — in a signed, published opinion — “one way or the other whether a design defect claim *requires* proof of a safer alternative design of the allegedly defective product.” *See Keffer*, 791 F. Supp. 2d at 547 (emphasis added) (recognizing lack of guiding decisional law).

At least one post-*Morningstar* decision of the Supreme Court of Appeals is apparently supportive of the proposition that a plaintiff must identify an alternative product design to prevail on a design defect claim. In *Church v. Wesson* — a 1989 ruling referred

to alongside *Morningstar* in Section 411’s “Notes and Sources” provision — the Court affirmed a directed verdict in favor of a defendant-manufacturer because the design defect plaintiff had failed to establish the existence of an alternative, feasible design for a “roof bolt wrench” that had injured him — such that the plaintiff “failed to establish a *prima facie* right of recovery.” See 385 S.E.2d 393, 396 (W. Va. 1989). The *Church* decision specifically concluded that the plaintiff’s proposed “forging”-based alternative design of the bolt wrench was “not feasible when the fractured wrench was manufactured,” and that the plaintiff’s evidence failed for that reason alone. *Id.* The Court did not resolve, however, that proof of an alternative, feasible wrench design was the only means available to the plaintiff for establishing a defective design, or that no other form of evidence could have advanced his claim to the jury — only that the plaintiff’s chosen evidence was deficient.¹¹

In defending Section 411’s alternative design requirement, Ethicon also relies heavily on this Court’s 2017 decision in *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). Therein, defendant Ford Motor — seeking to fend off a West Virginia strict liability design defect claim — argued that *Morningstar* actually articulated a requirement “to prove

¹¹ On appeal, the Shearses emphasize the limited nature of *Church*’s reasoning, and take issue with Section 411’s reliance thereon because *Church* is designated as a per curiam opinion. *Church* is not a signed opinion that — as the Supreme Court of Appeals has emphasized — carries greater weight than a per curiam ruling. In its 2001 *Walker v. Doe* decision, the Court explained that it “will use signed opinions when new points of law are announced and those points will be articulated through syllabus points.” See 558 S.E.2d 290, 296 (2001); accord *State v. McKinley*, 764 S.E.2d 303, 313 (2014). Per curiam opinions, the Court emphasized, apply “settled principles of law to facts necessarily differing from those at issue in signed opinions.” See *Walker*, 558 S.E.2d at 296. The *Church* decision therefore brings nothing to the table that *Morningstar* did not already decide.

that a reasonably prudent manufacturer would have adopted a safer design during the relevant time period.” *Id.* at 234. Plaintiff Nease countered that the Supreme Court of Appeals has never enforced such a rule, and our decision acknowledged that “West Virginia law on the matter is not crystal clear.” *Id.* Nevertheless, we agreed with Ford Motor “that *Morningstar* can only be read to require the production of evidence on reasonable alternative design, to gauge what ‘should have been.’” *Id.* (quoting *Morningstar*, 253 S.E.2d at 683). More specifically, *Nease* resolved that, “[a]lthough *Morningstar* does not use the phrase ‘alternative design,’ a plaintiff in a design case, for all practical purposes, must identify an alternative design in order to establish the state of the art.” *Id.*

Ethicon contends in this appeal that, after *Nease*’s endorsement of the “alternative design” standard, there is no open question whether Section 411’s inclusion of that requirement is faithful to West Virginia tort law. And while it is certainly true that we must abide by our own prior decisions, a ruling by this Court cannot and does not propound new principles of state law. To be sure, if the Supreme Court of Appeals arrived at a conclusion contrary to *Nease*, that determination would control. *See Passaro v. Virginia*, 935 F.3d 243, 252-53 (4th Cir. 2019). While our *Nease* decision would likely prove sufficient to resolve this matter were the only question before us whether proof of an alternative, feasible product design is requisite to a successful design defect claim, we are presently faced with a significantly broader inquiry — whether the whole of Section 411 spells out the correct burden of proof. And as described further below, neither *Church* nor *Nease* have settled that issue. At bottom, while the preliminary portion of Section 411 does

find some degree of footing in West Virginia decisional law (and in the precedent of this Court), there is simply no decision of the Supreme Court of Appeals that has squarely resolved whether proof of an alternative, feasible design is an essential element of a design defect claim, or whether other sorts of evidence can demonstrate — with equal force — that a product is “not reasonably safe for its intended use.”¹²

2.

After reciting that proof of an “alternative, feasible design” is imperative for establishing a defective product design, Section 411 goes on to lay out its most important aspect in the context of this proceeding — that is, the Section 411 Elimination Mandate. That requirement specifies that such an alternative design must completely “eliminate[] the risk that injured” the plaintiff. And it was on that basis that the trial court limited the testimony of Dr. Klinge, insofar as his expert report spoke only to alternative pelvic mesh

¹² As the MDL court observed in its Reconsideration Ruling, Sections 409 and 410 of the PJI also speak to strict liability design defect claims, with the former laying out the general elements of a design defect claim as articulated by *Morningstar*, and the latter describing *Morningstar*’s risk-utility test. Section 410, for its part, provides that “[t]o determine whether a design was defective,” the jury is to “decide if the benefits of the design outweigh the risks,” considering, inter alia, the “feasibility of an alternative, safer design”; the “cost of an alternative design”; any “disadvantages of an alternative design”; and “other relevant factors.” See Reconsideration Ruling 9.

The MDL court evidently accepted Section 410’s inclusion of “alternative, safer designs” in its presentation of the risk-utility test as validating Section 411’s requirement of an alternative, feasible design to prove a defective design. But Section 410 relies exclusively on *Morningstar* for authority in its “Notes and Sources” provision. And as explained above, *Morningstar* sets forth no such explicit condition. Moreover, Section 410’s incorporation of “other relevant factors” into the risk-utility test begs the question of whether Section 411 wrongly cabins the “defectiveness” inquiry to the existence of an alternative product design.

designs that would have lessened the risk of mesh erosion. Although Section 411’s first requirement of an alternative product design can — as now explained — claim at least some basis in West Virginia law, the Section 411 Elimination Mandate appears to lack a similar legal foundation.

As previously mentioned, the first published version of Section 411 relied on two putatively authoritative decisions of the Supreme Court of Appeals in its “Notes and Sources” provision — *Morningstar* and *Church*. But neither of those decisions actually discuss the “elimination” of a product’s risk of danger or any analogue to the same effect. *Morningstar*, for its part, discusses only — and quite generally — the role of product design in a “defectiveness” inquiry. It never considered the extent to which a potential or alternate product design might shift the end result’s likelihood of causing harm.¹³ And the *Church* decision — as we heretofore emphasized — was centered around the infeasibility of the plaintiff’s proffered alternative product design. Given the plaintiff’s failure to put forth an adequate alternative, the Court in *Church* had no reason to speculate as to what impact the alternative may have had on the odds of the plaintiff suffering an injury.

¹³ At oral argument, Ethicon’s lawyer pointed out that a footnote in the *Morningstar* decision contemplates “[t]he manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness.” See 253 S.E.2d at 681 n.20. That footnote, however, was used only to spell out an alternative formulation of the risk-utility test (included in a broad survey of other jurisdictions’ standards for defining a product “defect”), which the Supreme Court of Appeals did not adopt in *Morningstar*.

In this appeal, Ethicon turns again to our *Nease* decision to contend that the Section 411 Elimination Mandate is legally sound.¹⁴ But *Nease* does no more to bolster that requirement than do the *Morningstar* and *Church* decisions. For starters, we again emphasize that our rulings about West Virginia law do not constitute controlling pronouncements thereof. And even if they did, the parties' dispute in *Nease* was whether *Morningstar* "requires a product liability plaintiff to prove that a reasonably prudent manufacturer would have adopted a *safer* design during the relevant time period" — not whether some other product design would have wiped out all risk of harm flowing from the product. *See* 848 F.3d at 233 (emphasis added). Ultimately, after concluding that *Morningstar* does call for proof of an alternative product design, *Nease* resolved that the plaintiff's expert testimony regarding alternative designs should have been excluded from the trial evidence, as it was not supported by adequate testing data. In so ruling, we observed that the plaintiff's expert "offered no data . . . to prove that the [alternative] designs were *less likely* to [fail] than the one" that had injured the plaintiff, in effect suggesting that alternative designs need only diminish a product's chances of generating harm. *Id.* at 234 (emphasis added).

¹⁴ The Shearses' appellate briefing advises us that the 2017 revised edition of the PJI added a citation to *Nease* within Section 411's "Notes and Sources" provision, alongside the previously mentioned citation to the MDL court's Reconsideration Ruling. *See supra* note 7. As explained herein, however, *Nease* does not provide any direct support for Section 411's characterization of a design defect plaintiff's burden of proof. Indeed, neither Section 411 nor the rest of the PJI were considered or discussed in *Nease*.

In short, we have identified no West Virginia precedent that ratifies the Section 411 Elimination Mandate. To the extent that evidence of an alternative, feasible product design is necessary to prevail on a design defect claim — or is otherwise supplied by a plaintiff, even if not required — it could be the case that the alternative design’s reduction of the risk of harm (as Dr. Klinge discussed in his expert report) suffices to establish that the subject product was “not reasonably safe for its intended use.” *See, e.g., Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 905 (S.D. Iowa 2020) (ruling — in an Ethicon pelvic mesh lawsuit remanded from the MDL court in 2019 — that under Iowa law, design defect claims require “expert testimony [that] establish[es] a reasonable alternative design and the ability of such design to reduce the foreseeable harm of the challenged product”). Because there is no West Virginia authority resolving that uncertainty — or suggesting one direction over the other — we lack any sound bases for predicting whether the Supreme Court of Appeals would sanction the Section 411 Elimination Mandate.

* * *

Given the shortage of instructive precedent, we are satisfied that “the available state law is clearly insufficient” to determine whether the Supreme Court of Appeals of West Virginia would conclude that Section 411 of the PJI — and, most notably, the Section 411 Elimination Mandate — correctly states the plaintiff’s burden of proof for a strict liability design defect claim. *See Roe v. Doe*, 28 F.3d 404, 407 (4th Cir. 1994). For the same reason, we are unable to resolve whether the trial court correctly limited the scope of the Shearses’ expert testimony. To be certain, the PJI — potentially an encapsulation of the Supreme Court of Appeals’ understanding of numerous areas of state law — present a

thorough definition of a design defect claim. When consulted to confirm the PJI's accuracy, however, West Virginia decisional law is largely silent. In these circumstances, we are constrained to seek the sound guidance of the Supreme Court of Appeals.

III.

In light of the foregoing, we again identify the controlling question of West Virginia law to be this:

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.

And we emphasize that the Supreme Court of Appeals of West Virginia may reformulate the certified question at its discretion. All of the parties in this matter are represented by counsel, whose names and addresses are provided hereunder, in accord with W. Va. Code § 51-1A-6(a)(4):

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Accordingly, pursuant to the privilege made available to this Court by the West Virginia Uniform Certification of Questions of Law Act, it is hereby ORDERED:

- (1) That the question set forth herein be certified to the Supreme Court of Appeals of West Virginia for resolution;
- (2) That the Clerk of this Court transmit to the Supreme Court of Appeals of West Virginia, under the official seal of this Court, a copy of this Order of Certification; and
- (3) That the Clerk of this Court provide the original or copies of all or such portion of the record before this Court as may be requested by the Supreme Court of Appeals of West Virginia, with any and all such requests being effective upon notification by ordinary means from the Clerk of the Supreme Court of Appeals.

This Order of Certification is entered by Judge King, with the concurrence of Judge Agee and Judge Heytens.

QUESTION CERTIFIED

FOR THE COURT:



Robert Bruce King
United States Circuit Judge