IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

DOCKET NO. 23-192

JUDITH A. SHEARS and GARY F. SHEARS, JR., PETITIONERS

v.

ETHICON, INC. and JOHNSON & JOHNSON, RESPONDENTS

PETITIONERS' BRIEF

On Certified Question from the United States Court of Appeals for the Fourth Circuit
Case No. 22-1399

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

W. Va. CODE, RULES, AND CONSTITUTION

OTHER

I. ASSIGNMENTS OF ERROR

While Rule W. Va. R. App. Pro. 10(c)(3) requires the Petitioners' Brief to include a section entitled "Assignments of Error," the present matter is before the Court on a certified question from the U.S. Court of Appeals for the Fourth Circuit. In its Order of Certification to the Supreme Court of Appeals of West Virginia (the "Certification Order"), the U.S. Court of Appeals for the Fourth Circuit framed the certified question (the "Certified Question") 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.
>
> 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.

Shears v. Ethicon, Inc., 64 F.4th 556, 558 (4th Cir. 2023). The U.S. Court of Appeals for the Fourth Circuit did not propose an answer to the Certified Question. Therefore, there are technically no assignments of error in this case. As such, unless this Court directs otherwise, Petitioners will treat the Certified Question as a "Question Presented." For the reasons discussed in detail below, Petitioners respectfully request that this Court answer the Certified Question in the **NEGATIVE**.

II. STATEMENT OF THE CASE

A. Statement of Relevant Facts

1. Ethicon's TVT Mesh

This is a product liability action concerning a surgical medical device known as TVT transvaginal mesh ("TVT"). The TVT is made of synthetic polypropylene "mesh" that is surgically implanted underneath a woman's urethra to treat stress urinary incontinence ("SUI")—a condition

in which a woman leaks urine during moments of physical activity that increase abdominal pressure, such as laughing, sneezing, or coughing. See Petitioners' "Brief of Appellants" filed in the U.S. Court of Appeals for the Fourth Circuit, Case No. 22-1399 (the "Petitioners' Fourth Circuit Brief"), at pp. 2-3. Ethicon manufactured, marketed, and sold the TVT. Ethicon is a wholly owned subsidiary of Respondent Johnson & Johnson. *Id.*, at p. 3.

The Shears presented the following evidence to the jury regarding design flaws associated with the TVT: (1) it is heavy in weight; (2) it has small pores; (3) it produces an intense and chronic inflammatory response; and (4) it is made of polypropylene—a material known to degrade when implanted in the human body. *Id.* These defects caused the mesh to erode resulting in a number of injuries, including those suffered by Judith Shears. *Id.*

An erosion means that the TVT mesh itself has become exposed to other internal organs adjacent to where the mesh is placed, including the urethra, the vagina, or—in this case—the bladder. *Id.* When an erosion occurs, it can cause the patient to experience chronic pain, dyspareunia (pain with intercourse), bladder infections, overactive bladder, and the formation of bladder stones. *Id.*

2. Judith Shears' Relevant Medical History

Beginning in October 2008, Mrs. Shears presented to her primary care physician with complaints of SUI, intermittent constipation, and a bulging feeling of her uterus which produced some pain with intercourse. *Id.* Shortly thereafter, Mrs. Shears was referred to a urogynecologist, Dr. Eddie H.M. Sze for evaluation. *Id.*, at p. 4. Dr. Sze noted that Mrs. Shears' incontinence was "progressively worsening" and that she had a significant degree of uterine prolapse. *Id.* Dr. Sze's treatment plan included a posterior repair (surgical correction of the uterine prolapse) and the placement of a TVT mesh sling to treat her SUI. *Id.*

On March 16, 2009, Mrs. Shears underwent surgery at West Virginia University Hospital, where Dr. Sze performed the posterior repair and implanted the TVT mesh. *Id.* Initially, Mrs. Shears felt somewhat better—her complaints of leaking, bulging, discomfort, and pain with intercourse due to the uterine prolapse had resolved. *Id.* But, Mrs. Shears returned to Dr. Sze's office in April, 2012 with new reports of urgency, frequency, and incontinence. *Id.*

In September, 2013, Mrs. Shears made an appointment to see Dr. Stanley Zaslau after experiencing continued complaints of recurrent urinary tract infections, pelvic pain, frequent urination, burning with urination, leaking urine, and dyspareunia (the medical term for painful sex). *Id.* These symptoms were incredibly painful for Mrs. Shears. She described the pain as "sharp" and "stabbing." Worse, she testified that "she couldn't even sit flat" without experiencing intense pain. *Id.*

On October 29, 2013, Mrs. Shears underwent a revision procedure performed by Dr. Zaslau, which included the surgical removal or excision of eroded TVT mesh, urethrolysis, and the surgical removal of a bladder stone. *Id.*, at p. 5. For the first time, Mrs. Shears began to feel relief from the pain. *Id.* However, following this procedure, in February 2014, Dr. Zaslau performed a cystoscopy which revealed more eroded mesh in the bladder. *Id.*

Unfortunately, the abdominal and bladder pain, incontinence/leaking urine, and recurrent bladder infections returned. *Id.* In addition to those symptoms, Mrs. Shears developed new problems as well, including incomplete bladder emptying, dysuria, and frequency. *Id.* Due to her difficulty voiding, Dr. Zaslau planned to perform a cystoscopy in order to see what, if anything, was obstructing her bladder. *Id.* The cystoscopy, revealed two large stones in Mrs. Shears' bladder and that the TVT was obstructing her bladder outlet. *Id.*

On June 25, 2021, Mrs. Shears underwent a second revision surgery performed by Dr. Zaslau which included the removal of the two bladder stones. *Id.* Dr. Zaslau told Mrs. Shears that "because she had a history of extruded mesh, [the mesh] was the leading cause of her recurrent bladder stones." *Id.*

B. Relevant Procedural History

1. The Multi-District Litigation

On June 28, 2013, this case was directly filed by Short Form Complaint in the Ethicon multi-district litigation consolidated before the Honorable Joseph R. Goodwin in the United States District Court for the Southern District of West Virginia. (JA 48-53); *In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327 (S.D. W. Va.) (hereinafter referred to as the "MDL"). The MDL was formed as a result of the use of transvaginal surgical mesh to treat two pelvic conditions that occur in women: SUI and pelvic organ prolapse ("POP"). Among all cases, the claims against Ethicon were the same: design defect, failure to warn, negligence, breach of express warranty, breach of implied warranty, and punitive damages. *Id.*

2. The *Mullins* Consolidation

On July 1, 2015, the MDL Judge consolidated thirty-seven (37) cases for trial, including the Shears' case. This consolidation was referred to as the *Mullins* consolidation. *See Mullins, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-02952 (S.D. W. Va.). The *Mullins* consolidation was made up of thirty-seven (37) plaintiffs all implanted with the same product—Ethicon's TVT, a product manufactured and designed by Ethicon to treat SUI. The MDL Judge consolidated the aforementioned cases for trial on the negligence and strict liability design defect claims.

3. Remand to the Northern District of West Virginia

On November 20, 2020, the MDL Judge entered a Transfer Order, remanding nine (9) cases for trial in the venues from which they arose, including the Shears' case. On March 3, 2021, the District Court entered a Scheduling Order, setting a ten (10) day jury trial to commence on March 7, 2022.

4. The District Court grants Ethicon summary judgment on the Shears' strict product liability design defect claim

On February 11, 2022, the District Court held a *Daubert* hearing to enter rulings on outstanding *Daubert* issues left undecided by the MDL Judge. JA 43-83. Before any argument was made on the *Daubert* issues, the District Court *sua sponte* requested oral argument on Petitioners' strict product liability design defect claim—specifically, "the requirement under West Virginia products liability law, as found by Judge Goodwin and as established in the pattern jury instructions, that the alternative feasible design must eliminate the risk of which the plaintiff complains that caused the injuries." *Id.*, at 45-46. Following extensive argument on the issue, the District Court ultimately found that the 'elimination of risk' standard was "the standard under West Virginia law and the pattern jury instructions." *Id.*, at 58. The District Court then noted that all of the opinions offered by the Shears' design expert were couched in terms of "reduction" of the risk as opposed to "elimination." *Id.*, at 78-80. After analyzing the Shears' "reduction of the risk" evidence against the erroneous "elimination of the risk" standard, the District Court excluded the expert opinions underpinning the Shears' strict product liability claim, thereby effectively granting summary judgment to Ethicon on said claim. *Id.*, at 78-80 and 83-86.

5. The jury returns a defense verdict

On March 16, 2022, the jury returned its verdict in favor of Ethicon. The first question on the verdict form read as follows: "Did the Plaintiffs prove, by a greater weight of the evidence, that the Defendants negligently designed the TVT?" The jury answered "No."

6. The Appeal

The Petitioners filed their Notice of Appeal on April 12, 2022. After the briefing was completed, the U.S. Court of Appeals for the Fourth Circuit heard oral argument on January 24, 2023. The U.S. Court of Appeals for the Fourth Circuit entered the Certification Order on April 5, 2023.

III. SUMMARY OF ARGUMENT

There are essentially three approaches throughout the United States to the evidentiary requirements associated with a design defect-based strict product liability test: (1) the "Consumer Expectations Approach"; (2) the Risk-Utility Approach; and (3) some combination of the two (the "Hybrid Approach"). The Consumer Expectation Approach neither requires nor even mentions the existence of an alternative design as a requirement to prove a design defect-based strict liability claim. The Risk Utility Approach lists the existence of a safer alternative design as one factor to be considered in determining whether or not a product is defective. Lastly, the Hybrid Approach permits, but does not require, a plaintiff to present evidence of a safer alternative design to prove that a product is defective. Critically, no jurisdiction in the entire United States, regardless of approach, requires a plaintiff to prove the existence of a feasible alternative design that would "eliminate the risk of harm."

In the seminal product liability opinion of *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979), this Court unequivocally held that West Virginia courts

subscribe to the Hybrid Approach. Respondents have offered no reason for this Court to reject *Morningstar* and adopt an evidentiary standard so extreme that not one other State has seen fit to adopt it through either legislation or judicial opinion.

For these reasons, as explained in detail below, Petitioners respectfully request that the Court reaffirm West Virginia's adherence to *Morningstar*, and expressly reject W. Va. Pattern Jury Instruction § 411 in its entirety. Simply stated, W. Va. Pattern Jury Instruction § 411 has **NEVER** been the law in West Virginia and **NEVER** should be.

IV. STATEMENT REGARDING ORAL ARGUMENT AND DECISION

Oral argument is necessary pursuant to the criteria set forth in W. Va. R. App. Pro. 18(a). Accordingly, this case should be set for oral argument under W. Va. R. App. Pro. 20(a) because it involves issues of fundamental public importance.

V. ARGUMENT

Under longstanding West Virginia law, a plaintiff has never been required to present evidence of an alternative feasible design to prevail on a design-defect based strict product liability claim. Nor has a plaintiff ever been required to prove that such alternative design would "eliminate the risk of injury" (the "Elimination Mandate"). W. Va. Pattern Jury Instruction § 411 did not change the law in West Virginia as the content of that Pattern Jury Instruction has not been codified by the W. Va. Legislature. Nor has W. Va. PJI § 411 appeared as a Syllabus Point in any opinion authored by this Court. Moreover, the W. Va. Pattern Jury Instructions have never been adopted by this Court through the administrative process. Instead, this Court's seminal product liability opinion in *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979), is and remains the controlling law in West Virginia.

For the reasons discussed in detail below, Petitioners respectfully request that this Court answer the Certified Question in the **NEGATIVE**. First, W. Va. PJI § 411 has never been the law in West Virginia. *Morningstar*, *supra*, is the controlling legal standard regarding the evidentiary standards associated with a design defect-based strict product liability claim. W. Va. PJI § 411, on the other hand, finds no legal support anywhere in West Virginia law.

Second, under *Morningstar*, a plaintiff need only to show that a product is not reasonably safe for its intended purpose to prevail on a design defect-based strict product liability claim. A requirement to prove the existence of an alternative, feasible design places a greater burden of proof on a plaintiff than what is required by West Virginia law. Furthermore, this Court has expressly rejected the Elimination Mandate. Lastly, adoption of the Elimination Mandate would not only place West Virginia in the minority, it would make West Virginia the **only** state in the Union with such a Draconian requirement!

A. Jurisdiction

The U.S. Court of Appeals for the Fourth Circuit submitted the Certified Question to this Court pursuant to W. Va. Code § 51-1A-1, *et. seq.*, the "Uniform Certification of Questions of Law Act" (the "Act"). Pursuant to the Act:

> The Supreme Court of Appeals of West Virginia may answer a question of law certified to it by any court of the United States or by the highest appellate court or the intermediate appellate court of another state or of a tribe or of Canada, a Canadian province or territory, Mexico or a Mexican state, if the answer may be determinative of an issue in a pending cause in the certifying court and if there is no controlling appellate decision, constitutional provision or statute of this State.

W. Va. Code § 51-1A-3.

B. Standard of Review

"From the language of W.Va. Code, 51-1A-1, together with the conventional construction placed by other courts on similar certification statutes, this Court, in answering a certified question,

must of necessity determine the present law bearing on the issue certified." Syl. Pt. 1, *Morningstar*, 162 W. Va. 857.

"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, *Light v. Allstate Ins. Co.*, 203 W. Va. 27, 506 S.E.2d 64 (1998).

C. The Court should answer the Certified Question in the negative and explicitly hold that West Virginia continues to adhere to *Morningstar* and does not require proof of an alternative feasible design in order to prevail on a design defect-based strict product liability claim.

1. W. Va. PJI § 411 has NEVER been the law in West Virginia.

When addressing a certified question, this Court must first determine the present state of the law bearing on the question. The following sections conclusively demonstrate that (1) *Morningstar* controls; and (2) W. Va. PJI § 411 is not and has never been the law in West Virginia.

i. *Morningstar* is the present state of the law bearing on the issue certified.

This Court directly addressed the evidentiary basis for a strict product liability claim based on design defect in the seminal case of *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979). In that case, this Court held that:

> 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.

Id. at Syl. Pt. 4 (emphasis added). This Court further held that:

> 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.**

Id. at Syl. Pt. 5 (emphasis added). This Court went on to explain that:

> . . . a defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels.
>
> **Characteristically, under the first two categories of defectiveness the inquiry centers on the physical condition of the product which renders it unsafe when the product is used in a reasonably intended manner.** In the third category of defectiveness the focus is not so much on a flawed physical condition of the product, as on its unsafeness arising out of the failure to adequately label, instruct or warn.

Morningstar, 162 W. Va. 888 (emphasis added).

As recently as 2018, this Court has reaffirmed the continuing vitality of *Morningstar*. Specifically, in *McNair v. Johnson & Johnson*, 241 W. Va. 26, 818 S.E.2d 852 (2018), on a certified question from the U.S. Court of Appeals for the Fourth Circuit, this Court explained:

> **In *Morningstar*, our modern seminal case on products liability**, this Court found that "[o]nce 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." 162 W.Va. at 883, 253 S.E.2d at 680; *see also Dunn*, 194 W.Va. at 46, 459 S.E.2d at 157 ("Product liability law in this State permits a plaintiff to recover where the plaintiff can prove a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries." (citation omitted)).

McNair, at 34 (emphasis added). Thus, as recently as 2018, this Court has reaffirmed that *Morningstar* remains the modern seminal case in products liability.

Historically, the United States District Courts in West Virginia have faithfully adhered to these legal tenets. For example, in *Keffer v. Wyeth*, 791 F. Supp. 2d 539 (S.D.W. Va. 2011), a product liability claim involving hormone replacement therapy medications, the defendant sought summary judgment on the plaintiff's strict liability design defect claim to the extent that the claim

was based on the existence of a safer alternative design. *Id.* at 547. The plaintiff countered by arguing that proof of a safter alternative design was not required to establish a design defect claim under West Virginia law and, in any event, the plaintiff had come forward with a safer alternative. *Id.*

In response to these arguments, U.S. District Court Judge John T. Copenhaver, Jr., correctly observed as follows:

> West Virginia's strict products liability doctrine has its origin in *Morningstar v. Black and Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (W. Va. 1979). Syllabus Point 4 of Morningstar provides as follows:
>
> > 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.
>
> *Id.*, at Syl. Pt. 4. Generally speaking, "[o]nce 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." *Id.* at 680. "[A] defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels." *Id.* at 682.
>
> **To be sure, the 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**. See Philip Combs & Andrew Cooke, Modern Products Liability Law in West Virginia, 113 W. Va. L. Rev. 417, 427 (2011) (noting lack of caselaw on the issue). **Nevertheless, even if it is not required, offering evidence of a safer alternative is at least one method of showing that a product is "not reasonably safe for its intended use" for the purposes of a design defect claim**.

Keffer, 791 F. Supp. 2d 547 (emphasis and underline added). In summary, U.S. District Court Judge Copenhaver correctly concluded that under West Virginia law: (1) there is no requirement to prove a safer alternative design to prevail on a design defect claim; and (2) evidence of a safer

alternative design is, ". . . at least one method of showing that a product is "not reasonably safe for its intended use" for the purposes of a design defect claim." *Id.*

U.S. District Judge Copenhaver's citation to Modern Products Liability Law in West Virginia is particularly instructive in this case for three reasons. First, Philip Combs, one of the authors of this law review article, is also local counsel for Ethicon in the present matter. Second, in this law review article, the authors lament the fact that tort reform in West Virginia has not yet reached the field of products liability:

> Obviously, products liability is an exceptionally important area of the law in this state. And, **due to the fact there has been substantial tort reform in other areas, such as medical malpractice and insurance bad faith litigation, but not in relation to products liability suits, we predict that the volume of products liability litigation will continue to increase.**

113 W. Va. L. Rev. 421 (emphasis added).

Third, with respect to alternative designs vis-à-vis design defect claims, the authors of that law review article state as follows:

> A threshold legal issue is whether the plaintiff, in her affirmative case-in-chief, must prove that there is a feasible, alternative design that will eliminate the risk and render the product "reasonably safe." In other words, **can the plaintiff merely argue that the manufacturer's design was flawed or must she also point to a feasible alternative design that appropriately eliminates that particular risk?**
>
> This issue has received little attention from the court because, as a practical matter, plaintiff's counsel almost always put forth an alternative design even in the absence of a requirement. **The only West Virginia Supreme Court of Appeals case addressing the issue is *Church v. Wesson*, in which the court in a per curiam opinion upheld a directed verdict for the defendant, in a strict liability context, on the ground that the plaintiff failed to establish the feasibility of a proffered alternative design.**

113 W. Va. L. Rev. 427 (emphasis added). Thus, as of 2011, Ethicon's own counsel recognized that there was no requirement under West Virginia law to offer evidence of a feasible, alternative design, much less one that would completely eliminate the risk of harm in a design defect claim.

U.S. District Court Judge Joseph R. Goodwin initially reached the same conclusion in the consolidated phase of the MDL:

> Next, Ethicon asserts that a consolidated trial on design defect is improper because the plaintiff must prove the existence of a safer alternative design, which requires plaintiff-specific evidence. Specifically, according to Ethicon, the plaintiffs must show "the alternative design would have materially reduced the plaintiff's injuries." (Defs.' Objection [Docket 27], at 3). First of all, "**the West Virginia Supreme Court of Appeals 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.**" *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547-48 (S.D. W. Va. 2011) (Copenhaver, J.). Admittedly, **whether required or not, evidence on the existence of a safer alternative is certainly relevant**, as explained in *Morningstar* Syllabus Point 5, which states that the "general state of the art of the manufacturing process" should be considered when determining whether a product is "unsafe." *Morningstar*, 253 S.E.2d at Syl. pt. 5.
>
> **But contrary to Ethicon's position, 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. In fact, my colleague has recently rejected this position**. *See Keffer*, 791 F. Supp. 2d at 548-49 (rejecting the proposition that a plaintiff must prove that an alternative drug design would have specifically prevented her injuries (citing *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 901 (E.D. Va. 2010))). Persuaded by this reasoning, I FIND that plaintiff-specific information is not required to develop or defend against state-of-the-art evidence of a safer alternative design, and Ethicon's objection is overruled.

Mullins v. Ethicon, Inc., 117 F. Supp. 3d 810 (S.D.W. Va., August 4, 2015) (emphasis added) (hereafter referred to as "*Mullins* 1").

On June 6, 2016, a mere eleven months later, Ethicon filed a motion for reconsideration of this order (the "Motion to Reconsider"). JA 1-10. What precipitated the Motion to Reconsider? Did this Court publish a new syllabus point requiring proof of a feasible, alternative design that would eliminate the risk of harm? **No**. The West Virginia Pattern Jury Instructions ("W. Va. PJIs") were published.

ii. W. Va. PJI § 411 has NEVER been the law in West Virginia.

The W. Va. PJIs were originally published in June of 2016. According to the Caveat contained in the Preface to the W. Va. PJI's:

> 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 jury instruction that is offered by a party or which a trial judge indicates will be read to a jury. On appeal, the Supreme Court will not be bound by the correctness of these pattern jury instructions. It is incumbent upon the lawyers in a trial to ensure the correctness of any pattern jury instruction that may be read to a jury.**

Id. (capitalization in original) (bold and underline added). According to the Drafting Note contained in the Preface, the W. Va. PJIs, while not binding, ". . . have gone through multiple edits and revisions after extensive research and editing by the reporters, the review committees, Judge Alsop, and Justice Ketchum." *Id.*

Section 400 of the W. Va. PJIs covers products liability. Conspicuously absent from Ehticon's Motion to Reconsider the *Mullins* I opinion in the MDL is the fact that Mr. Combs, local counsel for Ethicon, was the reporter for Section 400, including W. Va. PJI § 411. Mr. Combs cited only two cases as the original legal basis for W. Va. PJI § 411: *Morningstar*, *supra*, and *Church v. Wesson*, 182 W. Va. 37, 385 S.E.2d 393 (1989).[1] Neither case contains any such

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[1] The W. Va. PJIs were supplemented in 2017. The supplemented version of W. Va. PJI § 411 contains a reference to *Mullins* 2 and *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). Unsurprisingly, the *Nease* opinion makes absolutely no mention of a requirement to prove the existence of feasible alternative design that would eliminate the risk of injury. Instead, the Court in *Nease* merely stated that:

> While it is true that West Virginia law on the matter is not crystal clear, we agree with Ford that *Morningstar* "can only be read to require the production of evidence on reasonable alternative design, to gauge what 'should have been.'" Restatement (Third) of Torts: Products Liability § 2, Reporter's Note (1998). Although *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."**

Nease, 848 F.3d 233 (emphasis added). The *Nease* opinion makes clear that a reasonable alternative design goes only to establishing the state of the art. It is not a requirement to prove a design defect, in general, in order to prevail on a design defect strict product liability claim. Moreover, the *Nease* opinion makes clear that the alternative design need

requirement. Moreover, just five years earlier, Mr. Combs stated in his law review article that *Church*, *supra*, (a *per curiam* opinion of very limited precedential value) merely upheld a directed verdict for the defendant, because the plaintiff failed to establish the feasibility of a proffered alternative design. 113 W. Va. L. Rev. 427. Significantly, the unsigned *Church* opinion contained only two Syllabus Points. The first relates to the standard for a directed verdict and the second repeats Syllabus 4 of *Morningstar*, reiterating this Court's adherence to that binding legal standard. Thus, based on Mr. Combs' very own admissions in his law review article, W. Va. PJI § 411 is **simply an attempt at tort reform disguised as legal authority**.

The foregoing legal analysis is embodied in the Certification Order from the U.S. Court of Appeals for the Fourth Circuit:

> **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**.

Shears, 64 F.4th at 563 (emphasis added). The U.S. Court of Appeals for the Fourth Circuit went on to explain that:

> **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

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only make the product safer: not entirely eliminate the risk of injury. In fact, the phrase "safer alternative" appears seven times in the opinion. The word "eliminate" appears only once and comes from a citation to a handbook produced by Ford.

> 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* 182 W. Va. 37, 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.**

Shears, 64 F.4th at 565 (emphasis added). "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.'"** *Id.*, 64 F.4th at 566 (emphasis added).

W. Va. PJI § 411 could become the law in the State of West Virginia in only one of three ways: (1) the West Virginia Legislature could codify it; (2) this Court could author an opinion containing a new syllabus point adopting it; or (3) this Court could adopt it through the statutorily-controlled administrative procedure. None of those three things have happened.

In the last ten years, the West Virginia Legislature has enacted two statutes that have altered the common law of products liability law. For example, in 2016, the West Virginia Legislature enacted W. Va. Code § 55-7-30, which limits liability for manufacturers or sellers in products liability actions who provide warnings to a learned intermediary.[2] In 2017, the West Virginia

[2] In Syllabus Point 3 of *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 647 S.E.2d 899 (2007), this Court held that, "[u]nder West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. **We decline to adopt the learned intermediary exception to this general rule**." (Emphasis added).

Legislature enacted W. Va. Code § 55-7-31 which restricts the scope of liability of sellers in product liability actions.[3] W. Va. Code § 55-7-30 and 31 make clear that the West Virginia Legislature is active in the modification of the common law of products liability in West Virginia. If there were strong policy considerations indicating that *Morningstar*'s adoption of the Hybrid Approach to defective design-based strict liability claims was no longer sound, certainly the W. Va. Legislature could have enacted legislation adopting another approach. The fact that the W. Va. Legislature has not seen fit to do so in the last forty-three (43) years is a strong indication that policy considerations supporting *Morningstar* remain as strong as ever.

With respect to judicial development of the common law, in *State v. McKinley*, 234 W. Va. 143, 149, 764 S.E.2d 303 (2014), the Supreme Court of Appeals of West Virginia, in its unanimous opinion, stated that, "[t]he scope and form of the decisions of [the Supreme Court of Appeals of West Virginia] are primarily governed by the West Virginia Constitution. Our decisions are required to address 'every point fairly arising upon the record' and are '**binding authority upon any court' if concurred in by a majority of the justices**. W. Va. Const. art. VIII, § 4." (Emphasis added).[4]

According to Syllabus Point 2 of *Walker v. Doe*, 558 S.E.2d 290 (2001) (overruled on other grounds by *McKinley*, *supra*), the Supreme Court of Appeals of West Virginia ". . . **will use signed opinions when new points of law are announced and those points will be articulated through**

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[3] In *Dunn v. Kanawha County Bd. of Educ.*, 194 W. Va. 40, 46, 459 S.E.2d 151 (1995), this Court stated that, "[s]trict 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. Because the product manufacturer is not always accessible to the plaintiff, strict liability extends to those in the product's chain of distribution. **Thus, an innocent seller can be subject to liability that is entirely derivative simply by virtue of being present in the chain of distribution of the defective product.**" (Emphasis added).

[4] "No decision rendered by the court shall be considered as binding authority upon any court, except in the particular case decided, unless a majority of the justices of the court concur in such decision." W. Va. Const. Art. VIII, § 4.

syllabus points as required by our state constitution." (Emphasis added).[5] Additionally, "[s]igned opinions containing original syllabus points have the highest precedential value because the Court uses original syllabus points to announce new points of law or to change established patterns of practice by the Court." Syl. Pt. 1 of *McKinley*, 234 W. Va. 143 (emphasis added).

This Court has further held that, "[s]igned opinions that do not contain original syllabus points also carry significant, instructive, precedential weight because such opinions apply settled principles of law in different factual and procedural scenarios than those addressed in original syllabus point cases." *Id.* at Syl. Pt. 2. Additionally, "[s]igned opinions, both those including new syllabus points and those not containing new syllabus points, are published opinions of the Court. As such, **they should be the primary sources relied upon in the development of the common law.**" *Id.* at Syl. Pt. 3 (emphasis added).

Lastly, this Court has stated the following regarding obiter and judicial dicta:

> Dicta normally comes in two varieties: obiter dicta and judicial dicta. **Obiter dicta are comments in a judicial opinion that are unnecessary to the disposition of the case. Judicial dicta are comments in a judicial opinion that are unnecessary to the disposition of the case, but involve an issue briefed and argued by the parties**. Judicial dicta have the force of a determination by a reviewing court and should receive dispositive weight in an inferior court. Similarly, obiter dicta of a court of last resort can be tantamount to a decision and therefore binding in the absence of a contrary decision of that court.' *People v. Williams*, 204 Ill. 2d 191, 788 N.E.2d 1126, 1136, 273 Ill. Dec. 250 (Ill. 2003) (internal quotations and citations omitted)."

Footnote 6, *W. Va. DOT v. Parkersburg Inn, Inc.*, 222 W. Va. 688, 671 S.E.2d 693 (2008)(per curiam)(emphasis added). However, this Court ". . . has made clear that '[o]biter dicta or strong

[5] "When a judgment or order of another court is reversed, modified or affirmed by the court, every point fairly arising upon the record shall be considered and decided; the reasons therefor shall be concisely stated in writing and preserved with the record; and it shall be the duty of the court to prepare a syllabus of the points adjudicated in each case in which an opinion is written and in which a majority of the justices thereof concurred, which shall be prefixed to the published report of the case." *Id.*

expressions in an opinion, where such language was not necessary to a decision of the case, **will not establish a precedent**.' *In re Assessment of Kanawha Valley Bank*, 144 W.Va. 346, 382-83, 109 S.E.2d 649, 669 (1959)." *Univ. Park at Evansdale, LLC v. Musick*, 238 W. Va. 106, 112, 792 S.E.2d 605 (2016) (emphasis added). As noted above in *Walker*, the Supreme Court of Appeals of West Virginia uses ". . . signed opinions when new points of law are announced and those points will be articulated through syllabus points as required by our state constitution."

To be perfectly clear, there is no authored opinion from this Court containing a syllabus point requiring a plaintiff making a claim for strict liability in a products liability case to identify an alternative design, much less one that would completely eliminate the risk of the particular injury. Nor does any case, authored or otherwise, from this Court contain any obiter dicta that would impose such a requirement.

The W. Va. PJIs, including W. Va. PJI § 411, were signed by a single West Virginia Supreme Court Justice, falling far short of the majority required by Article VIII, § 4 of the West Virginia Constitution. *See McKinley*, *supra*. In fact, because W. Va. PJI § 411 does not appear in a single judicial opinion, it qualifies as neither obiter nor judicial dicta. *See Parkersburg Inn*, *supra*. Thus, W. Va. PJI § 411 has no precedential value whatsoever.

The final way that this Court could conceivably have adopted W. Va. PJI § 411 is through the administrative process set forth in Article VIII, Section 3 of the West Virginia Constitution and W. Va. Code § 51-1-4.[6] The Administrative Orders of the Supreme Court of Appeals of West

[6] Article VIII, § 3 of the West Virginia Constitution states, in pertinent part, that, "[t]he court shall have power to promulgate rules for all cases and proceedings, civil and criminal, for all of the courts of the State relating to writs, warrants, process, practice and procedure, which shall have the force and effect of law.

W. Va. Code § 51-1-4 states, in pertinent part, that, "The Supreme Court of Appeals may, from time to time, make and promulgate general rules and regulations governing pleading, practice and procedure in such court and in all other courts of record of this State. . . The Judicial Council of West Virginia is hereby designated as advisory committee to make observation and report to the Supreme Court of Appeals, from time to time, such recommendations as may, in its judgment, be proper; and **all rules promulgated by the Supreme Court of Appeals under the authority of this**

Virginia from 2010 to present can be found on the West Virginia Supreme Court's website.[7] These Administrative Orders never even so much as mention the W. Va. PJIs, much less demonstrate compliance with the process mandated by W. Va. Code § 51-1-4. Simply put, this Court has clearly never adopted the W. Va. PJIs through the administrative process as mandated by the West Virginia Constitution and W. Va. Code § 51-1-4.

2. W. Va. PJI § 411 should NEVER be the law in West Virginia.

While Syllabus Point 2 of *Morningstar*, *supra*, makes clear that this Court possesses the authority to modify the common law, Respondents have come forward with absolutely no justification for such a modification. The following sections conclusively demonstrate that W. Va. PJI § 411 should NEVER be the law in West Virginia.

i. A new requirement to prove the existence of an alternative, feasible design places a greater burden of proof on a plaintiff than what is required by West Virginia law.

In order to prevail on a strict liability claim based on a design defect claim under West Virginia law, a plaintiff needs to show only that the product was not reasonably safe for its intended use. *See* Syl. Pt. 4 of *Morningstar*, 162 W. Va. 857. The safeness of a 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." *Id.* at Syl. Pt. 5.

The Supreme Court of Appeals went on to explain the role of the risk/utility analysis in establishing a product defect:

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section shall, before taking effect, be referred to the Chairman of the Judicial Council, the President of the West Virginia Bar Association and to the judge of every court affected thereby." (Emphasis added.)

[7] http://www.courtswv.gov/legal-community/recent-rules-orders.html (last accessed on June 26, 2023)

> **We believe that a risk/utility analysis does have a place in a tort product liability case by setting the general contours of relevant expert testimony concerning the defectiveness of the product.** In a product liability case, the expert witness is ordinarily the critical witness. **He serves to set the applicable manufacturing, design, labeling and warning standards based on his experience and expertise in a given product field.**
>
> Through his testimony the jury is able to evaluate the complex technical problems relating to product failure, safety devices, design alternatives, the adequacy of warnings and labels, as they relate to economic costs. **In effect, the expert explains to the jury the risk/utility standards and gives the jury reasons why the product does or does not meet such standards, which are essentially standards of product safeness.**

Morningstar, 162 W. Va. 887 (emphasis added).

Given these inherent complexities, this Court intentionally adopted a *flexible standard* for proving a product defect:

> We also recognize that **in this opinion we cannot formulate a solution for every problem that may arise in future product liability cases**. We do state that the cause of action rests in tort, and that **the initial inquiry, in order to fix liability on the manufacturer, focuses on the nature of the defect and whether the defect was the proximate cause of plaintiff's injury.**
>
> Characteristically, under the first two categories of defectiveness the 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 (emphasis added) (emphasis added).

Under this controlling case law, a design defect claim can be proven in myriad ways by simply demonstrating that the product in question falls short of what a reasonably prudent manufacturer would accomplish with regard to product safety. For example, a plaintiff can prove a design defect claim under West Virginia law by showing that the product in question fails to meet the safety standards of the general state of the art. *See* Syl. Pt. 5 of *Morningstar*, *supra*. In many cases, state of the art designs cannot completely eliminate every risk associated with a product. Furthermore, some products are so inherently dangerous that they simply cannot be made

safe. Does West Virginia product liability foreclose a strict liability design defect claim in such cases because no feasible, alternative design that would eliminate the risk of injury exists? Based on Syllabus Point 4 of *Morningstar*, the answer is a resounding "NO!"

Additionally, West Virginia law expressly allows for a strict product liability claim even where the plaintiff cannot identify the specific defect:

> "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." Syl. Pt. 3, *Anderson v. Chrysler Corp.*, 184 W. Va. 641, 403 S.E.2d 189 (1991).

Syl. Pt. 9, *Adkins v. K-Mart Corp.*, 204 W. Va. 215, 511 S.E.2d 840 (1998) (emphasis added). This is commonly referred to as the "Malfunction Theory." Under the Malfunction Theory, a plaintiff need not identify the specific design defect to prevail on a strict product liability claim. It would defy logic to simultaneously require that same plaintiff to demonstrate the existence of a feasible alternative design that would eliminate the risk created by the unidentifiable defect.

Moreover, a plaintiff can prove a product defect where the product in question fails the risk/utility test. As this Court observed in *Morningstar*, *supra*, the ". . . risk/utility analysis does have a place in a tort product liability case by setting the general contours of relevant expert testimony concerning the defectiveness of the product." *Id.*, at 887. The relevant factors in the risk/utility test include:

> (1) The usefulness and desirability of the product -- its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product -- the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) **The availability of a substitute product which would meet the same need and not be as unsafe.**

> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Morningstar, 162 W. Va. 857, at FN 20 (*quoting Cepeda v. Cumberland Engineering Co.*, 76 N.J. 152, 386 A.2d 816, 826-827 (1978) (overruled on other grounds by *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 406 A.2d 140, (1979)) (emphasis added). Notably, the risk/utility analysis takes into account numerous factors, including both safer product alternatives and the defendant's ability to eliminate the unsafe character of the product. In direct conflict with the risk/utility analysis, W. Va. PJI § 411 impermissibly restricts said analysis to a single factor: the availability of a feasible, alternative design that eliminates the risk of injury.

In Summary, W. Va. PJI § 411 impermissibly eliminates a plaintiff's ability to prove a design defect through evidence of either a safer or the safest design under the relevant state of the art where the safer or safest design was incapable of completely eliminating the risk that injured the plaintiff. *See* Syl. Pts. 4 and 5 of *Morningstar*, *supra*. Additionally, W. Va. PJI § 411 impermissibly eliminates a plaintiff's ability to prove a design defect through circumstantial evidence under the malfunction theory. *See* Syl. Pt. 9 of *Adkins*, *supra*. Furthermore, W. Va. PJI § 411 entirely eliminates the risk/utility analysis. In essence, W. Va. PJI § 411 unreasonably requires plaintiffs to demonstrate that a defect-free product was feasible under the relevant state of the art, even where the specific product defect cannot be identified and the product fails the risk/utility test. Such a requirement is completely contrary to controlling West Virginia law.

As explained above, W. Va. PJI § 411 completely displaces *Morningstar*'s intentionally flexible standard in every case where no feasible, alternative design would completely eliminate the risk of injury to a plaintiff. Such a rigid rule, in effect, eviscerates strict product liability claims based on design defect where feasible, *safer* alternative designs exist which would have *reduced* the risk of injury, where the specific design defect *cannot be identified* and where that product *fails* the risk/utility test. This Court expressly avoided such a rigid standard in *Morningstar*, *supra*. Accordingly, W. Va. PJI § 411 is an incorrect statement of West Virginia strict product liability law and this Court should answer the Certified Question in the **NEGATIVE**.

ii. This Court has expressly rejected the Elimination Mandate.

In addition to articulating the legal standard for proving a product defect, *Morningstar* also expressly rejected the *Rylands v. Fletcher* Doctrine: "[w]e decline to adopt the *Rylands v. Fletcher* Doctrine into our tort product liability law." *Morningstar*, 162 W. Va. 857, at Syl Pt. 8. In support of this ruling, this Court explained as follows:

> We are asked in the final part of the certification whether the power saw is an inherently dangerous product under the *Rylands v. Fletcher* Doctrine, which declared that those conditions or activities which are intrinsically dangerous will result in liability even though there is no proof of any negligence. The doctrine originally arose from cases involving dangerous activities conducted on one's property which escaped control and damaged others in their person or property. We have recognized the *Rylands* Doctrine in several cases, but none involved a product placed in commerce. *See, e.g., Whitney v. Ralph Myers Contracting Corp.*, 146 W. Va. 130, 118 S.E.2d 622 (1961) (blasting operations); *Weaver Mercantile Co. v. Thurmond*, 68 W. Va. 530, 70 S.E. 126 (1911) (water escaping from tanks).
>
> We are not cited, nor have we found, any authority which suggests that the *Rylands v. Fletcher* Doctrine has been imported wholesale into the product liability field. **Its essential characteristic is that the activity or object is abnormally or exceptionally dangerous. W. Prosser, The Law of Torts (4th ed. 1971) § 78. In the ordinary product liability case, the product, if safely made, is not dangerous, but becomes so only by virtue of a defect.**
>
> ***Rylands* looks only to the resulting harm and creates absolute liability on the part of the defendant and no negligence or defect need be shown.** The defendant

> is an insurer -- a standard which the overwhelming majority of courts refuses to impose on the manufacturer of a product.

Morningstar, 162 W. Va. 891 (emphasis added, some internal citations omitted).

Like the *Rylands v. Fletcher* Doctrine, W. Va. PJI § 411 looks only to the resulting harm caused by the product and creates absolute liability for the defendant for failing to adopt a feasible, alternative design that would have eliminated the risk of injury. This Court has expressly rejected such an approach. Instead, strict product liability law in West Virginia focusses on the defective condition of the product itself. *See* Syl. Pts. 4 and 5 of *Morningstar*, *supra*. Accordingly, W. Va. PJI § 411 is an incorrect statement of law and this Court should answer the Certified Question in the **NEGATIVE**.

iii. Adoption of the Elimination Mandate would not only place West Virginia in the minority, it would make West Virginia the only State in the Union with such a Draconian requirement.

An examination of the evidentiary standards associated with design defect-based strict product liability in other jurisdictions vis-à-vis alternative designs reveals two important facts. First, only a handful of States require evidence of a feasible alternative design as part of design defect-based strict product liability claim. See JA 89-90. On the other hand, a significant number of States permit a plaintiff to submit evidence of a feasible alternative design as part of design defect-based strict product liability claim. *Id.* Second, not a single jurisdiction in the United States has adopted the Elimination Mandate. *Id.* Legal authority from other jurisdictions makes clear that the alternative design need only be safer than the product at issue.

The American Law Reports summarizes the role of evidence of feasible alternative designs in design defect-based strict product liability claims as follows:

> The reasonableness of choosing from among various alternative product designs and adopting the safest one if it is feasible is not only relevant in a design defect action, but is at the very heart of the case. The essential inquiry is whether the design

> chosen was a reasonable one from among the feasible choices of which the defendant was aware or should have been aware. This feasibility is a relative, rather than an absolute, concept; the more scientifically and economically feasible the alternative is, the more likely it is that the product will be found to be defectively designed.
>
> **Some courts, however, have held that in a products liability action alleging a design defect, the existence of a feasible, safe alternative design is not an essential element of proof (§ 3). But another group of courts has ruled that the plaintiff in such an action has the burden of proving the existence of a feasible, safe alternative design (§ 4)**, that in crashworthy or second-collision cases impugning the design of an automobile the plaintiff has that burden (§ 5), **or that a plaintiff who has relied solely on the existence of such an alternative design in presenting the plaintiff's case has that burden (§ 6)**. A third group of courts has ruled that in a products liability action alleging a design defect, the manufacturer has the burden of proving the nonexistence of a feasible, safe alternative design (§ 7).

78 A.L.R.4th 154: Burden of proving feasibility of alternative safe design in products liability action based on defective design (emphasis added).

In *Blankenship v. GM Corp.*, 185 W. Va. 350, 406 S.E.2d 781 (1991), this Court analogized the cost-spreading function in products liability to insurance. Manufacturers take potential liability and the cost of purchasing insurance into account when determining the price of their products. Thus, a component of the purchase price represents an insurance premium that consumers pay to compensate those consumers who are injured by the product. It would be both unwise and unfair to West Virginia consumers to require them to pay the product liability premium and then make it nearly impossible for them to collect on the insurance in the event they are injured by a defective product, especially when citizens of other States have much easier access. Accordingly, Petitioners respectfully request that this Court answer the Certified Question in the **NEGATIVE**.

VI. CONCLUSION

The *Morningstar* standard for design defect-based strict product liability claims is, by design, a flexible one. The Hybrid Approach adopted in *Morningstar* remains the controlling legal

precedent in West Virginia. Its continuing validity has been recognized by this Court as recently as 2018 and a significant number of States have adopted a similar approach. W. Va. PJI § 411, on the other hand, has never been the law in West Virginia and represents a marked departure from *Morningstar*. The evidentiary requirement suggested by W. Va. PJI § 411 is entirely inconsistent with purposes of strict product liability and replaces *Morningstar*'s flexible standard with an extremely rigid standard that no other jurisdiction in the United States has seen fit to adopt. *See* JA 89-90.

WHEREFORE, on the foregoing facts, legal standards, evidentiary standards and argument, Petitioners respectfully request that this Court answer the Certified Question in the **NEGATIVE**.

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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

DOCKET NO. 23-192

JUDITH A. SHEARS and GARY F. SHEARS, JR., PETITIONERS

v.

ETHICON, INC. and JOHNSON & JOHNSON, RESPONDENTS

CERTIFICATE OF SERVICE

On Certified Question from the United States Court of Appeals for the Fourth Circuit
Case No. 22-1399

I, Jason P. Foster, counsel for the Petitioners, Judith A. Shears and Gary F. Shears, Jr., do hereby certify that I have caused to be served true and accurate copies of the foregoing *Petitioners' Brief*, upon the following counsel of record this 26th day of June, 2023, via United States Mail, postage prepaid, addressed as follows:

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