

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

January 2024 Term

No. 23-192

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SUPREME COURT OF APPEALS
OF WEST VIRGINIA

JUDITH A. SHEARS AND GARY F. SHEARS, JR.,
Petitioners,

V.

ETHICON, INC., AND JOHNSON & JOHNSON,
Respondents.

Certified Questions from the
United States Court of Appeals for the Fourth Circuit
The Honorable Robert B. King, G. Steven Agee,
and Toby J. Heytens, Circuit Judges
Appeal No. 22-1399

CERTIFIED QUESTIONS ANSWERED

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JUSTICE BUNN delivered the Opinion of the Court.

SYLLABUS BY THE COURT

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.

2. “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.” Syllabus point 5, *Morningstar v. Black & Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979).

3. “In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The 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.” Syllabus point 4, *Morningstar v. Black & Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979).

4. “The cause of action covered by the term ‘strict liability in tort’ is designed to relieve the plaintiff from proving that the manufacturer was negligent in some particular fashion during the manufacturing process and to permit proof of the defective condition of the product as the principal basis of liability.” Syllabus point 3, *Morningstar v. Black & Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979).

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.

BUNN, Justice:

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.¹ 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

[I]f 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.

¹ We appreciate the participation of Amicus Curiae, The Product Liability Advisory Council, Inc., which submitted a brief in support of Respondents, Ethicon, Inc., and Johnson & Johnson. We considered its arguments in answering the certified questions.

I.

FACTUAL AND PROCEDURAL HISTORY

The action from which these certified questions arose was part of a multi-district litigation proceeding (“MDL”) against Respondent, Ethicon, Inc., a wholly-owned subsidiary of Respondent Johnson & Johnson (collectively “Ethicon”), over alleged injuries caused by Ethicon’s Tension-Free Vaginal Tape (“TVT”), a mesh sling used to treat stress urinary incontinence.² Petitioner Judith Shears underwent surgery to implant a TVT device, which initially diminished her symptoms.³ Later, Mrs. Shears began experiencing renewed incontinence, urinary tract infections, pelvic pain, and urinary frequency and urgency. After a urologist discovered that the TVT mesh had partially eroded into Mrs. Shears’ bladder, the device was surgically removed along with an attached bladder stone. The next year, additional eroded mesh was discovered in Mrs. Shears’ bladder, and she has continued to experience recurrent bladder stones and severe bladder and urinary difficulties.

Mrs. Shears and her husband, petitioner Gary Shears, filed suit against Ethicon in the United States District Court for the Southern District of West Virginia as

² This case was one of more than 28,000 cases pending at one time in the Ethicon pelvic mesh MDL.

³ These facts are primarily gleaned from the Fourth Circuit’s Order of Certification, and they are recited merely to provide context for our analysis. We do not resolve any facts that might be disputed if this case is further litigated.

part of the MDL,⁴ asserting numerous claims for relief, including a strict liability claim alleging the TVT device was defectively designed. In June 2015, the district court consolidated the Shearses’ case with thirty-six similar West Virginia-based actions pending against Ethicon for trial solely to resolve the defective design element of the TVT claims, which included claims founded on both negligence and strict liability. The consolidated cases were styled *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952 (S.D.W. Va.). Ethicon objected to the consolidation, arguing, in relevant part, that “the existence of a safer alternative design” had to be proven on a plaintiff-specific basis. *Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 821 (S.D.W. Va. 2015), *reconsidered*, No. 2:12-cv-02952, 2016 WL 7197441 (S.D.W. Va. Dec. 9, 2016). Further, Ethicon contended that “the plaintiffs must show the alternative design would have *materially reduced* the plaintiff’s injuries.” *Id.* (quotations omitted; emphasis added). The district court overruled Ethicon’s objection to consolidation and rejected its argument regarding the plaintiffs’ burden of proof, commenting that “there is no West Virginia authority requiring plaintiffs to prove, as part of their *prima facie* case, that the proposed safer alternative design would have reduced an individual plaintiff’s specific injuries.” *Id.*⁵

⁴ The MDL is captioned *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, No. 2:12-md-02327.

⁵ The district court concluded that plaintiff-specific information is not required to develop evidence of a safer alternative design. *Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 821 (S.D.W. Va. 2015), *reconsidered*, No. 2:12-cv-02952, 2016 WL 7197441 (S.D.W. Va. Dec. 9, 2016).

Thereafter, in 2016, this Court published the *West Virginia Pattern Jury Instructions for Civil Cases* (“PJI”), as reported by Justice Menis E. Ketchum. Relevant to the questions now before the Court, one pattern jury instruction addressing product liability provides:

§ 411. Design Defect—Necessity of an Alternative, Feasible Design

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*].

After the PJI were published, Ethicon filed a motion for reconsideration of the district court’s prior decision that overruled its objection to the consolidation order. Ethicon argued that PJI § 411 contravened the district court’s prior ruling. The district court agreed and granted Ethicon’s motion. Based primarily on PJI § 411 and the authority cited along with it,⁶ the court found that “in a West Virginia strict liability design defect . . . 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.”

⁶ Notes and sources provided with PJI § 411 initially cited only *Morningstar v. Black & Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979); and *Church v. Wesson*, 182 W. Va. 37, 385 S.E.2d 393 (1989) (per curiam). When the PJI were supplemented in 2017, two additional citations were added: *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2016 WL 7197441 (S.D.W. Va. Dec. 9, 2016) (order on reconsideration); and *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017).

Mullins v. Ethicon, Inc., No. 2:12-cv-02952, 2016 WL 7197441, at *5 (S.D.W. Va. Dec. 9, 2016) (order on reconsideration).⁷

In November 2020, after the consolidated cases proceeded through discovery and some were resolved by summary disposition, the district court transferred nine of the remaining cases, including the Shearses' case, to the United States District Court for the Northern District of West Virginia, the venue from which they arose. During a February 11, 2022 hearing on pending *Daubert*⁸ motions, the district court considered Ethicon's motion to limit the testimony of the Shearses' design and materials expert, Dr. Uwe Klinge. Dr. Klinge was to testify regarding alternative designs for Ethicon's TVT mesh sling relative to the Shearses' strict liability design defect claim.⁹ Because Dr. Klinge opined

⁷ Alternatively, Ethicon asked the district court to certify a question to this Court. The court denied Ethicon's request as moot. *Mullins*, 2016 WL 7197441, at *5.

⁸ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) (establishing a gatekeeping analysis to ensure that scientific expert testimony is reliable and relevant pursuant to Federal Rule of Evidence 702).

⁹ According to the Fourth Circuit's certification order,

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 material[s] for treatment of stress urinary incontinence than Ethicon's TVT Prolene mesh.”

that there were “*safer* alternative mesh material[s] for treatment of stress urinary incontinence than Ethicon’s TVT Prolene mesh,”¹⁰ Ethicon argued that Dr. Klinge’s opinion fell short of the requirement that the alternative, feasible design would have “*eliminated* the risk that injured [Mrs. Shears].” W. Va. P.J.I. § 411 (emphasis added). The district court agreed, granted Ethicon’s motion, and barred Dr. Klinge from testifying about alternative mesh designs. The Shearses contend that this ruling effectively granted summary judgment to Ethicon as to their strict liability design defect claim.

At trial, the Shearses pursued both their strict liability and negligence claims against Ethicon. However, the district court’s adoption of PJI § 411 and restraint of Dr. Klinge’s testimony foreclosed the Shearses’ ability to prove a strict liability design defect claim. Therefore, they pursued their strict liability claim pursuant to a malfunction theory.¹¹ At the close of the Shearses’ case in chief, the district court granted Ethicon’s motion for

Shears v. Ethicon, Inc., 64 F.4th 556, 562 (4th Cir. 2023) (citations omitted).

¹⁰ *Id.* (emphasis added).

¹¹ *See* Syl. pt. 3, *Anderson v. Chrysler Corp.*, 184 W. Va. 641, 403 S.E.2d 189 (1991) (“Circumstantial evidence may be sufficient to make a *prima facie* case in a strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect. Moreover, the plaintiff must show there was neither abnormal use of the product nor a reasonable secondary cause for the malfunction.”). The district court referred to the Shearses’ malfunction theory claim as one asserting a design defect; however, the malfunction theory applies when “the precise nature of the defect cannot be identified.” *Id.*

judgment as a matter of law on the Shearses’ malfunction theory claim. Thereafter, the jury returned a verdict for Ethicon on the Shearses’ negligence claim. Appealing to the United States Court of Appeals for the Fourth Circuit, the Shearses primarily challenged two rulings by the district court: (1) that in West Virginia, a strict liability design defect claim requires proof of an alternative, feasible design that would have “eliminated the risk that injured [Mrs. Shears],” pursuant to W. Va. P.J.I. § 411; and (2) that Dr. Klinge’s testimony regarding an alternative, feasible design must be excluded because it failed to meet the PJI § 411 standard. Finding no controlling appellate decision or statute addressing this standard of proof issue, and no basis from which to reasonably speculate on how this Court would decide the question of whether PJI § 411 represents the controlling law in West Virginia, the Fourth Circuit, sua sponte, certified the following questions to this Court pursuant to the Uniform Certification of Questions Law Act, West Virginia Code §§ 51-1A-1 to -13:

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.

By order entered on October 16, 2023, we accepted the certified questions and set this case for oral argument under Rule 20 of the West Virginia Rules of Appellate Procedure. *See* W. Va. R. App. P. 17(b).

II.

STANDARD OF REVIEW

We exercise plenary review of a question certified by the Fourth Circuit: “‘A de novo standard is applied by this Court in addressing the legal issues presented by a certified question from a federal district or appellate court.’” Syl. pt. 1, *Martinez v. Asplundh Tree Expert Co.*, 239 W. Va. 612, 803 S.E.2d 582 (2017) (quoting Syl. pt. 1, *Light v. Allstate Ins. Co.*, 203 W. Va. 27, 506 S.E.2d 64 (1998)). *See also* Syl. pt. 1, *Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 522 S.E.2d 424 (1999) (“This Court undertakes plenary review of legal issues presented by certified question from a federal district or appellate court.”).

III.

DISCUSSION

The questions certified to us by the Fourth Circuit seek clarification of West Virginia law as to the burden of proof borne by a plaintiff asserting a strict liability design defect claim. We address the questions in three parts. First, we consider whether PJI § 411 correctly expresses West Virginia law. Finding that it does not, we next analyze whether a

plaintiff asserting a design defect claim using a strict liability theory must establish an alternative, feasible product design that was available when the product was manufactured. Because we find an alternative, feasible design is required, we finally explore whether a plaintiff must establish that the available alternative design must have “eliminated the risk that injured” the plaintiff. W. Va. P.J.I. § 411.

A. Pattern Jury Instructions § 411

The pattern jury instruction at issue in this case obliges a plaintiff asserting a strict liability design defect claim to prove “that there was an alternative, feasible design that *eliminated the risk* that injured” the plaintiff. W. Va. P.J.I. § 411 (emphasis added). The Shearses label this an “elimination mandate,” and argue that it has never been the law in West Virginia nor any other United States jurisdiction. Ethicon responds that PJI § 411 has its roots in West Virginia law and is consistent with other jurisdictions. We agree with the Shearses that PJI § 411 does not accurately reflect West Virginia law.

Notes following the text of PJI § 411 provide four sources of authority for the pattern instruction. Two of these sources were cited when the PJI were initially published in 2016: Syllabus point 4, *Morningstar v. Black & Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979); and *Church v. Wesson*, 182 W. Va. 37, 385 S.E.2d 393 (1989) (per curiam). Two additional sources were added when the PJI were supplemented in 2017: *Mullins*, 2016 WL 7197441; and *Nease v. Ford Motor Co.*, 848

F.3d 219 (4th Cir. 2017). We will discuss each of these authorities to demonstrate that none of them provide support for requiring a plaintiff in a strict liability design defect case to prove the existence of an alternative, feasible design that “eliminated the risk” that injured the plaintiff.

First, the Notes and Sources section of PJI § 411 quotes Syllabus point 4 of *Morningstar*, which provides:

In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The 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.

Syl. pt. 4, *Morningstar*, 162 W. Va. 857, 253 S.E.2d 666. As we explain more thoroughly below, we find that *Morningstar’s* holding, by establishing a “reasonable safeness” standard that considers what “a reasonably prudent manufacturer’s standards should have been,” supports a requirement for proof of an alternative, feasible design in a strict liability claim based on a design defect. *Id.* However, there is nothing in this language to indicate that the alternative, feasible design must eliminate the risk that injured the plaintiff as required by PJI § 411.

Second, *Church* similarly fails to support PJI § 411’s requirement for an alternative, feasible design that must have eliminated the risk that injured the plaintiff.

According to the notes accompanying PJI § 411, *Church* “relies upon Syl. Pt. 4 of *Morningstar* to uphold a directed verdict for [the] defendant, in a strict liability context, on the ground that the plaintiff had failed to establish [the] feasibility of a proffered alternative design.” W. Va. P.J.I. § 411 Notes and Sources. The circuit court in *Church* granted the defendant’s motion for a directed verdict, in part, because the plaintiff had failed to present sufficient evidence that the roof-bolt wrench at issue had been defectively designed.¹² This Court affirmed, observing that the plaintiff’s expert suggested a manufacturing procedure that “may have been a more appropriate design,” but “it was undisputed” that the suggested procedure “was not feasible” at the time the wrench was manufactured. *Church*, 182 W. Va. at 40, 385 S.E.2d at 396. Additionally, the expert’s “credibility was severely impeached when he admitted that he had never designed nor manufactured” a roof-bolt wrench, and he was not familiar with the roof bolting machine it was a component of. *Id.* This Court found no error in the circuit court’s directed verdict because the plaintiff had failed to establish a prima facie right of recovery. *Id.* Importantly, because there was no evidence of an alternative, feasible design, the *Church* Court never addressed the

¹² The roof-bolt wrench at issue in *Church* fractured at a welded joint and a piece of the wrench struck and injured the plaintiff. The plaintiff’s expert opined that the defendant defectively designed the wrench to be manufactured using a welding process. The expert suggested that “a forging procedure would have been more appropriate,” but he admitted on cross examination that “he had absolutely no experience in designing or manufacturing roof bolt wrenches” *Church*, 182 W. Va. at 39, 385 S.E.2d at 395. The defendant provided expert evidence that the welding process was state of the art; that three major roof bolt wrench manufacturers welded their wrenches; and that, at the time the wrench at issue was manufactured, forging such a wrench was impossible. *Id.*

requirement for an alternative design that eliminated the risk that injured the plaintiff as set forth in PJI § 411; so, *Church* does not provide support for that pattern instruction.

PJI § 411 also cites *Mullins*, 2016 WL 7197441, as a third basis of support. However, this citation merely refers to the district court's decision on Ethicon's motion to reconsider the court's alternative design ruling, which was rendered in the litigation of thirty-seven consolidated TVT cases that included the Shearses' suit against Ethicon. While *Mullins* does require an alternative design that would have eliminated the risk that injured the plaintiff, its conclusion is based upon PJI § 411; therefore, it cannot provide support for the pattern instruction. On reconsideration following the publication of PJI § 411, the district court declined to either ignore the PJI as nonbinding or find that it is an incorrect statement of West Virginia law. The court reasoned that "while the PJI is certainly not binding precedent in the way a published opinion is, the persuasive force behind the PJI in helping me predict how the West Virginia Supreme Court would rule on this issue is substantial." *Id.*, at *3. The district court then concluded, based upon PJI § 411, that in a West Virginia strict liability design defect 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." *Id.* at *5. Because the district court's decision is primarily based on the language of PJI § 411, the PJI's reliance on *Mullins* as a source of support for PJI § 411 is circular and unpersuasive. Furthermore, the district court's conclusion is not binding on this Court. *See Caperton v. A.T. Massey Coal Co.*, 225

W. Va. 128, 162, 690 S.E.2d 322, 356 (2009) (“It is generally acknowledged that ‘the lower federal courts do not have appellate jurisdiction over the state courts and their decisions are not conclusive on state courts.’” (quoting *State v. Robinson*, 82 P.3d 27, 30 (2003))); *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 477 n.18, 647 S.E.2d 899, 913 n.18 (2007) (commenting that, “[w]hile federal court opinions applying West Virginia law are often viewed persuasively, we are not bound by those opinions,” and collecting cases), *superseded by statute on other grounds as stated in J.C. by and through Michelle C. v. Pfizer, Inc.*, 240 W. Va. 571, 814 S.E.2d 234 (2018).

The Fourth Circuit’s decision in *Nease* is listed as the last source of authority for PJI § 411 yet provides no support for requiring an alternative design to eliminate the risk that caused a plaintiff’s injury. The *Nease* court merely concluded that, applying *Morningstar*, “a plaintiff in a design case, for all practical purposes, must identify an alternative design in order to establish the ‘state of the art.’” *Nease*, 848 F.3d at 234. The *Nease* court found that the plaintiff’s expert failed to prove that his proposed alternative designs were safer than the allegedly defective design at issue, or that the alternative designs would have been adopted by reasonably prudent manufacturers. *Nease* contains no indication that the Fourth Circuit interpreted West Virginia law as requiring a plaintiff to prove the existence of an alternative, feasible design that eliminates the risk that injured the plaintiff as required by PJI § 411.

Finally, the PJI themselves plainly state that they do not constitute binding precedent in West Virginia and contain the following warning:

Caveat — These are pattern jury instructions that were written to help trial judges and lawyers instruct the jury in a civil case. **THEY ARE NOT BINDING ON THE TRIAL JUDGE.** Although they are pattern instructions, the lawyers have an obligation 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. On appeal, the Supreme Court is not bound by the correctness of these pattern instructions. It is incumbent on the lawyers in a trial to ensure the correctness of any pattern instruction that may be read to the jury.

W. Va. P.J.I. Preface. This caveat is clear in demonstrating that the PJI are merely an aid and may not correctly reflect the law.

Because we find no support in West Virginia law for PJI § 411’s requirement for an alternative, feasible design that “eliminated the risk” that injured the plaintiff, we hold that *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. Accordingly, we answer the first certified question in the negative.

B. Alternative, Feasible Product Design

Having concluded that PJI § 411 does not accurately reflect West Virginia law, we now address whether a plaintiff must prove the existence of an alternative, feasible design in making a prima facie case of strict liability founded on a design defect. The

Shearses argue that *Morningstar* adopted a flexible approach and that proof of an alternative, feasible design is but one way plaintiffs may satisfy their burden in strict liability design defect claims.¹³ Ethicon maintains that the only reasonable reading of *Morningstar* is that it requires proof of an alternative, feasible design in a strict liability design defect claim. We agree with Ethicon and find that *Morningstar* supports requiring a plaintiff to prove that an alternative, feasible design existed at the time the contested product was manufactured.

This Court has not rendered a straightforward pronouncement on this issue. *See Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547 (S.D.W. Va. 2011) (“[T]he West Virginia Supreme Court 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.”); Philip Combs,¹⁴ Andrew Cooke, *Modern Products Liability Law in West Virginia*, 113 W. Va. L. Rev. 417, 427 (2011) (observing that the question of whether an alternative design is required “has

¹³ By way of example, the Shearses argue that proof of an alternative, feasible design is not required when the product is inherently dangerous or when a plaintiff asserts a malfunction theory. Notably, the Shearses do not claim to have asserted that the TVT mesh sling is inherently dangerous. They did raise the malfunction theory, see *supra* note 11; however, the questions certified by the Fourth Circuit do not address either of these theories. Because these theories are beyond the scope of the questions certified, we decline to address them.

¹⁴ We note that Philip Combs represents the respondents in this case.

received little attention” in West Virginia “because, as a practical matter, plaintiffs['] counsel almost always put forth an alternative design.”).

While this Court has made no clear statement on the issue, we have strongly implied that there is a requirement for an alternative, feasible design. West Virginia’s seminal case on strict liability in tort, *Morningstar*, 162 W. Va. 857, 253 S.E.2d 666, explained that a design defect inquiry “centers on the physical condition of the product which renders it unsafe when the product is used in a reasonably intended manner.” *Id.* at 888, 253 S.E.2d at 682. Tellingly, the opinion clarified that,

[t]he 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.

Syl. pt. 5, *id.*, 162 W. Va. 857, 253 S.E.2d 666. The Court further held:

In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The 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.*

Syl. pt. 4, *id.* (emphasis added).¹⁵ By establishing a standard for strict liability centered on what a reasonably prudent manufacturer would have accomplished at the time the challenged product was made, *Morningstar* effectively required proof of an alternative, feasible design to establish a prima facie case for a design defect. In fact, the Fourth Circuit has noted that *Morningstar* “can only be read to require the production of evidence on reasonable alternative design, to gauge what ‘should have been.’” *Nease*, 848 F.3d at 234. The *Nease* court observed 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.* (citing *Church*, 182 W.Va. at 40, 385 S.E.2d at 396). Accordingly, we find that a plaintiff asserting a strict liability claim for a design defect must prove that an alternative, feasible design was available to the manufacturer at the time the product in question was manufactured, and so we answer the second certified question in the affirmative.

¹⁵ In adopting a “not reasonably safe” standard, the *Morningstar* Court rejected the “unreasonably dangerous” standard used in the Restatement (Second) of Torts § 402(A) (Am. L. Inst. 1965), finding the standard expressed in *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963), to be more appropriate. *See Morningstar*, 162 W. Va. at 891, 253 S.E.2d at 684. Still, the Court clarified that the “not reasonably safe” definition of a defective design adopted in *Morningstar* was “somewhat more restrictive” than the California definition. *Id.*

C. Proof Required for an Alternative, Feasible Design

Our final task is to clarify a plaintiff's burden with respect to establishing an alternative, feasible design in a strict liability design defect claim. We find that an alternative, feasible design that substantially reduces the risk of the specific injury suffered by the plaintiff is the appropriate standard for this type of strict liability claim.

Because “the general test for establishing strict liability in tort is whether the involved product is defective,” we consider the meaning of “defective” product as it relates to a design defect claim. Syl. pt. 4, *Morningstar*, 162 W. Va. 857, 253 S.E.2d 666. Pursuant to *Morningstar*, a product is defective if it is “not reasonably safe for its intended use.” *Id.* Viewed in the context of an alternative design, this means that an appropriate alternative, feasible design should be, at least, “reasonably safe.” *See id.* (holding, in part, 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.” (emphasis added)). *Morningstar’s* use of the term “reasonably” signifies that a product is safe if it meets “fair or sensible standards.” *Reasonably*, New Oxford American Dictionary (3rd ed. 2010). *See also Reasonable*, XIII The Oxford English Dictionary (2d ed. 1989) (defining “reasonable” as “[o]f such an amount, size, number, etc., as is judged to be appropriate or suitable to the circumstances or purpose.”); *Reasonably*, Webster’s Third New Int’l Dictionary (unabridged ed.1970) (“to a fairly sufficient extent”).

While some jurisdictions require only that the alternative, feasible design be “safer,”¹⁶ we find this criterion is too vague and does not meet *Morningstar*’s “reasonably safe” standard for an alternative design. Because a product could be safer than a defective product yet remain defective or “not reasonably safe,” this standard is an ineffective guide for what a reasonably prudent manufacturer should have produced. Syl. pt. 4, *Morningstar*. 162 W. Va. 857, 253 S.E.2d 666. Similarly, we decline to follow those jurisdictions that require an alternative, feasible design that would have “prevented” the injury,¹⁷ as this standard requires more than a “reasonably safe” alternative and imposes a greater burden on plaintiffs than *Morningstar* requires.

We find a standard that falls between these two extremes, requiring an alternative, feasible design that would have substantially reduced the risk of the specific

¹⁶ See, e.g., *Primal Vantage Co., Inc. v. O’Bryan*, 677 S.W.3d 228, 248 (Ky. 2022) (“To prevail on a design-defect claim, a plaintiff must present proof of ‘an alternative safer design, practicable under the circumstances.’” (citation omitted)); *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 735 (N.Y. 1995) (“[T]he New York standard for determining the existence of a design defect . . . demands an inquiry into such factors as . . . the availability of a safer design.”).

¹⁷ See, e.g., *Reynolds v. Bordelon*, 172 So. 3d 607, 614 (La. 2015) (explaining that, in a product liability claim for design defect, the plaintiff must show “[t]here existed an alternative design for the product that was capable of preventing the claimant’s damage” (quoting La. Stat. Ann. § 9:2800.56)); *Zang v. Cones*, 34 N.E.3d 955, 961 (Ohio Ct. App. 2015) (“A product will not be considered defective unless the plaintiff demonstrates that a practical and technically feasible alternative design to the product was available and would have prevented the harm for which the plaintiff seeks to recover.” (citing Ohio Rev. Code § 2307.75(F))).

injury suffered by the plaintiff, to be in line with *Morningstar's* “reasonable safeness” requirement. We also find this intermediate standard is appropriate because the plaintiff’s burden of proof for a strict liability claim is already lightened relative to fault-based theories of liability:

The cause of action covered by the term ‘strict liability in tort’ is designed to relieve the plaintiff from proving that the manufacturer was negligent in some particular fashion during the manufacturing process and to permit proof of the defective condition of the product as the principal basis of liability.

Syl. pt. 3, *Morningstar*, 162 W. Va. 857, 253 S.E.2d 666. *See also id.* at 883, 253 S.E.2d at 680 (“[T]he key component of [strict liability in a product liability claim] is to remove the burden from the plaintiff of establishing in what manner the manufacturer was negligent in making the product. Once it can be shown that the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff’s injury, a recovery is warranted absent some conduct on the part of the plaintiff that may bar his recovery.”); *Dunn v. Kanawha Cnty. Bd. of Educ.*, 194 W. Va. 40, 46, 459 S.E.2d 151, 157 (1995) (“Strict liability in tort relieves the plaintiff from proving the manufacturer was negligent, and instead permits proof of the defective condition of the product as the basis for liability.”).

In fact, requiring an alternative, feasible design to have substantially reduced the risk of the specific injury suffered by the plaintiff is nearly identical to the standard Ethicon advocated in the district court, where Ethicon asserted that “the plaintiffs must

show ‘the alternative design would have *materially reduced* the plaintiff’s injuries.’” *Mullins*, 117 F. Supp. 3d at 821 (emphasis added). Other jurisdictions also apply this standard. *See MCI Sales & Serv., Inc. v. Hinton*, 272 S.W.3d 17, 31 (Tex. App. 2008) (explaining that “[a]n alternative design must *substantially reduce the risk of injury* and be both economically and technologically feasible.” (citing Tex. Civ. Prac. & Rem. Code Ann. § 82.005; emphasis added), *aff’d*, 329 S.W.3d 475 (Tex. 2010)); *DeWitt v. Eveready Battery Co.*, 550 S.E.2d 511, 519 (N.C. Ct. App. 2001) (“A showing that a defendant acted unreasonably . . . requires evidence the proposed alternative design or formulation was ‘a safer, practical, feasible, and otherwise reasonable’ design or formulation; that the alternative design or formulation ‘could then have been reasonably adopted’; the alternative design or formulation ‘would have prevented or *substantially reduced the risk of harm*’ complained of; and the alternative design or formulation would not have ‘substantially impaired the usefulness, practicality, or desirability of the product.’” (quoting N.C. Gen. Stat. § 99B-6(a)(1); emphasis added), *aff’d*, 565 S.E.2d 140 (N.C. 2002)).¹⁸

¹⁸ While some jurisdictions accept an alternative, feasible design that would have merely reduced the injury suffered by the plaintiff, such an alternative design would not achieve *Morningstar’s* “reasonable safeness” standard. Therefore, we decline to follow those jurisdictions. *See, e.g., Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 169 (Iowa 2002) (“[A] plaintiff seeking to recover damages on the basis of a design defect must prove ‘the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design.’”); *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 975 (N.J. 1998) (“To succeed on his design-defect claim, plaintiff was required to prove that a practical and feasible alternative design existed that would have reduced or prevented his harm.”); Restatement (Third) of Torts: Prod. Liab. § 2 (Am. L. Inst. 1998) (providing,

Based upon these considerations, we answer the final certified question by holding that, 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. By adopting this standard, we reject the definition of a design defect set out in the Restatement (Third) of Torts: Prod. Liab. § 2 (Am. L. Inst. 1998).¹⁹ To the extent that the West Virginia Intermediate Court of Appeals recently adopted the Restatement’s standard for design defect claims in *Ford Motor Co. v. Tyler*, 249 W. Va. 471, 896 S.E.2d 444 (Ct. App. 2023), it is overruled.

IV.

CONCLUSION

As explained in the body of this opinion, we answer the questions certified to this Court by the Fourth Circuit 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

in relevant part, that “A product is defective when, at the time of sale or distribution, it . . . is defective in design A product: . . . (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe”).

¹⁹ See, supra, note 18 for the relevant text of the Restatement (Third) of Torts: Prod. Liab. § 2.

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

[I]f 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.

Certified Questions Answered.