SUPREME COURT OF APPEALS OF WEST VIRGINIA

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Judith A. Shears and
Gary F. Shears, Jr.,

Petitioners,a

v. **Docket No. 23-192**

Ethicon, Inc. and Johnson & Johnson,

Respondents.

BRIEF OF RESPONDENTS ETHICON, INC. AND JOHNSON & JOHNSON

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

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CERTIFIED QUESTION PRESENTED FOR CONSIDERATION

This case comes before the Court on certified question from the United States Court of Appeals for the Fourth Circuit. This Court has been asked to answer this question:

> Whether Section 411 of the *West Virginia Pattern Jury Instructions for Civil Cases*, entitled "Design Defect — Necessity of an Alternative, Feasible Design," correctly specifies the plaintiff's burden of proof for a strict liability design defect claim pursued under West Virginia law.
>
> More specifically, whether a plaintiff alleging a West Virginia strict liability design defect claim is required to prove the existence of an alternative, feasible product design — existing at the time of the subject product's manufacture — in order to establish that the product was not reasonably safe for its intended use. And if so, whether the alternative, feasible product design must eliminate the risk of the harm suffered by the plaintiff, or whether a reduction of that risk is sufficient.

Shears v. Ethicon, Inc., 64 F.4th 556, 558 (4th Cir. 2023).

STATEMENT OF THE CASE

I. Procedural history.

Petitioner Judith Shears and her husband Gary Shears ("Petitioners") sued Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") on July 12, 2013. They filed their complaint in the Ethicon pelvic mesh MDL pending in the Southern District of West Virginia ("the MDL Court"), where it was consolidated with thirty-six other cases involving West Virginia plaintiffs alleging injuries caused by

Ethicon's TVT mid-urethral sling.[1] *See Mullins et al. v. Ethicon, Inc. et al.*, Case No. 2:12-cv-02952 (S.D. W. Va.).

Petitioners sought to hold Ethicon strictly liable for alleged design defects in the TVT, among other claims. Early in the proceedings, the MDL Court was asked to clarify the parameters of a strict liability–design defect claim under West Virginia law, or, if necessary, predict how this Court would rule. *See Corder v. Antero Res. Corp.*, 57 F.4th 384, 392 (4th Cir. 2023) (In cases falling under federal diversity jurisdiction, a federal court applies state law to settled issues and "if necessary, predict[s] how the state's highest court would rule on an unsettled issue.").

The MDL Court initially predicted this Court would not require proof of a safer alternative design as a *prima facie* element of a strict liability–design defect claim, though such evidence was "certainly relevant" in determining whether a product is unsafe. *Mullins v. Ethicon Inc.*, 117 F. Supp. 3d 810, 821 (S.D.W. Va. 2015) (citing *Morningstar v. Black & Decker Manf. Co.*, Syl. Pt. 5, 162 W. Va. 857, 253 S.E.2d 666 (1979)).

The MDL Court reconsidered this ruling after this Court, in June 2016, published its West Virginia Pattern Jury Instructions for Civil Cases ("PJI"). The MDL Court's ruling was premised in part on PJI § 411, which states:

[1] The *Shears* case was one of more than 28,000 cases pending at one time in the Ethicon pelvic mesh MDL.

§ 411 Design Defect–Necessity of an Alternative, Feasible Design

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

West Virginia PJI § 411. Based on its thorough review of West Virginia case law and the PJI, the MDL Court's "inescapable conclusion" was that § 411 accurately reflects West Virginia law. *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2016 WL 7197441, at *5 (S.D.W. Va. Dec. 9, 2016).

The MDL Court also gave deference to the fact that the instructions were reviewed, edited, and approved by two West Virginia judges (Justice Ketchum, at the time, a seated justice on this Court, and Judge Alsop, a Circuit Judge). The MDL Court held that a West Virginia strict liability–design defect claim requires proof of "an alternative, feasible design" that "eliminate[s] the risk that injured the plaintiff." *Mullins*, 2016 WL 7197441, at *5.

On November 20, 2020, Plaintiffs' case was remanded to the United States District Court for the Northern District of West Virginia ("District Court"). The District Court promptly set Petitioners' surviving design defect and negligence claims for trial. On February 11, 2022, at a hearing on Ethicon's unresolved *Daubert* motions, the District Court granted Ethicon's motion to exclude the testimony of Dr. Uwe Klinge, Petitioners' materials expert, because he did not testify that his

proposed alternative designs would eliminate the risk of Ms. Shears' injury. *See* JA079–81 (hearing transcript); JA085–87 (Order following *Daubert* hearing).

Importantly, the District Court did not grant "summary judgment" on Petitioners' design defect claim. Recognizing there can be more than one way to prove defective design in certain cases, Petitioners merely pivoted to a theory of product malfunction. The District Court allowed the claim to proceed to trial but granted judgment as a matter of law on the strict liability–design defect claim at the end of Petitioners' case in chief. Petitioners proceeded to the jury on their remaining claim for negligent design defect. On March 16, 2022, the jury returned a defense verdict.

Petitioners timely noticed their appeal to the United States Court of Appeals for the Fourth Circuit. They raised three assignments of error, only one of which is relevant to the certified question now presented for review: whether the District Court was correct in adopting West Virginia PJI § 411 and requiring Petitioners to identify an alternative design that eliminated the risk of injury.

Upon completion of briefing, the Fourth Circuit held oral argument on January 24, 2023. On April 5, 2023, the Fourth Circuit entered an order certifying the question now presented for review.

This Court entered a briefing order on April 26, 2023. Petitioners filed their opening brief on June 26, 2023 ("Petitioners' Br.").

II. Factual background.

a. Ethicon's TVT

Ethicon's TVT ("Tension-Free Vaginal Tape") has been marketed since 1998 and has a proven record of safety and efficacy. The TVT sling is the most studied anti-incontinence device and surgical option for treating stress urinary incontinence ("SUI") in the world, with hundreds of randomized, controlled trials and cohort studies with up to 17 years follow-up supporting its continued use. Ethicon continues to market the TVT today, more than 24 years after its introduction to the U.S. market. The evidence produced at trial from both parties' experts established that mid-urethral slings, like the TVT sling used to treat Ms. Shears' SUI, are considered the gold standard for treatment of SUI and are recommended for use by the surgical organizations that treat women's incontinence. *See* JA 1163–66 in *Shears v. Ethicon, Inc.*, ECF No. 18 (4th Cir. Case No. 22-1399) ("Fourth Circuit JA") (Position Statement on Mesh Midurethral Slings for Stress Incontinence (2013)).

b. Ms. Shears' medical history

On March 16, 2009, Ms. Shears was implanted with Ethicon's TVT device for the treatment of SUI. Fourth Circuit JA 201, 5585. Three years later, in April 2012, Ms. Shears reported complaints of urinary tract infections ("UTIs") and painful urination. *Id.* at 525. In September 2013, she saw a urologist for these complaints. *Id.* at 532. A CT exam revealed a bladder stone attached to a small piece

of TVT mesh that had eroded into the bladder tissue. *Id.* at 536. Ms. Shears underwent surgery to remove the bladder stone and the mesh fibers attached to it. *Id.* at 537. The surgery was successful and there is no evidence of further bladder erosion in Ms. Shears. *Id.* at 6450–51.

Mesh erosion into the bladder is a rare but well-known complication that happens in less than 1 percent of patients. Fourth Circuit JA 6252. Mesh can be inadvertently placed in the bladder after undetected perforation of the bladder at the time of surgery. *Id.* at 6249–50. Bladder erosion can also occur when the TVT is placed by the implanting surgeon within the muscularis of the bladder. *Id.* at 6250–51. Bladder erosion is not a complication unique to TVT. Erosion is a known risk of every bladder surgery that uses mesh (whether Ethicon's mesh or any other mesh) and it is a recognized risk of non-mesh surgeries where sutures and other permanent grafts are used. *Id.* at 6420–21, 6458–59.

SUMMARY OF ARGUMENT

The Court should answer the certified question in the affirmative. Specifically, the Court should hold that proof of a feasible, alternative product design existing at the time the allegedly defective product was manufactured is a *prima facie* element of a West Virginia strict liability-design defect claim. The Court should further hold that the alternative design proffered by the plaintiff must eliminate the risk of harm suffered by the plaintiff.

West Virginia uses a risk-utility test to evaluate product defectiveness in design defect cases. *Morningstar*, 162 W. Va. 857, 253 S.E.2d 666 at Syl. Pts. 4, 5. And although *Morningstar* does not make this point explicit, defining "reasonable safeness" by "what a reasonably prudent manufacturer's standards *should have been*" can only be construed as requiring proof of a safer alternative design. *Id.* at Syl. Pt. 4. This Court's later decision in *Church v. Wesson* recognizes this requirement, as does the Fourth Circuit's opinion in *Nease v. Ford Motor Company*, as does the Third Restatement of Torts.

The alternative design requirement is the very essence of design defect liability. A jury simply cannot determine whether a manufacturer's design specifications create unreasonable risks without reference to a standard *outside* those specifications. And allowing recovery without proof of an alternative design is untenable; it effectively transforms *strict* liability into *absolute* liability. The requirement of an alternative design is widely accepted. Indeed, in the decades since *Morningstar*, all other states within the Fourth Circuit have recognized alternative design as a vital element of a design defect claim. The Restatement (Third), which this Court has cited favorably in other cases, propounds this requirement as well.

As for whether the alternative design must eliminate or merely reduce the risk of injury suffered by the plaintiff, elimination is the better rule. "Elimination of the risk" is consistent with this Court's prior jurisprudence in the negligence context and

ensures a causal relationship between the manufacturer's allegedly deficient design and the proposed alternative. It is also the rule of several other jurisdictions that require the alternative design to avoid or prevent–not reduce–the plaintiff's harm.

Petitioners support their arguments on design defect liability with a fifty-state survey created by their counsel. But their survey inaccurately represents design defect jurisprudence in this country and should not be relied on. Most jurisdictions use risk-utility balancing to determine liability for defective design, and of these, most recognize evidence on alternative design as the central feature of the analysis.

STATEMENT REGARDING ORAL ARGUMENT AND DECISION

This case should be selected for Rule 20 argument because it involves an important issue that the Fourth Circuit has asked this Court to address: whether a West Virginia strict liability–design defect claim requires proof of an alternative, feasible product design that would eliminate the risk of injury suffered by the plaintiff. W. Va. R. App. P. 20(a).

ARGUMENT

I. The Requirement of a Safer Alternative Design is an Essential Element of a Strict Liability–Design Defect Claim under Existing West Virginia Law.

a. Morningstar endorsed a risk-utility test as the primary means of proving a design defect in West Virginia.

A product is defective if "it is not reasonably safe for its intended use." *Morningstar*, 162 W. Va. at 888, 253 S.E.2d at 683. "[A] defective product may fall

into three broad, not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use of defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels." *Id.* at 888, 682.

Whether a product's design is "not reasonably safe for its intended use" has traditionally been determined through resort to one of two methods of proof: the risk-utility test and the consumer expectations test. *See Mullins v. Ethicon, Inc*, 117 F. Sup. 3d 810, 815; *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010). Under the consumer expectations test, a product is unsafe if it fails to perform to the expectations of an ordinary consumer. *Mullins*, 117 F. Supp. d3d at 815; *see also* Restatement (Second) of Torts § 402A; *Lloyd v. Gen. Motors Corp.*, 275 F.R.D. 224, 228 (D. Md. 2011). The risk-utility test, on the other hand, balances product risk against utility. *See Morningstar*, 162 W. Va. at 885–87, 253 S.E.2d at 681–82. Folded into this balancing is a seven-factor test that considers the desirability of the product, the severity of the risk it poses, and the manufacturer's ability to avoid the unsafe character of the product without impairing product utility, among other things. *See Morningstar*, 162 W. Va. at 886, 253 S.E.2d at 681 n.20 (describing factors).

West Virginia has unambiguously adopted a risk-utility test for determining product defectiveness. In *Morningstar v. Black & Decker Manufacturing Co.*, this

Court pronounced the risk-utility test that governs West Virginia strict liability claims for design defect:

> 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.
>
> 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.

Syl. Pts. 4, 5, 162 W. Va. at 857, 253 S.E.2d at 667. Since *Morningstar*, the risk-utility test has been universally accepted as the test to prove design defect in a strict liability action under West Virginia law. *See Mullins*, 117 F. Supp.3d at 821 (*Morningstar* "craft[ed] . . . a coherent risk-utility test that applies to all products"); *Keffer v. Wyeth*, 791 F. Supp.2d 539, 547 (S.D.W. Va. 2011) (noting standard of reasonable safeness); *Knight v. Boehringer Ingelheim Pharm., Inc.*, 323 F. Supp. 3d 809, 833 (S.D.W. Va. 2018) (same); *see also Shears*, 64 F.4th at 565 (noting that *Morningstar*'s adoption of a risk-utility test).

Morningstar does not endorse, and West Virginia law does not support, use of the consumer expectations analysis in design defect cases. To the contrary, *Morningstar* expressed reservations about the consumer expectations test when it adopted the risk-utility test. 162 W. Va. at 884–86, 253 S.E.2d at 681–82 (noting concerns with aspects of Restatement (Second)). Other West Virginia courts have

similarly rejected the consumer expectations approach. *See Mullins*, 117 F. Supp.3d at 816–17. The risk-utility test, with its requirement of a safer alternative design, is the only test used in West Virginia.[2]

b. The requirement of a feasible alternative design is at the heart of the risk-utility test and the only reasonable reading of *Morningstar*.

Morningstar's risk-utility test is an objective one. Thus, the manufacturer's design "is . . . 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." *Morningstar* at Syl. Pt. 5; *see also id.* at Syl. Pt. 4 (defectiveness is determined by "what a reasonably prudent manufacturer's standards should have been at the time" of manufacture). Determining "what the reasonably prudent manufacturer would accomplish" and what the manufacturer's standard "should have been" requires reference to some

[2] Petitioners are thus incorrect when they characterize *Morningstar*'s rule as a "hybrid" approach to design defect liability. *See* Petitioners' Br. at 18. A hybrid approach describes a combination of the consumer expectations and risk-utility tests. Jurisdictions adopting a hybrid approach to strict liability typically reserve the risk-utility analysis for complex design cases requiring expert testimony. *See Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010) (describing hybrid tests and concluding that "[s]ome form of the risk-utility test is employed by an overwhelming majority" of jurisdictions in the United States); *Ford Motor Company v. Trejo*, 402 P.3d 649, 654 (Nev. 2017) (identifying California and Illinois as two jurisdictions using a hybrid test).

design standard *outside* the manufacturer's design specifications. *See* Restatement (Third) of Torts: Prod. Liab. § 2 cmt. d (1998) (hereinafter "Restatement Third").

By defining defectiveness in the context of another manufacturer's design standards, *Morningstar* can only be understood to create an alternative design requirement. 162 W. Va. at 888, 253 S.E.2d at 682–83; *see* Restatement (Third) § 2 (*Morningstar*'s language can only be read to require the production of evidence on reasonable alternative design, to gauge "'what should have been.'"). Because the plaintiff could not show that a proposed design alternative was feasible for the manufacturer to adopt, she "failed to establish a *prima facie* right of recovery." *Id*.

Although it is a *per curiam* opinion, this Court's decision in *Church v. Wesson*, 182 W. Va. 37, 385 S.E.2d 393 (1989) (per curiam) required a feasible alternative design. In *Church*, this Court applied *Morningstar* and upheld a directed verdict for the defendant, in a strict liability case, because the plaintiff failed to establish a feasible alternative design. *Id.* at 396. This result was possible only if *Morningstar* required a design defect plaintiff to establish an alternative design.

Liability without proof of an alternative design effectively transforms strict liability into absolute liability. This is an untenable solution; one that transforms manufacturers into insurers of their products and would result in the withdrawal of many useful products from the market. *Morningstar*, 162 W. Va. at 877–78, 253 S.E.2d at 677 ("Strict liability does not make the manufacturer or seller an insurer

nor does it impose absolute liability."); *see also Am. Tobacco Co.*, *Inc. v. Grinnell*, 951 S.W.2d 420, 433 n. 10 (Tex. 1997) ("By arguing for liability even in the absence of a reasonably safer alternative design, the Grinnells effectively propose that we adopt a system of categorical liability with respect to cigarettes."); *see also* Harvey M. Grossman, *Categorical Liability: Why the Gates Should be Kept Closed*, 36 S. Tex. L. Rev. 385, 391 (1995) (describing an alternative design as the "threshold requirement" of the risk-benefit calculus, where reasonable design choice becomes the focus of the analysis, not product prohibition). Manufacturers need not design a risk-free product, and are free to respond to "the wide variety of individual consumer needs, wants, and preferences, so long as the products they market are reasonably safe as measured by the range of available design options." Grossman, 36 S. Tex. L. Rev at 391.

Petitioners' argument that proof of an alternative design is just one of many optional factors in the risk-utility analysis is not supported by *Morningstar*. As *Morningstar* explained, in the 1970s, Dean John Wade introduced a seven-factor test for determining whether a product is unreasonably dangerous for purposes of strict tort liability. The ability of the manufacturer to eliminate the unsafe aspect of the product was one factor. *Morningstar* acknowledges the Wade factors but, as the Fourth Circuit recognized in this case, *Shears*, 64 F.4th at 566 n.12, does not expressly adopt them or describe their utility in determining product defect.

Morningstar, 162 W. Va. at 681, 253 S.E.2d at 886 n.20 (citing *Cepeda v. Cumberland Eng'g Co., Inc.*, 386 A.2d 816 (N.J. 1978)).

If the Wade factors play any role in modern West Virginia product liability law, it is merely to assist the factfinder in determining whether an alternative design is reasonable and whether its omission renders the product reasonably unsafe. *See* Restatement (Third) § 2 cmt. f (describing factors relevant to the analysis). *Morningstar* does not hold that proof of an alternative design is a mere factor in the design defect analysis; to the contrary, an alternative design standard that the manufacturer allegedly should have adopted is essential to the analysis. *See Morningstar* at Syl. Pt. 4.

The Restatement (Third) reporters criticized the practice of using alternative design as a factor in the risk-utility analysis. The reporters acknowledge the reasoning of some courts that had adopted a narrow carve-out to the alternative design requirement when the "designs of some products are so manifestly unreasonable, in that they have low social utility and high degree of danger, that liability should attach even absent proof of a reasonable alternative design." Restatement (Third) § 2 cmt. e; *see also id.* cmt. d (noting alternative design requirement "applies in most instances even though the plaintiff alleged that the category of product sold by the defendant is so dangerous that it should not have been marketed at all"). This leaves only two options when judging a product using

risk-utility guidelines: "Either the product should have been reasonably designed to avoid the risk of foreseeable injury or the product should not have been marketed at all. The former invokes reasonable alternative design and the latter comment e [manifestly unreasonable design]."[3] Restatement (Third) § 2 cmt. b. Without proof of an alternative design, there is simply no objective way to judge the reasonableness of the manufacturer's design choice.

c. The Fourth Circuit has agreed that proof of a safer design alternative is a *prima facie* part of a West Virginia design defect claim.

The Fourth Circuit has interpreted *Morningstar* as requiring evidence of an alternative design as an element of a design defect claim. *Nease v. Ford Motor Co.*, 848 F.3d 219, 234 (4th Cir. 2017). *Nease* is a products liability case in which the plaintiff was injured when his vehicle's speed control cable became stuck and he could not decelerate. *Id.* at 222–23. A West Virginia jury found Ford liable under a strict liability design defect theory.

[3] Petitioners never invoked the "manifestly unreasonable design" theory in this case and have now waived their right to assert it. Further, federal preemption bars assertion of the theory here, *see Mutual Pharm. Co. v. Bartlett* 570 U.S. 472, 488 (2013). In any event, if invoked in this case, such a theory would require Ethicon to stop selling the TVT–an FDA-cleared device–in order to avoid liability in West Virginia. This "stop-selling" rationale is preempted by federal law. *See id.* ("[A]n actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

On appeal, Ford contended that to establish a design defect, *Morningstar* requires a plaintiff to prove "that a reasonably prudent manufacturer would have adopted a safer design during the relevant time period." *Id.* at 233. The Fourth Circuit agreed, finding that West Virginia law requires proof of a feasible alternative design in a strict liability case for design defect:

> [W] e 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." . . . 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."

Id. at 234 (internal citations omitted).

In the Fourth Circuit's view, *Morningstar*'s alternative design requirement was not a close question. And in certifying the question presently before the Court, the Fourth Circuit acknowledged that its *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." *Shears*, 64 F.4th at 566. In other words, the Fourth Circuit's interpretation of *Morningstar*–including its requirement of an alternative design–has not changed.

d. All other states within the Fourth Circuit require proof of a design alternative as part of risk-utility balancing.

Every other state in the Fourth Circuit requires evidence of a feasible alternative design to establish a defect when using risk-utility balancing. West

Virginia would be a regional outlier if this Court declined to expressly adopt such a requirement.

South Carolina: The Supreme Court of South Carolina has reasoned that "[t]he very nature of feasible alternative design evidence entails the manufacturer's decision to employ one design over another." *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 16 (S.C. 2010). "This weighing of costs and benefits attendant to that decision is the essence of the risk-utility test." *Id. Branham* cited favorably the work of Professor David G. Owen, who wrote: "In design defect litigation, th[e] basic issue [that must be proved] involves the following fundamental question: whether the manufacturer's failure to adopt a particular design feature proposed by the plaintiff was, on balance, right or wrong." *Id.* (quoting David G. Owen, *Toward a Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits*, 75 Tex. L. Rev. 1661, 1687 (1997) (internal quotation marks omitted). "In sum," *Branham* concluded, "in a product liability design defect action, the plaintiff must present evidence of a reasonable alternative design." *Id.*

North Carolina: North Carolina has adopted the reasonable alternative design requirement by statute. To establish a claim of inadequate design, the plaintiff must prove that at the time of manufacture, the manufacturer acted unreasonably in designing or formulating the product, and that the conduct was a proximate cause of the harm for which damages are sought. N.C. Gen. Stat. Ann. § 99B-6(a).

Further, the plaintiff must also prove that "[a]t the time the product left the control of the manufacturer," either "the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been 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," or "the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consumer a product of this design." N.C. Gen. Stat. Ann. § 99B-6(a). The first of these options invokes risk-utility balancing, with the element of safer alternative design; the second essentially requires proof of a manifestly unreasonable design. *See* Restatement (Third) § 2 cmt. e. After establishing the necessity of an alternative design as part of the risk-utility test, the North Carolina statute identifies several factors used to determine whether the manufacturer acted unreasonably. *Id.* § 99B-6(b). Notably, these factors are separate from the alternative-design requirement, which is an indispensable feature of the design defect test. *Morningstar* is consistent with this analysis, endorsing factors for evaluating a product defect before reemphasizing the objective manufacturer's design standard as central to the analysis.

Virginia: Virginia requires proof of a feasible alternative design as part of a claim for negligent design.[4] *Evans v. Nacco Materials Handling Grp., Inc.*, 810 S.E.2d 462 (Va. 2018). Like *Morningstar*, *Evans* held that a product is unreasonably dangerous in design where "the manufacturer failed to meet objective safety standards prevailing at the time the product was made." *Id.* at 469. Industry practices and reasonable consumer expectations inform the question of whether the manufacturer's design was negligent. *Id.* at 469–70. Even if the plaintiff can show that reasonable consumers expected a safer design, "a design is not objectively unreasonable unless the plaintiff can show that an alternative design is safer overall than the design used by the manufacturer." *Id.* at 471.

Maryland: Maryland applies either the consumer expectations test or the risk-utility test to a claim of defective design, depending on the facts of the case. *Lloyd v. Gen. Motors Corp.*, 275 F.R.D. 224, 229–30 (D. Md. 2011) (employing the risk-utility test). In *Lloyd*, the court distinguished the risk-utility test, which shifts the "focus from the consumer to the manufacturer of the product" and "asks whether a manufacturer, knowing the risks inherent in the product, acted reasonably by putting it on the market." Under the risk-utility test, "[a] product is defective in design when the foreseeable risk of harm could have been reduced or avoided by the

[4] Virginia does not recognize strict liability. *Evans*, 810 S.E.2d at 469.

adoption of a reasonable alternative design. *It is the omission of a reasonable alternative design that renders the product not reasonably safe.*" *Id.* at 229.

The uniform approach to application of the risk-utility test for design defect claims by Maryland, North Carolina, South Carolina, and Virginia should demonstrate to the Court that evidence of an alternative design is critical in a case of design defect. *Morningstar*'s analysis aligns with the approach of these states, and this Court should confirm that plaintiffs must establish an alternative design.

e. The Restatement Third of Torts recognizes the alternative design requirement as the essence of the risk-utility test.

The Restatement (Second) of Torts § 402A was published in 1965 and greatly expanded strict liability for harmful products. By abandoning the traditional rule of privity, the Restatement (Second) led to marked increase in products liability litigation of which *Morningstar* is a part. *See* Am. Jur. 2d Products Liab. § 362; *Morningstar*, 253 S.E.2d at 679–80 (noting that § 402A permitted recovery for personal injuries from a manufacturer of a product, even when no privity of contract existed between the injured party and manufacturer and in the absence of any negligence on the part of the manufacturer).

The Restatement (Second) imposes liability on the manufacturer of "any product in a defective condition unreasonably dangerous" but does not distinguish between different defect types. *See* Restatement (Second) of Torts § 402A (1965). *Morningstar* shared this early criticism of the publication, noting the Restatement

(Second) failed to provide a "suitable definition of the term 'defect.'" 253 S.E.2d at 680; *see* John H. Chun, *The New Citadel: A Reasonably Designed Products Liability Restatement*, 79 Cornell L. Rev. 1654, 1657 (1994) (explaining that the Restatement (Second)'s unitary standard for product liability cases gave way to "confusion over what standards to apply to different types of product defects").

The American Law Institute sought to rectify the issue with publication of the Restatement (Third). The Restatement (Third) identifies three categories of product defect: manufacturing defects, design defects, and failure to warn. *See* Restatement (Third) § 2(a), (b), and (c). Each subpart relates to a different type of product defect, with subpart (b) stating the principles that apply to defective design. Section 2(b) adopts a risk-utility balancing test that asks the jury to weigh the risks and benefits of the manufacturer's design against the risks and benefits of a design alternative:

> A product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . and the omission of the alternative design renders the product not reasonably safe[.]

Id. § 2(b). Under the Restatement (Third), liability for design defect hinges on whether "the omission of a reasonable alternative design renders the product not reasonably safe." *Id.* cmt. f. The Restatement (Third)'s alternative design requirement provides the jury with an objective basis to evaluate the reasonableness

of the manufacturer's design specifications. *Id.* cmt. d. (design defect "requires reference to a standard outside the [design] specifications").

The Court should follow the Restatement's lead and expressly adopt a reasonable alternative design as the predominant method for establishing defective design in West Virginia.[5]

f. The express adoption of an alternative design requirement would not foreclose plaintiffs from proving a defective design through other means.

Petitioners argue that the adoption of an alternative design requirement would "impermissibly eliminate[]" a plaintiff's ability to prove a design defect in other ways. Petitioners' Br. at 24. This is simply untrue. A reasonable alternative design is the primary method–not the only method–for establishing a design defect under West Virginia law. A plaintiff need not produce evidence of an alternative design, for example, where she proceeds under a theory of product malfunction. *See* Syl. Pt. 3, *Anderson v. Chrysler*, 184 W. Va. 641, 403 S.E.2d 189 (1991) (recognizing malfunction theory of strict liability design defect liability); *see also* Restatement (Third) Products Liability § 3 (same).

[5] While West Virginia has not adopted Restatement (Third) § 2, this Court has relied on § 3 of the Restatement (Third) in other product liability cases. *Bennett v. Asco Servs., Inc.*, 218 W. Va. 41, 49, 621 S.E.2d 710, 718 (2005).

g. The West Virginia Pattern Jury Instructions are backed by the blessing of this Court and are persuasive authority the Court should consider.

The question certified by the Fourth Circuit asks this Court to directly address whether PJI § 411 is a correct statement of West Virginia law. Petitioners spend much of their brief arguing that the PJI have no precedential value. *See* Petitioners' Br. at 20–21. But while the PJI are not binding authority, they are still relevant. The PJI represent the reasoned analysis of experienced West Virginia practitioners, a West Virginia circuit judge, and a former justice of this Court.

Further, the PJI were drafted and reviewed by practitioners from both the defense and plaintiffs' bar. Petitioners argue that the Court should reject § 411 of the PJI because Philip Combs, trial counsel for Ethicon, served as the reporter of the Product Liability and Warranty instructions. As this Court is aware, and as is expressly recognized in the Preface to the West Virginia PJI Instructions, the process for the Product Liability and Warranty Instructions was as follows: (1) the Section Reporter (Philip Combs)[6] prepared a draft of the instructions; (2) the reviewing committee (Deborah L. McHenry (see below); Pamela D. Tarr; West Virginia Supreme Court of Appeals Law Clerk Tom McQuain; West Virginia Supreme Court

[6] Mr. Combs was selected by Justice Ketchum to be the Reporter for the Products Liability and Warranty Section because Mr. Combs had co-authored Combs and Cooke, *Modern Products Liability Law in West Virginia*, 113 W. Va. L. Rev. 417 (2011).

of Appeals Justice Menis E. Ketchum and West Virginia Circuit Judge Jack Alsop) then edited the instructions; and (3) the instructions were then approved by the PJI Reporter (Justice Ketchum) and the Supervising Judge (Judge Alsop). The Drafting Note in the Preface to the instructions makes clear:

> Drafting Note – Although these instructions are not binding, they have gone through multiple edits and revisions after extensive research and editing by the reporters, the review committees, Judge Alsop, and Justice Ketchum. In addition, there was an extended effort to put the instructions in plain language that can be understood by a lay jury.

Preface to the PJI. Tellingly, in Petitioners' effort to spin a web of conspiracy regarding the drafting of the instructions, they fail to mention that Deborah McHenry, one of the reviewers of the PJI on products liability, was an attorney at the Segal law firm–the law firm representing Petitioners–when the PJI were drafted. *See* Preface to the PJI at iv.

Finger pointing aside, the West Virginia PJI got the law right on strict liability design defect. Prepared under the direction of Justice Ketchum and Judge Alsop, Section 411 went through edits and revisions after "extensive research and editing" by the entire Products Liability Committee which included a Supreme Court Law Clerk, a Supreme Court Justice, and a highly respected Circuit Judge. *See* Preface to PJI. To this day, the Court continues to endorse the PJI by offering them for publication on the Court's website and Instruction 411 was not changed when the instructions were supplemented in September 2017. While Ethicon readily agrees

the instructions do not bind the Court, § 411 constitutes a well-reasoned synopsis of the law in West Virginia as established in *Morningstar* and *Church*.

II. This Court Should Uphold Section 411's Requirement that the Alternative Design "Eliminate" the Risk of Injury.

If this Court agrees with *Church*, the Restatement (Third), the prior federal opinions interpreting West Virginia law (*Mullins* and *Nease*), PJI § 411, and every other state within the Fourth Circuit that a plaintiff must prove a feasible alternative design as an element of her strict liability design defect claim, the question then becomes: what role must the required alternative design play vis-à-vis the risk of plaintiff's injury? And basically, there are two choices. This Court can hold that the alternative design must "reduce" the risk of injury or that the alternative design must "eliminate/avoid/prevent" the risk of injury. As explained below, this Court should approve the West Virginia PJI's requirement that the alternative design must "eliminate" the injury because this is the only way to ensure the alleged design defect actually caused the injury at issue.

a. Section 411's elimination requirement has its roots in West Virginia law and is consistent with other jurisdictions.

The "elimination mandate" found in § 411 is grounded in this Court's negligence opinions, which established a duty on the defendant to "avoid" injury to plaintiff. *Lynch v. Alderton*, 124 W. Va. 446, 20 S.E.2d 657, 662 (1942); *Buchanan v. Norfolk v. W. Railway Co.*, 102 W. Va. 426, 135 S.E. 384, 386 (1926). Both cases

involved vehicular accidents and addressed the question of a defendant's liability for negligence considering the contributory negligence of another. *Buchanan* holds that "[i]f . . . a person who negligently places himself in a situation of imminent danger is injured by one who, by the exercise of reasonable care could have avoided such injury, the negligence of the former will not bar recovery." 135 S.E. at 386. This pair of cases establishes that liability attaches where a different choice by the defendant would have avoided (*i.e.*, eliminated), not just reduced, the injury.

Petitioners argue that no other jurisdiction has adopted a standard akin to § 411's "elimination" mandate. To the contrary, many other jurisdictions go beyond the Restatement (Third)'s "reduce or avoid" language to expressly require an alternative design to prevent the plaintiff's injury.

In Kentucky, Michigan, Mississippi, Louisiana, and Washington, reduction of injury is insufficient–the plaintiff must demonstrate that the alternative design would have prevented the harm. *See, e.g.*, *Jackson v. E-Z-GO Div. of Textron, Inc.*, 326 F. Supp. 3d 375, 391–92 (W.D. Ky. 2018) ("[A] plaintiff must prove that the feasible alternative design would have prevented the injury.") (citation and internal quotation marks omitted); *see also Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004) (same); Mich. Comp. Laws § 600.2946 ("In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product

was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that . . . a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others."); Miss. Code. Ann. § 11-1-63 (manufacturer will not be held liable for design defect unless "there existed a feasible design alternative that would have to a reasonable probability prevented the harm"); La. Rev. Stat. Ann. § 9:2800.56 ("A product is unreasonably dangerous in design if, at the time the product left its manufacturer's control: . . . There existed an alternative design for the product that was capable of preventing the claimant's damage . . . .); Wash. Rev. Code Ann. § 7.72.030 ("A product is not reasonably safe as designed, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm . . . outweighed the burden on the manufacturer to design a product that would have prevented those harms[.]").

There is no difference between a "prevention of injury" and "elimination of injury" standard. For instance, the district court in *Jacobs v. Tricam Indus., Inc.*, 816 F. Supp. 2d 487, 493 (E.D. Mich. 2011), partially excluded the alternative design opinions of the plaintiff's expert on alternative designs because the expert did not sufficiently explain how his proposed alternative "would have prevented [the

plaintiff's] accident." *Id.* This reasoning parallels the decision of the district court in this case to exclude Petitioners' alternative design evidence under *Daubert*.

b. The requirement that the alternative design "eliminate" the risk of injury is needed to ensure a sufficient causal relationship between the plaintiff's injury and the manufacturer's design decision.

Morningstar holds that a manufacturer is not liable for a defective product unless the product defect caused the plaintiff's harm. *See Morningstar*, 162 W. Va. at 883, 253 S.E.2d at 680. Section 411's "elimination mandate" ensures a sufficient causal link between the defect and injury.

In this case, both sides experts acknowledged that erosion was a risk of every bladder surgery, whether mesh is used or not. Recognizing an alternative design that merely reduces, in some amorphous way or to some minute degree, the risk of injury means that liability can be imposed even when the manufacturer's design and the alternative both expose the plaintiff to the same harm. In that case, the plaintiff could suffer the same injury even if the manufacturer adopted a different design. And where the adoption of an alternative design would make no meaningful difference in the plaintiff's outcome, it is impossible to prove causation between the defect and injury.

To illustrate, consider an example. If an alternative would reduce the risk of harm by 1%, it cannot be reliably said that the manufacturer's chosen design caused the plaintiff's injury in the first place. *See Couturier v. Bard Peripheral Vascular,*

Inc., 548 F. Supp. 3d 596, 608 (E.D. La. 2021) ("The requirement that an alternative design be capable of preventing the injury essentially asks whether the defendants' design decisions were a substantial factor in bringing about plaintiff's injuries, *i.e.*, whether plaintiff's injuries would have been prevented "but for" defendant's failure to adopt an alternative design."); *see also Tunnell v. Ford Motor Co.*, 385 F. Supp. 2d 582, 584 (W.D. Va. 2005), *aff'd*, 245 F. App'x 286 (4th Cir. 2007) ("[I]t is a basic concept imbedded in any defectiveness analysis, requiring that a proposed alternative design actually cure a product of its alleged defects."). The "elimination" requirement in § 411 is needed to ensure that a manufacturer is held liable only for a design choice that caused the plaintiff harm.

On this point, the facts here attest to the need for the "elimination" requirement. Ms. Shears suffered a bladder erosion which is a surgical risk inherent in every anti-incontinence surgery, with or without use of the TVT. Plaintiffs alleged that the TVT mesh was defective as designed because the mesh eroded into Ms. Shears' bladder. At trial, Plaintiff's experts conceded that an alternative mesh material would also put Ms. Shears at risk for bladder erosion. Given that the feasible alternative design presents the same risk as the allegedly defective design (a fact conceded by her experts), *see* Fourth Circuit JA 6420–21, 6458–59 (Case No. 22-1399), it is impossible to conclude that Ethicon's design choice caused Ms. Shears' injury. Requiring that the alternative design *eliminate* the risk that injured the

plaintiff creates a sufficient causal connection in which the manufacturer can be said with confidence to have caused the plaintiff's injury by not adopting the alternative.

c. If the Court rejects § 411's "eliminate the risk" standard, the Court should require alternative design evidence to substantially reduce the risk of harm.

Even if the Court determines that § 411's elimination requirement goes too far, a simple "reduce or avoid" standard, like that endorsed by the Restatement (Third) is not appropriate. Showing that the alternative would merely "reduce the risk" should not create a jury question in a design defect case. As stated, such a standard would result in the imposition of liability on the manufacturer where the alternative design achieves only a *de minimis* change in safety.

North Carolina and Texas are just two examples of jurisdictions that require more than simple reduction of risk, but less than prevention or elimination of the risk. *See, e.g.*, N.C. Gen. Stat. Ann. § 99B-6(a)(1) (alternative design must have "prevented or *substantially reduced* the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product") (emphasis added).Tex. Civ. Prac. & Rem. Code Ann. § 82.005(b)(1) (defining "safer alternative design" as a design that "would have prevented or *significantly reduced* the risk of the claimant's personal injury") (emphasis added). Should the Court adopt something less than an elimination standard, the Court should make clear that only a significant or substantial reduction in risk will suffice.

III. The Court Should Give No Weight to Petitioners' "Survey."

Petitioners were granted leave to supplement the joint appendix with the results of a fifty-state survey created by their counsel. The survey purports to provide the Court with an overview of each state's approach to product liability claims for design defect. Their survey is misleading, lacks nuance, and, at times, is flat out wrong. Particularly problematic is the chart Petitioners created to summarize the approach to design defect claims in each state, including whether an alternative design is a requisite element of the cause of action. Respondents do not attempt here to address the law of each jurisdiction, but instead identify several examples where Petitioners' assertions are misleading.

In the column marked with the heading "Safer Alternative Design Required (Y/N)," Petitioners incorrectly characterize the law of Idaho, Iowa, and Maine, all of which appear to require proof of a safer alternative design. *Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 169 (Iowa 2002) (adopting Restatement (Third)'s definition of design defect, including its alternative design requirement); *Puckett v. Oakfabco, Inc.*, 979 P.2d 1174, 1181 (Idaho 1999) (upholding summary judgment for manufacturer where plaintiff could not show the product "exposes users to an unreasonable risk of harm which could be reduced or avoided by adopting a reasonable alternative design"); *Reali v. Mazda Motor of Am., Inc.*, 106 F. Supp. 2d

75, 80 (D. Me. 2000) ("[I]n Maine, a plaintiff in a design defect case must prove that an alternative design is feasible and safer.").

By way of further example, Petitioners' assertions that Connecticut and Minnesota substantive law do not require proof of an alternative design is misleading. *See* JA 089. Plaintiffs claim that evidence of a safer alternative design is "optional" in these states. *Id.* In fact, Connecticut and Minnesota ordinarily require an alternative design but simply adopt the narrow exception described above for exceptionally or manifestly dangerous products. *See Wagner v. Hesston Corp.*, 450 F.3d 756, 760 (8th Cir. 2006) (discussing Minnesota Supreme Court precedent and concluding that an alternative design is not required only in the "rare case" where the product is so dangerous that it should be removed from the market entirely; describing argument that proof of an alternative design is unnecessary "misleading"); *Fajardo v. Boston Sci. Corp.*, 267 A.3d 691, 706–07 (Conn. 2021) (explaining that Connecticut will apply the risk-utility test in all cases except those for which expert testimony is not necessary, and proof of an alternative design will be necessary unless the product's design is so "manifestly unreasonable" that a reasonable consumer would not purchase the product). Characterizing the requirement of an alternative design as "optional" in these states creates the false impression that the plaintiff may simply choose whether or not to produce this critical evidence.

Petitioners' incorrect and misleading assertions illustrate why the Court should afford their survey no weight. Petitioners frequently cite the results of their survey without any direct citation to case law. *See, e.g.*, Petitioners' Br. at 26 (claiming that "a significant number of States [sic] *permit* a plaintiff to submit evidence of a feasible alternative design as part of design defect-based strict product liability claim [sic]" without providing a single case citation). These broad assertions, backed by only the results of their counsel's misleading survey, should be viewed with skepticism.

A thorough survey of the various approaches to design defect can be found in other sources, including Restatement (Third) § 2 (comprehensively surveying each state's approach to liability for defective products); *see also* David G. Owen, *Design Defect Ghosts*, 74 Brooklyn L. Rev. 927 (2009); *Branham*, 701 S.E.2d at 220–23; Aaron D. Twerski and James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Designs: the Triumph of Risk-Utility*, 74 Brooklyn L. Rev. 1061, 1079–93 (2009); Mike McWilliams and Margaret Smith, *An Overview of the Legal Standard Regarding Product Liability Design Defect Claims and a Fifty State Survey on the Applicable Law in Each Jurisdiction*, 82 Def. Counsel J. 80 (2015). There is simply no need for the Court to rely on Petitioners' inaccurate survey.

CONCLUSION

This Court should answer the certified question in the affirmative and find that § 411 of the West Virginia PJI correctly specifies the plaintiff's burden of proof for a strict liability design defect claim pursued under West Virginia law.

Dated: July 26, 2023

Respectfully submitted,

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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

Judith A. Shears and
Gary F. Shears, Jr.,

Petitioners,

v. **Docket No. 23-192**

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, Natalie R. Atkinson, counsel for the Respondents, Ethicon, Inc. and Johnson & Johnson, do hereby certify that on this 26th day of July, 2023, I served the foregoing *Respondents' Brief* on all counsel of record via the Court's E-Filing system and United States Mail, postage prepaid, addressed as follows:

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