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' REPLY BRIEF[1]

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

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[1] Rule 38(c) of the West Virginia Rules of Appellate Procedures limits Reply Briefs to twenty (20) pages. Under W. Va. R. App. Pro. 10(g), that limit is automatically extended to thirty (30) pages in cases where more than one response brief is filed. In addition to the Response Brief filed by Ethicon, the Product Liability Advisory Council also filed a Brief in support of Ethicon's Response Brief. Therefore, by operation of W. Va. R. App. Pro. 10(g), the page limitation for this Reply Brief is automatically extended to thirty (30) pages.

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I. INTRODUCTION

Ethicon's unfounded and misguided arguments make it abundantly clear that WVPJI § 411 is contrary to West Virgnia law and has absolutely no place in our jurisprudence. *Morningstar* continues to be the controlling case in West Virginia products liability law and Ethicon has failed to come forward with any persuasive arguments to depart from *Morningstar* and its progeny.

II. PROCEDURAL HISTORY

During the February 11, 2022, *Daubert* hearing before the District Court, the Shears' counsel specifically objected to the District Court's application of WVPJI § 411 to the Shears' design-based strict product liability claim. *See* JA 82-84. Thus, while the District Court did not specifically grant Ethicon summary judgment on the Shears' design-based strict product liability claim, the District Court did exclude the expert opinions upon which the claim was based because the Shears' expert could not opine that the proffered alternative designs would eliminate the risk of injury as mandated by WVPJI § 411. However, he did opine that the proffered alternative designs were safer than the TVT at issue in this case. *Id*.

III. ARGUMENT

A. The Requirement of a Safer Alternative Design is NOT an Essential Element of a Strict Liability–Design Defect Claim under Existing West Virginia Law.[2]

There is not, and there never has been, a requirement to prove the existence of a safer alternative design as part of design defect-based strict product liability claim in West Virginia. *Morningstar*'s controlling syllabus points were drafted broadly to provide a flexible legal standard, adaptable to ever-changing factors in products liability law. For these reasons, as explained more

[2] Ethicon's own heading for Section 1 of its Argument states that, "[t]he Requirement of a **Safer** Alternative Design is an Essential Element of a Strict Liability–Design Defect Claim under Existing West Virginia Law." *See* Ethicon's Brief at pp. ii and 8 (bold and underline added). Ethicon's own argument further highlights that WVPJI § 411's Elimination Mandate was fabricated.

fully below, WVPJI § 411 is an incorrect statement of West Virginia strict product liability law and this Court should answer the Certified Question in the **NEGATIVE**.

1. *Morningstar* DID NOT endorse a risk-utility test as the primary means of proving a design defect in West Virginia.

In a stunning misrepresentation of controlling case law, Ethicon argues that *Morningstar* endorsed the risk-utility test as "the primary means of proving a design defect in West Virginia." *See* Ethicon's Brief at pp. 8-11. Nothing could be further from the truth. First, neither *Morningstar* nor any case in this State contains a syllabus point embodying Ethicon's argument. Second, neither *Morningstar* nor any case in this State contains any dicta embodying Ethicon's argument. Third, the Court in *Morningstar* properly fixed the role of the risk-utility in West Virginia product liability, through dicta, as follows:

> **New Jersey**, in *Cepeda v. Cumberland Engineering Co., Inc*., 76 N.J. 152, 386 A.2d 816 (1978), **has adopted what it terms the "risk/utility analysis" proposed by Dean Keeton and Dean Wade**, consisting of seven factors which should be weighed to determine if the product is defective. The court in *Cepeda* suggests it is following Section 402A when it substitutes the term "defective condition unreasonably dangerous" for the term "not duly safe" suggested by Dean Wade for a model instruction:
>
> > "'A [product] is not duly safe if it is so likely to be harmful to persons [or property] that a reasonable prudent manufacturer [supplier], who had actual knowledge of its harmful character would not place it on the market. It is not necessary to find that this defendant had knowledge of the harmful character of the [product] in order to determine that it was not duly safe.'" [76 N.J. at, 386 A.2d at 827, quoting from Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825, (39-40 (1973)]
>
> It is difficult to determine whether the *Cepeda* rule is limited only to design defect cases. Certainly the Wade instruction is not so limited. The New Jersey court does say in *Cepeda* that the risk/utility analysis "rationalizes what the great majority of the courts actually do in deciding design defect cases. . . ." [76 N.J. at , 386 A.2d at 826] The court also suggested that the seven-factor risk/utility analysis (note 20, supra at 31] is not easily susceptible to a jury instruction.
>
> **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.

Morningstar v. Black & Decker Mfg. Co., 162 W. Va. 857, 885 (1979) (emphasis added).

The foregoing passage makes clear that this Court was well-aware of the risk-utility test, along with its backing by Deans Keeton and Wade and its adoption into New Jersey jurisprudence, at the time *Morningstar* was authored. Instead of adopting the risk-utility test, this Court properly limited the role of the test to fit in with this Court's overarching themes embodied in *Morningstar*'s syllabus points. Thus, while the risk-utility test does have a place in West Virginia law, it is **not** the primary means of proving a design defect in West Virginia. The primary means of proving design defect in West Virinia is to show that, ". . . 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." *See* Syl. Pt. 4, 162 W. Va. 857.

2. The requirement of a feasible alternative design is NOT at the heart of the risk-utility test and NOT a reasonable reading of *Morningstar*.

Ethicon's second argument is based entirely on the false premise that *Morningstar* adopted the risk-utility test. The plain wording of *Morningstar*, as highlighted in Section II(A)(1) above dispels this falsehood. Moreover, *Morningstar* clearly embodies the salient aspects of the consumer expectation tests. As explained by the Supreme Court of California *in Kim v. Toyota Motor Corp*., 6 Cal. 5th 21, "[t]he existence of a design defect may be established according to one of two alternative tests. (*Barker*, *supra*, 20 Cal.3d at pp. 429–430.) **First, under the so-called consumer expectations test, a design is defective 'if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an**

intended or reasonably foreseeable manner.' (*Id*. at p. 429.)" (Emphasis added). Under Syllabus Point 4 of *Morningstar*, a product is defective if: (1) it is not reasonably safe; (2) for its intended use. Syllabus Point 4 of *Morningstar* goes on to address the first prong of defect as follows: "[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." *Id*.

Syllabus 6 of *Morningstar* addresses the second prong of defect as follows: "[t]he question of what is an intended use of a product carries with it the concept of **all those uses a reasonably prudent person might make of the product, having in mind its characteristics, warnings and labels**." *Id*. (emphasis added). Both components of defect contained in Syllabus Points 4 and 6 of *Morningstar* fit neatly into the analytical framework of the consumer expectations test as enunciated by the Supreme Court of Appeals of California in *Kim*, *supra*. Neither component of defect fits into the risk-utility test as outlined in Footnote 20 of *Morningstar*, *supra*. This analysis is reinforced by the fact that this Court chose not to adopt that risk-utility test in *Morningstar* and has not adopted the risk-utility test in the four and a half decades since *Morningstar* was authored.

Once again, Ethicon turns to *Church v. Wesson*, 182 W. Va. 37, 385 S.E.2d 393 (1989), in a futile effort to support its flawed argument. Church, by its own facts, was limited to the finding that the directed verdict entered against the plaintiff was proper because he based his design defect claim entirely on an alternative design that was not feasible. As the U.S. Court of Appeals for the Fourth Circuit aptly noted in the Certification Order, authored by U.S. Circuit Judge Robert B. King:

> **It is of importance to us, however, that at no point has the Supreme Court of Appeals definitively stated — in a signed, published opinion — "one way or the other whether a design defect claim requires proof of a safer alternative**

> **design of the allegedly defective product**." *See Keffer*, 791 F. Supp. 2d at 547 (emphasis added) (recognizing lack of guiding decisional law).
>
> At least one post-*Morningstar* decision of the Supreme Court of Appeals is apparently supportive of the proposition that a plaintiff must identify an alternative product design to prevail on a design defect claim. In *Church v. Wesson* — a 1989 ruling referred to alongside *Morningstar* in Section 411's "Notes and Sources" provision — the Court affirmed a directed verdict in favor of a defendant-manufacturer because the design defect plaintiff had failed to establish the existence of an alternative, feasible design for a "roof bolt wrench" that had injured him — such that the plaintiff "failed to establish a prima facie right of recovery." *See* 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 v. Ethicon, Inc., 64 F.4th 556, 565 (bold and underline added).

Ethicon goes on to falsely argue that "[l]iability without proof of an alternative design effectively transforms strict liability into absolute liability." *See* Ethicon's Brief at p. 12. If this statement were true, the Malfunction Theory announced in Syllabus Point 9 of *Adkins v. K-Mart Corp*., 204 W. Va. 215, 511 S.E.2d 840 (1998), would impose absolute liability on product manufacturers. The Malfunction Theory does not impose absolute liability. If this statement were true, every jurisdiction that utilizes the consumer expectations test would impose absolute liability on product manufacturers. The consumer expectations test does not impose absolute liability. If this statement were true, every jurisdiction that has ever imposed liability under the risk-utility test when the single element of the existence of a safer alternative design was absent would impose absolute liability on product manufacturers. A failed risk-utility test does not impose absolute liability.

In reality, *Morningstar* unquestionably represents a flexible approach to the concept of strict products liability. As this Court explained in *Morningstar*:

> 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).

In Summary, WVPJI § 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, WVPJI § 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, WVPJI § 411 entirely eliminates the risk/utility analysis. In essence, WVPJI § 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.

3. The Fourth Circuit's *Nease* Opinion <u>INCORRECTLY</u> predicted that proof of a safer design alternative is a *prima facie* part of a West Virginia design defect claim.

While the U.S. Court of Appeals for the Fourth Circuit may have predicted in *Nease v. Ford Motor Co*., 848 F.3d 219 (4th Cir. 2017), that proof of a safer design alternative is a *prima facie* part of a West Virginia design defect claim, that prediction has <u>correctly</u> been called into

question. In the Certification Order, authored by U.S. Circuit Judge King, the U.S. Court of Appeals for the Fourth Circuit stated as follows:

> **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 (bold and underline 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).

Shears, 64 F.4th at 565 (emphasis added). To put an even finer point on the continued vitality of *Nease*'s prediction, the U.S. Court of Appeals for the Fourth Circuit went on to state with laser sharp language as follows:

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

> **design is an essential element of a design defect claim, or whether other sorts of evidence can demonstrate — with equal force — that a product is "not reasonably safe for its intended use.**"

Shears, 64 F.4th at 566 (bold and underline added). The foregoing makes crystal clear that the Nease opinion lends no support to Ethicon's arguments.

4. Ethicon's argument that all other states within the Fourth Circuit require proof of design alternative as part of risk-utility balancing is, at best, MISLEADING.

Ethicon's argument that "[a]ll other states within the Fourth Circuit require proof of a design alternative as part of risk-utility balancing" (*see* Ethicon's Brief at p. 16) is dubious, at best, for several reasons. First, it should be noted that Ethicon cleverly omits the fact that **NONE** of these states have adopted the Elimination Mandate. Second, this Court has seldom, if ever, looked to the law of the States of South Carolina, North Carolina, Virginia or Maryland for direction in the development of the common law of product liability. Instead, West Virginia has relied on the well-reasoned product liability jurisprudence from States such as California.[3]

Third, West Virginia product liability law is markedly different from the law in South Carolina, North Carolina and Virginia. For example, Virginia does not permit strict product liability claims in any form whatsoever. *See Evans v. NACCO Materials Handling Grp., Inc*., 295 Va. 235, 246 (2018 Va.). South Carolina has expressly adopted the risk-utility test. *See Branham v. Ford Motor Co*., 390 S.C. 203, 220 (2010 S.C.). West Virginia has not adopted the risk-utility test. North Carolina statutorily requires a plaintiff to offer proof that, "[a]t the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been

[3] "We find that the rule expressed in *Greenman v. Yuba Power Products, Inc*., 59 Cal.2d 57, 27 Cal. Rptr. 697, 377 P.2d 897 (1963), permitting recovery in a tort product liability case, where a defective product causes personal injury, is a more appropriate rule than Section 402A of the Restatement, Second, Torts (1965), which requires the defective condition to be unreasonably dangerous." Syl. Pt. 7, *Morningstar*, 162 W. Va. 857.

reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product." *See* N.C. Gen. Stat. § 99B-6(a)(1). West Virginia does not require such proof, statutorily or otherwise.

In summary, there is only one point of uniformity in the approach that States within the Fourth Circuit take with respect to the standard of proof in design-based strict product liability claims: **NONE of them utilize the Elimination Mandate**.

5. This Court has NOT adopted and SHOULD NOT adopt Section 2 of the Restatement (Third).

This Court has historically been skeptical of the Restatement in the formulation of this State's product liability law.[4] Additionally, this Court has neither adopted nor relied upon any portion of the Restatement (Third): Products Liability for the formulation of West Virginia product liability law.[5] Furthermore, this Court has declined to adopt the risk-utility test as explained in Section II(A)(1) above. Lastly, this Court has already cured any veiled criticisms that West Virginia case law fails to differentiate among the different categories of product defect:

> . . . 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.

[4] *See*, e.g., Syl. Pt. 7, *Morningstar*, 162 W. Va. 857 (rejecting Section 402A of the Restatement, Second's requirement that the defective condition to be unreasonably dangerous."

[5] Ethicon suggests to this Court that *Bennett v. ASCO Servs*., 218 W. Va. 41 (2005) relied on the Restatement (Third) in formulating the Malfunction Theory (originally announced in Syllabus Point 3 of *Anderson*, 184 W.Va. 641). It would have been quite difficult for this Court to have relied on the Restatement (Third), published in 1998, when *Anderson*, was authored in 1991. In reality, the Restatement (Third) is merely consistent with *Anderson* and *Bennett*: it is not their foundation.

Morningstar, 162 W. Va. 888 (emphasis added). Four years later, this Court thoroughly addressed use defectiveness in *Ilosky v. Michelin Tire Corp*., 172 W. Va. 435 (1983). Thus, *Morningstar* and *Ilosky* already address the categories of product defect and the standard of proof associated therewith. These cases, along with *Morningstar*'s unambiguous rejection of the risk-utility as the only method of proving a design defect, renders adoption of Section 2 of the Restatement (Third): (1) superfluous with respect to the parts of the Restatement (Third) that are consistent with existing West Virginia law (i.e., categories of product defect); and (2) improper with respect to the parts of the Restatement (Third) that are inconsistent with existing West Virginia law (i.e., adoption of the risk-utility test as the only method of proving a design defect). Therefore, Ethicon's argument is fatally flawed.

6. The express adoption of an alternative design requirement FORECLOSES plaintiffs from proving a defective design through the Malfunction Theory.

The Malfunction Theory and WVPJI § 411 simply cannot coexist. As explained in Syllabus Point 9 of *Adkins*, 204 W. Va. 215:

> "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*, 204 W. Va. 215 (emphasis added). On the other hand, WVPJI § 411 explicitly requires a plaintiff to prove that there was an alternative, feasible design that eliminated the risk of injury. *See* JA 011. Thus, if WVPJI § 411 were to become the law, this Court would have to overrule *Adkins* and eliminate the Malfunction Theory in the context of design defect claims.

In a thinly veiled effort to reconcile this intractable inconsistency, Ethicon argues for the first time that "[a] reasonable alternative design is the primary method–not the only method–for establishing a design defect under West Virginia law." *See* Ethicon's Brief at p. 22. This stunning retreat from the language of WVPJI § 411 demonstrates the fallacy of Ethicon's argument. WVPJI § 411 MANDATES proof of an alternative feasible design and offers NO EXCEPTIONS. There is simply no honest way to reconcile WVPJI § 411 with the Malfunction Theory. Fortunately, the solution is easy. The Malfunction Theory is embodied in a Syllabus Point authored by this Court and, therefore by Constitution, is the law of West Virginia. WVPJI § 411, conjured solely from the imagination of Ethicon's local counsel must yield to the West Virginia Constitution and the existing syllabus points authored by this Court.

7. The West Virginia Pattern Jury Instructions are NOT backed by the blessing of this Court and WVPJI § 411 is NOT a correct statement of the law.

This Court is constitutionally bound to announce new points of law through syllabus points.[6] In Syllabus Point 2 of *Walker v. Doe*, 558 S.E.2d 290 (2001) (*overruled on other grounds by McKinley*, *supra*), this Court held that it, ". . . **will use signed opinions when new points of law are announced and those points will be articulated through syllabus points as required by our state constitution**." (Emphasis added). This Court can also promulgate rules through the administrative process set forth in Article VIII, Section 3 of the West Virginia Constitution and W. Va. Code § 51-1-4. There is no provision under either the Constitution or the common law of West Virginia that permits this Court to "bless" statements of law and transform them into binding precedent or to overrule properly formulated points of law and administrative rules. Nor is there

[6] "The 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." *State v. McKinley*, 234 W. Va. 143, 149, 764 S.E.2d 303 (2014).

any evidence that this Court has "blessed" the WVPJIs. The persuasive value of the WVPJIs is only as strong as the legally binding authority upon which they are based. As the U.S. Court of Appeals for the Fourth Circuit correctly concluded in the Certification Order, there is absolutely NO binding authority from this Court to support WVPJI § 411.

Ethicon also incorrectly argues that the Shears ask this Court to reject WVPJI § 411 because it was authored by Phillip Combs, Ethicon's local counsel in this case. *See* Ethicon's Brief at p. 23. In reality, the Shears ask this Court to reject WVPJI § 411 because it is an incorrect statement of law. The only reason that the Shears point out Mr. Combs' authorship of WVPJI § 411 is because Mr. Combs was also one of the authors of the law review article: Modern Products Liability Law in West Virginia, 113 W. Va. L. Rev. 417 (2011). In that law review article, Mr. Combs writes 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. No additional case law on this issue was developed between 2011 and the 2016 release of the WVPJIs.

The Shears have never argued that WVPJI § 411 was developed through some conspiracy. To be clear, the Shears' assertion is that WVPJI § 411 is an incorrect statement of the law. However, Ethicon's fanciful recitation of the process by which WVPJI § 411 was developed identifies the terrible flaws in the process by which WVPJI § 411 was published. Specifically, Ethicon leaves this Court with the false impression that Deborah McHenry, Esq. ("Ms. McHenry"), an attorney formerly employed by The Segal Law Firm, consented to the form and content of WVPJI § 411. That is simply not true.

On August 7, 2023, Ms. McHenry executed an affidavit in which she describes the formulation of the Product Liability section of the WVPJIs, with specific reference to WVPJI § 411, as follows[7]:

> 4. In approximately 2013, I was contacted by former West Virginia Supreme Court Justice Menis Ketchum ("Justice Ketchum") to sit as a reviewer on the West Virginia Pattern Jury Instruction project.
>
> 5. Specifically, I was a reviewer for Section 400 (Product Liability) and Section 1500 (Punitive Damages) of the Pattern Jury Instructions (hereinafter referred to as "PJIs").
>
> 6. This Affidavit concerns my work on the Product Liability PJIs.
>
> 7. The product liability PJI Committee consisted of a reporter (Philip Combs, Esq. "Combs"") and three additional reviewers (Pamela C. Tarr, Esq. "Tarr," Judge Jack Alsop, and Justice Ketchum).
>
> 8. Specifically, Combs, Tarr, and myself were tasked with drafting various PJIs regarding West Virginia product liability and warranty law.
>
> 9. Based upon my understanding of this process, the draft PJIs were to be unanimous as to the substance with myself, Combs, and Tarr (the "Attorneys"). Then, they were to be submitted to then Justice Ketchum.
>
> 10. It is also my understanding that Tom McQuain, Esq. ("McQuain"),

[7] On August 8, 2023, the Shears filed a "Second Motion to Supplement the Appendix" (the "Second Motion to Supplement") with a copy of the affidavit attached. The Second Motion to Supplement is incorporated herein by reference. That same day, Ethicon filed an objection to the Second Motion to Supplement. As of the date of the filing of this Reply Brief, the Court has not yet ruled on the Second Motion to Supplement.

who upon information and belief, was one of Justice Ketchum's law clerks at the West Virginia Supreme Court of Appeals at the time, is also listed as a reviewer of the product liability and warranty section of the PJIs.

11. I also understood that Judge Alsop would decide any issues that could not be decided unanimously by myself and the Attorneys.

12. During our deliberations on the PJIs, it became abundantly clear that the Attorneys and I had a fundamental disagreement on how the product liability PJIs should be drafted.

13. Specifically, it was my position that the Attorneys and I should only rely on syllabus points (as required by the West Virginia Constitution when announcing new law), including but not necessarily limited to, the following cases: *Morningstar v. Black & Decker,* 162 W.Va. 857 (1979), *Ilosky v. Michelin Tire Corp*., 307 S.E.2d 603 (1983), and *Church v. Wesson,* 182 W.Va. 37 (1989).

14. In early January 2014, Justice Ketchum held a teleconference with Tarr and me to discuss the PJIs and our inability as a committee to come to a unanimous consensus on the substance of the product liability PJI. It was my understanding that Combs was traveling and was unable to attend the teleconference. It is also possible that Judge Alsop attended this teleconference.

15. Due to our inability to agree on the substance of the product liability PJIs, among other reasons, the Attorneys had missed a submission deadline for a draft of the PJIs.

16. Justice Ketchum advised Tarr and me to submit our current drafts of the PJIs to Judge Alsop.

17. Understanding that my position to only use syllabus points from the preceding cases would not be accepted, I drafted a communication objection addressed to Tarr and Combs memorializing my well know objections to the then-drafted PJIs. This communication was transmitted to Tarr and Combs prior to the teleconference discussed in Paragraph 14, above.

18. Thereafter, Tarr, after contacting Combs, submitted the proposed product liability PJIs to Judge Alsop with the communication regarding my objections to the Attorneys' decision to include language in the instructions that, in my opinion, were not a correct recitation of West Virginia product liability law.

19. **After this submission, it was my understanding that the Attorneys would be further involved in subsequent drafts and revisions to the PJIs, and any minority views, such as mine, would be included in the final**

PJIs. However, I received no further communication from the Attorneys, Judge Alsop, Justice Ketchum, or anyone else involved in the project.

20. To the best of my recollection, these events took place in 2013 and 2014.

21. It is my understanding that the West Virginia PJIs were then finalized and published in 2016.

22. PJI 411, as published, does not reflect my objections as submitted in the communication to the Attorneys, nor my opinions on West Virginia product liability law.

See Affidavit of Deborah L. McHenry, Esq. (emphasis added). As if WVPJI § 411's gross misstatement of the law was not enough, the process by which this pattern jury instruction made it into the final draft is even more concerning. The framers of our Constitution obviously knew what they were doing when they narrowly circumscribed the process by which the common law of West Virginia is to be developed. Neither our judicial system nor the people of this State can abide by these types of shadowy efforts and backroom deals to rewrite our common law in favor of corporate interests. *See* JA 89-90.

B. This Court Should STRIKE § 411's Requirement that the Alternative Design "Eliminate" the Risk of Injury.

Ethicon urges this Court to adopt the Elimination Mandate for one reason and one reason only: to abolish design defect-based strict product liability claims in West Virginia. This Court adopted that cause of action in Morningstar based on sound policy decisions. Ethicon wants it abolished simply on the basis of corporate greed. For these reasons, as explained more fully below, 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**.

1. WVPJI § 411'S Elimination Mandate has NO ROOTS IN THE LAW OF ANY JURISDICTION.

Astonishingly, Ethicon equates "elimination of injury" to "prevention of injury." *See* Ethicon's Brief at p. 27. This position is absurd for at least three reasons. First, WVPJI § 411 does not use the phrase "elimination of injury." It uses the phrase "**eliminated the risk** that injured [*him/her*]." *See* JA 011 (emphasis added). This was no innocent typographical error in the drafting of Ethicon's Response Brief. It was a deliberate change meant to materially alter the radical language used in WVPJI § 411 and make it seem more consonant with well-reasoned legal principles.

Second, the phrase "prevention of injury" is synonymous with "proximate cause," which already exists as an element of design defect-based strict product liability under West Virginia law. *See Morningstar*, 162 W. Va. 857, 883 (stating 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." (Emphasis added)). "Elimination of the risk," on the other hand, is a concept that is foreign to not only the law of West Virginia, but foreign to the law of EVERY State in the Union.

Third, "prevention of injury" is diametrically opposed to "elimination of the risk." As noted above, "prevention of injury" is synonymous with "proximate cause." This Court has long held that, "'[p]roximate cause' must be understood to be that cause which in actual sequence, unbroken by any independent cause, produced the wrong complained of, **without which the wrong would not have occurred**." *Spencer v. McClure*, 217 W. Va. 442 (2005) (emphasis added) (internal citation omitted). The element of proximate cause, in relation to a design defect-based strict

product liability claim, must be proven by a preponderance of the evidence.[8] Thus, a plaintiff in West Virginia must prove, by a preponderance of the evidence, that the plaintiff's injury would not have occurred in the absence of a design defect. The Elimination Mandate, on the other hand, would require the plaintiff to prove the existence of an alternative design that goes much further than just preventing the injury. The Elimination Mandate would require the plaintiff to prove, by a preponderance of the evidence, that a feasible alternative design existed that would have completely eliminated the risk created by the product. In practice, the plaintiff would have to find an expert who could opine, by a greater weight of the evidence, that the alternative design would 100% eliminate the risk. Not even a prosecutor in a first-degree murder case faces such an insurmountable and inconsistent burden of proof.

2. Not Even Paid Industry Advocates support WVPJI § 411's Elimination Mandate.

Not even the paid industry advocates represented by the Products Liability Advisory Council ("PLAC") believe that the Elimination Mandate should be included as a component of West Virginia common law. Simply put, the PLAC advocates for the abandonment of *Morningstar* and its progeny and the adoption of Section 2(b) of the Restatement (Third). As explained above and in Petitioners' Brief, such a course of action is both unnecessary and unwise. It is unnecessary because West Virginia law already strikes the proper balance between protecting consumers from defective products and providing industry with concrete, consistent and predictable guideposts. There can be no doubt that the PLAC and its constituents would like to see every State in the Union adopt Section 2(b) of the Restatement (Third). While such a sea change would undoubtedly

[8] "A preponderance, of course, is our traditional burden of proof in a civil case. *See Hovermale v. Berkeley Springs Moose Lodge No. 1483*, 165 W. Va. 689, 271 S.E.2d 335 (1980); *Lester v. Flanagan*, 145 W. Va. 166, 113 S.E.2d 87 (1960); *Burk v. Huntington Dev. & Gas Co*., 133 W. Va. 817, 58 S.E.2d 574 (1950)." *McClure v. McClure*, 184 W. Va. 649, 652 (1991).

increase corporate profits to the delight of PLAC's constituents, it would make it even harder for consumers injured by defective products to receive adequate compensation. Such a result is anathema to this State's strong public policy to compensate people injured by the tortious actions of others[9] and the very concepts underpinning West Virginia's strict product liability law.[10]

3. The Elimination Mandate is NOT needed to ensure a sufficient causal relationship between the plaintiff's injury and the manufacturer's design decision.

Ethicon argues to this Court that *Morningstar*'s proximate cause requirement is insufficient to ensure a sufficient causal relationship between the plaintiff's injury and the manufacturer's design decision. *See* Ethicon's Brief at p. 30. This argument is as irresponsible as it is ridiculous! This Court's long-standing formulation of proximate cause is as much a part of the bedrock of tort law as duty, breach and damages. Does Ethicon really expect this Court to believe that there has been a gaping hole in West Virginia's product liability jurisprudence since 1979? Does Ethicon really expect this Court to believe that only the Elimination Mandate can fill this gaping hole? Forty-four years of decisional law from this Court forecloses any serious consideration of Ethicon's misguided arguments. The adequacy and sufficiency of this Court's formulation of proximate cause and its application to strict product liability has never been seriously called into question, and it is not seriously called into question now. Simply put, under *Morningstar*, a plaintiff's design-defect strict product liability claim cannot survive summary judgment in the absence of proof that the defective product proximately caused the plaintiff's injury. Thus, contrary

[9] *See Paul v. National Life*, 177 W. Va. 427, 433 (1986) (stating that, "[i]t is the strong public policy of this State that persons injured by the negligence of another should be able to recover in tort.").

[10] "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.

to Ethicon's arguments, *Morningstar*'s proximate cause requirement IS sufficient to ensure a sufficient causal relationship between the plaintiff's injury and the manufacturer's design decision.

4. This Court SHOULD REJECT the Elimination Mandate and require a plaintiff basing a design defect-based strict product liability claim on the risk utility test to submit proof of a SAFER alternative design.

As explained above in Section II(A)(2), *Morningstar*'s product defect test is, by design, both flexible and adaptable. To the extent that a plaintiff asserting a design defect-based strict product liability claim utilizes the risk-utility test, proof that an alternative design is "safer" than the subject product is all that is required. Under existing principles of West Virginia tort law, to prove that an alternative design is "safer," the plaintiff must prove, by a preponderance of the evidence, that the alternative design would not have proximately caused the plaintiff's injury. Displacing the existing proximate cause element of such a claim with the Elimination Mandate would virtually eliminate a plaintiff's ability to prove a design defect using the risk-utility test. Such a restriction is inconsistent with the goals of strict product liability enunciated in *Morningstar*.

5. Adoption of the Elimination Mandate would FORECLOSE plaintiffs from proving a defective design through other means.

The Shears adequately demonstrated that adoption of the Elimination Mandate would FORECLOSE plaintiffs from proving a defective design through other means in Section V(C)(2)(i) of their Opening Brief. *See* Petitioners' Brief at pp. 21-25. Those arguments are incorporated here by reference in the interests of brevity. Ethicon's arguments to the contrary are simply unsupported by either law or logic.

C. The Court should accord Petitioners' "Fifty-State Survey" its due weight.

Ethicon's criticism of the Fifty-State Survey is nothing more than another attempt to distract from how radical is the Elimination Mandate. Unable to equate "elimination of the risk" with "prevention of the injury", Ethicon attempts to normalize the Elimination Mandate by nit-picking a brief survey of the design defect strict product liability in the fifty States. Notably, Ethicon does not quarrel with the fact that the Fifty-State Survey discloses that NO OTHER State in the Union has adopted an Elimination Mandate. Moreover, the Fifty-State Survey accurately reflects that several jurisdictions have adopted a hybrid approach to design defect-based strict product liability claims such as Alabama, California, Illinois and Indiana, to name a few. Thus, the Fifty-State Survey shows that West Virginia's hybrid approach is consistent with several other jurisdictions, and the Elimination Mandate finds NO support in the law of ANY OTHER STATE.

Comically, Ethicon argues that the Shears have "apparently" improperly characterized the law of Idaho, Iowa and Maine under the "Safer Alternative Design Required (Y/N)" column. *See* Ethicon's Brief at p. 31. In reality the Fifty-State Survey lists "Undetermined" for Idaho and "Optional" for Iowa and Maine. In an effort to lend credence to its argument, Ethicon cites to the Supreme Court of Idaho's decision in *Puckett v. Oakfabco, Inc*., 132 Idaho 816 (1999). That is one of the Idaho cases the Shears cite in the Fifty-State Survey. *See* JA 116. Similarly, just as Ethicon does, the Shears cite to *Wright v. Brooke Group Ltd*., 652 N.W.2d 159 (2002 Iowa) in the Fifty-State Survey for Iowa. *See* JA 120. The listing of "Optional" in the Summary Chart instead of "Y" was merely a transcription error. The same is true of the law from Maine. The Shears cite to *Walker v. General Electric Co*., 968 F.2d 116 (1st Cir. 1992) (applying Maine law and stating that, "[s]uch proof involves an examination of the utility of the product's design, the risk of such design and the feasibility of safer alternatives.") *See* JA 125. Ethicon cites to *Reali v. Mazda Motor of Am., Inc*.,

106 F. Supp. 2d 75 (D. Me. 2000), for the same proposition. Both opinions rely on the Supreme Judicial Court of Maine's decision in *Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144 (1983). Thus, the Fifty-State Survey accurately reflects the law of these States. Ethicon's remaining criticisms of the Fifty-State Survey are equally invalid.

IV. CONCLUSION

The *Morningstar* standard for design defect-based strict product liability claims is, by design, a flexible one. The Hybrid Approach adopted in *Morningstar*, by the forward-thinking Justice Thomas Miller, 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. WVPJI § 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 WVPJI § 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.

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' Reply Brief*, upon the following counsel of record this 9th day of August, 2023, via File & Serve Xpresss, addressed as follows:

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