PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 16-2279

CAROL SUE CAMPBELL; CHRIS RENE WILSON,

Plaintiffs - Appellees,

and

JEANIE BLANKENSHIP; KAREN MARIE CANTERBURY; DONNA KAY BILLINGS; BEVERLY SEXTON; VIRGIL SEXTON; TAMMY HENDRICKS; STANLEY HENDRICKS; DREAMA MOORE; JACQUELYN TYREE; ROBERT TYREE; SHARON PUGH; THOMAS WILEY PUGH; NEASHA R. WORKMAN,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant - Appellant,

FEDERATION OF DEFENSE & CORPORATE COUNSEL; PRODUCT LIABILITY ADVISORY COUNCIL, INCORPORATED,

Amici Supporting Appellant.

Appeal from the United States District Court for the Southern District of West Virginia, at Charleston. Joseph R. Goodwin, District Judge. (2:12-cv-08633)

Argued: December 7, 2017 Decided: February 6, 2018

Before WILKINSON and DIAZ, Circuit Judges, and SHEDD, Senior Circuit Judge.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Diaz and Senior Judge Shedd joined.

ARGUED: Daniel Brandon Rogers, SHOOK HARDY & BACON L.L.P., Miami, Florida, for Appellant. Anthony J. Majestro, POWELL & MAJESTRO, PLLC, Charleston, West Virginia, for Appellees. **ON BRIEF:** Robert T. Adams, SHOOK, HARDY & BACON L.L.P., Kansas City, Missouri, for Appellant. Scott A. Love, CLARK, LOVE & HUTSON, GP, Houston, Texas, for Appellees. Jeffery A. Kruse, BAKER STERCHI COWDEN & RICE LLC, Kansas City, Missouri; Robert E. Scott, Jr., Marisa A. Trasatti, SEMMES, BOWEN & SEMMES, Baltimore, Maryland, for Amicus Supporting Appellant Federation of Defense & Corporate Counsel. Terri S. Reiskin, Eric C. Tew, DYKEMA GOSSETT PLLC, Washington, D.C.; Hugh F. Young, Jr., PRODUCT LIABILITY ADVISORY COUNCIL, INC., Reston, Virginia, for Amicus Supporting Appellant Product Liability Advisory Council, Inc.

WILKINSON, Circuit Judge:

This case involves a consolidated trial of four products liability cases that are each part of a multidistrict litigation encompassing over twenty-five thousand total cases. The jury returned verdicts for the plaintiffs, awarding over $4 million to each. Defendant Boston Scientific Corporation asserts that the consolidation itself rendered the trial unfair, disputes two evidentiary rulings, claims there was insufficient evidence to support the verdicts, and challenges one of the district court's jury instructions. We reject each of these arguments, and affirm the judgments.

I.

Boston Scientific Corporation (BSC) manufactured a transvaginal mesh prescription medical device called the Obtryx Transobturator Mid-Urethral Sling System. The Obtryx was designed to be permanently implanted as a treatment for severe stress urinary incontinence. The Food and Drug Administration approved the Obtryx in 2004 under the 510(k) process for medical device approval. Approval through the 510(k) process indicates that the FDA found the Obtryx to be "substantially equivalent" to a device already legally on the market, and thus did not require clinical trials of the Obtryx before it was marketed. Prior to marketing, the FDA also approved the Obtryx's directions for use, which included information for physicians on potential complications including pain, dyspareunia (pain with intercourse), and urinary retention.

The Obtryx is made of Marlex polypropylene. While polypropylene mesh has long been used in implantable medical devices, Marlex polypropylene's manufacturer included a caution on its Material Safety Data Sheet (MSDS) stating that it should not be

used "in medical applications involving permanent implantation in the human body." J.A. 4355. The plaintiffs' experts testified at trial that Marlex can degrade when implanted transvaginally, and that it can elicit scar tissue that causes the mesh to shrink.

The plaintiffs whose cases were consolidated for trial below are four women who received Obtryx implants to treat their severe stress urinary incontinence and who allege that they experienced severe complications from the implants. The first plaintiff received her Obtryx implant in 2011. When she later complained of dyspareunia, she was diagnosed with an erosion of the Obtryx, and received follow-up surgery to excise portions of the mesh. The second plaintiff had her Obtryx implanted in 2009, and had the Obtryx sling released in 2012 after complaining of voiding dysfunction. The third plaintiff had the Obtryx implanted in 2010. She received a sling-release procedure in 2013 after she was diagnosed with narrowing of the urethra. The final plaintiff received her Obtryx implant in 2010, and subsequently complained of chronic pelvic pain and dyspareunia.

Each of these four women filed separate lawsuits against BSC. Prior to their individual cases being filed, the Judicial Panel on Multidistrict Litigation had created MDL 2326, *In re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation*, which is pending in the Southern District of West Virginia. The plaintiffs filed their separate cases against BSC directly in this MDL, with each seeking compensatory and punitive damages based on theories of negligence and strict liability for both design defects and failure to warn.

Before case-specific discovery began in any of these cases, the district court consolidated eleven cases for trial under Federal Rule of Civil Procedure 42. Of these eleven, six cases were dismissed and one was removed from the consolidated action prior to trial. At the close of discovery, BSC moved to conduct separate trials for the remaining four cases, arguing that the similarities did not predominate. This motion was denied.

Prior to trial, the court also decided two evidentiary motions relevant to this appeal. BSC moved to exclude evidence of the Marlex polypropylene's MSDS, but the district court denied this motion. However, the district court granted the plaintiffs' motion to exclude evidence concerning the FDA's 510(k) process and approval.

Following an eleven-day trial, the jury returned verdicts awarding past-compensatory damages of $250,000 and punitive damages of $1,000,000 to each plaintiff. Additionally, the jury awarded future-compensatory damages of $3 million to the first plaintiff, $3 million to the second, $3.5 million to the third, and $4 million to the fourth. Since trial, BSC has reached settlements with two of the plaintiffs, while BSC appeals the judgments in favor of the remaining two plaintiffs on the grounds that the district court abused its discretion by consolidating the four cases for trial, by permitting the MSDS evidence, and by excluding the FDA 510(k) evidence. BSC also challenges the verdicts for lacking sufficient evidence. Finally, BSC challenges the punitive damages awards based on what it asserts was an erroneous jury instruction.

II.

BSC's primary contention is that the trial was rendered unfair by the consolidation of four independent cases for trial. We review decisions regarding consolidation for

abuse of discretion. *Arnold v. Eastern Air Lines, Inc.*, 681 F.2d 186, 192 (4th Cir. 1982), *rev'd on other grounds*, 712 F.2d 899 (4th Cir. 1983) (en banc). No such abuse occurred here.

Consolidation is governed by Federal Rule of Civil Procedure 42(a), which provides that: "If actions before the court involve a common question of law or fact, the court may: (1) join for hearing or trial any or all matters at issue in the actions; (2) consolidate the actions; or (3) issue any other orders to avoid unnecessary cost or delay." As this court has previously explained, proper application of Rule 42(a) requires the district court to determine "whether the specific risks of prejudice and possible confusion" from consolidation "were overborne by the risk of inconsistent adjudications . . . , the burden on parties, witnesses, and available judicial resources posed by multiple lawsuits, the length of time required to conclude multiple suits as against a single one, and the relative expense to all concerned of the single-trial, multiple-trial alternatives." *Arnold*, 681 F.2d at 193.

The district court appropriately considered these factors in ultimately ordering consolidation. It first identified the many common questions of law and fact across the trials: The four plaintiffs were each diagnosed with stress urinary incontinence before being implanted with Obtryx devices made by BSC. Each plaintiff alleged that she had experienced similar complications from the Obtryx that required additional medical treatment. Each plaintiff received her Obtryx implant in West Virginia and asserted the same design-defect and failure-to-warn claims under West Virginia law. Because of these many similarities among the cases, the plaintiffs shared expert witnesses and relied on

much of the same evidence from BSC documents. BSC asserted in all four cases both that the Obtryx was not defective and that the Obtryx's directions for use provided sufficient warnings. These many similarities certainly provided the "common question[s] of law or fact" required by Rule 42(a). They also make clear that separate trials would have been largely repetitive, and thus would have implicated the burdens, delays, and expense that *Arnold* noted help justify consolidation.

Of course, regardless of efficiency concerns, consolidation is not appropriate if it would deny a party a fair trial. Alert to this risk, the district court endeavored throughout the trial to limit any potential jury confusion or prejudice resulting from the consolidation. At the outset of trial, the district court instructed the jury that the trial concerned four separate claims and informed them that they must treat each as "as if each have been tried by itself." J.A. 1705–06. During the trial, BSC had the opportunity to address each plaintiff's claims independently, and in fact pursued a comparative negligence defense as to one plaintiff that it did not pursue as to the other plaintiffs. Following trial and prior to jury deliberations, the district court emphasized that the jurors were not to "even consider that more than one claim was brought" in weighing the evidence and that they must consider each case separately. J.A. 1084. To promote independent review of each case, the district court made use of special interrogatories on separate verdict forms for each plaintiff.

BSC contends that despite these protections, it was prejudiced by the admission of evidence in the consolidated trial that was admissible as to only some of the plaintiffs. It chiefly complains of evidence regarding events that took place after some of the plaintiffs

had received their implants, arguing that these events were irrelevant as to those plaintiffs. But it is not clear that this evidence is irrelevant as to any of the plaintiffs. For example, e-mail chains among BSC employees in May 2009 may shed light on what BSC knew in April 2009, when one of the plaintiffs received her implant. Similarly, studies published after the women received their implants, and evidence of how BSC reacted to those studies, may be relevant both to the actual safety of the product and to BSC's general policies regarding how to handle evidence of safety risks. It may well have been within a district court's discretion to admit all of this evidence as to each of the plaintiffs even in separate trials. Indeed, BSC's objections go more to the weight of the evidence than to its admissibility. We certainly cannot say that allowing this evidence in the consolidated trial prejudiced BSC to the extent that consolidation itself was an abuse of discretion.

Further, BSC lacks evidence that the district court's safeguards were inadequate or that consolidation in fact resulted in any prejudice or jury confusion. Instead, it asks us to infer jury confusion based on the similarities of the damages awarded to each plaintiff. Attempting to reverse engineer the jury's thought processes based on its verdicts is always a dangerous enterprise, because we have no way of knowing what really happened during jury deliberations. *See United States v. Powell*, 469 U.S. 57, 66–69 (1984) (declining to review verdicts for inconsistency because of "the general reluctance to inquire into the workings of the jury"). Here, there is little reason to be suspicious of the verdicts given that BSC had a chance to fully develop its defenses and that the judge properly instructed the jury throughout the trial to keep the cases separate. What is more,

the four plaintiffs did not receive identical damages awards, but instead received damages that varied by $1 million across plaintiffs. That the total damages awards were of the same order of magnitude appears to reflect the very similarities between the cases that justified consolidation in the first place.

In the end, it is best not to do a comparative analysis of the damages awards, but instead to ask, as we would in separate trials, whether each award is supported by substantial evidence. Each plaintiff provided evidence that she faced severe complications from her Obtryx implant, including the chronic pelvic pain and dyspareunia experienced by all of the plaintiffs. The plaintiffs also presented evidence that their Obtryx implants had degraded, causing tissue damage and scarring, among other complications. Each of the plaintiffs underwent additional treatment after receiving the Obtryx in order to alleviate some of the symptoms. Despite these interventions, each plaintiff is expected to experience continuing pain and discomfort for the rest of her life. BSC may not like the fact that all four plaintiffs received significant awards, but the harms suffered were serious in each case, and the evidentiary support for each damages award was substantial.

Ultimately, it is clear that the district court was well within its discretion in consolidating these four cases for trial. To hold otherwise would be to sacrifice the substantial savings of time and money that consolidation offers. Both plaintiffs and defendants benefit from lessened litigation costs and the reduced need for expert testimony. Witnesses benefit from reduced demands on their time by limiting the need for them to provide repetitive testimony. The community as a whole benefits from reduced

demands on its resources, including reduced demand for jurors. The judicial system benefits from the freedom consolidation affords judges to conscientiously resolve other pending cases.

The Multidistrict Litigation (MDL) procedure out of which these cases originated reflects the need to promote efficiency without sacrificing fairness in the resolution of large-scale disputes. *See* Stanley J. Levy, *Complex Multidistrict Litigation and the Federal Courts*, 40 Fordham L. Rev. 41 (1971). Through the MDL process, "[w]hen civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). Following consolidated pretrial proceedings, cases that have not been resolved are to be transferred back to their district of origin for trial. *Id.*

The specific MDL of which these cases were a part illustrates the effectiveness of streamlining the judicial process when federal courts are faced with a large number of closely related complaints. The BSC Obtryx MDL, which is still ongoing in the Southern District of West Virginia, involved over 25,000 cases. Of these, over 6,000 cases remain pending as of January 2018. Many of these disputes will be resolved without a trial. The district court judge supervising the MDL also saw the utility of bellwether trials to promote settlement, and thus consolidated a small number of cases for trial in West Virginia and another group of cases for trial in Florida. *See* J.A. 161–67; *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304, 1311–12 (11th Cir. 2017). These efforts appear to have been effective, as thousands of cases have since settled out of the MDL. *See*

Plaintiffs' Response Br. at 30 (quoting Boston Scientific Corporation's Opposition to Petition for Writ of Mandamus at 4, *In re C. Jane Mowry*, No. 16-2333 (4th Cir. Nov. 30, 2016)).

While unfounded products liability suits may run the risk of discouraging product innovation in areas important to public health and safety, BSC fails to make the case that consolidation in and of itself heightens that danger. Consolidation does not alter the basic standard of care required of manufacturers, and its benefits would seem to run to both plaintiffs and defendants. It is not the tool itself, but how it is utilized.

The results here were not purchased at the cost of fairness to any party. In these cases, common questions of fact and law formed a substantial part of each suit, and, as we have noted, the district court bent over backwards to ensure that distinct questions of fact and law could be appropriately developed at trial and distinguished by the jury. It would be inconceivable to hold that the trial court abused its discretion in these circumstances.

III.

BSC also complains of two separate evidentiary decisions: the decision to exclude evidence of the FDA's 510(k) approval of the Obtryx and the decision to permit evidence of the manufacturer's warning on the Material Safety Data Sheet (MSDS). We review district court evidentiary decisions for abuse of discretion. *Cisson v. C.R. Bard, Inc.*, 810 F.3d 913, 920 (4th Cir. 2016). As explained below, we find that the district court acted within its discretion in both of these rulings.

A.

The Obtryx was approved through the 510(k) process, meaning that the FDA found it to be "substantially equivalent" to a product already legally marketed. According to BSC, the Obtryx's approval by the FDA is relevant to show both that the product is reasonably safe for its intended use and that BSC acted reasonably in deciding to market the Obtryx. The district court excluded BSC's proffered evidence regarding the FDA's 510(k) approval process pursuant to Federal Rule of Evidence 403, which provides that courts "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." The district court concluded that the 510(k) evidence was at best of questionable relevance, and that it was "inadmissible because of its potential to confuse the issues and mislead the jury" even if marginally relevant. J.A. 800–01.

Our circuit precedent governs this issue. Two prior Fourth Circuit decisions support the exclusion of 510(k) evidence. In *Cisson v. C.R. Bard, Inc.*, 810 F.3d 913 (4th Cir. 2016), this court affirmed the exclusion of 510(k) evidence in a products liability case involving another manufacturer's transvaginal mesh device. As here, the manufacturer sought to introduce evidence of regulatory compliance to show that its conduct was reasonable, a point that it argued was relevant both to the design-defect claim and to the question of punitive damages. We noted in response that "the probative value of [regulatory compliance] evidence must depend on the extent to which the regulatory framework safeguards consumer safety." *Id.* at 920. Yet the 510(k) process, although "certainly not a rubber stamp program for device approval, [] does operate to

exempt devices from rigorous safety review procedures." *Id.* Thus, "[w]hile 510(k) clearance might . . . say something about the safety of the cleared product, it does not say very much that is specific." *Id.* at 922.

We reaffirmed this conclusion in *Huskey v. Ethicon, Inc.*, 848 F.3d 151 (4th Cir. 2017), another products liability case involving a transvaginal mesh device. The manufacturer in *Huskey* attempted to distinguish *Cisson* based on the specifics of each product's regulatory compliance processes, but we rejected this argument, reasoning that focusing on these details "would only amplify the risk" of "confusion and wasted time." *Id.* at 160–61.

Like the manufacturer in *Huskey*, BSC has tried, and failed, to avoid *Cisson*. BSC faults both *Cisson* and *Huskey* for failing to address the distinction between 510(k) clearance based on a predicate device that was grandfathered in when the process was created and clearance based on a predicate device that itself received a thorough safety evaluation. But this argument, in fact, closely mirrors the argument we rejected in *Huskey*. Admitting the evidence on these grounds would invite a battle of the experts regarding the exact meaning of 510(k) approval in these circumstances, and would risk the same jury confusion we feared in *Cisson*.

In the face of this binding precedent, our decision is clear: the district court was within its discretion to exclude evidence of the Obtryx's 510(k) FDA approval.

B.

Next, BSC objects to the admission of the MSDS Caution evidence. That Caution, included on the Material Safety Data Sheet for the Marlex polypropylene that the Obtryx

was made from, stated that Marlex should not be used "in medical applications involving permanent implantation in the human body." J.A. 4355. BSC argues that the Caution was inadmissible hearsay.

But the MSDS Caution was not hearsay evidence, because it was not admitted for its truth. Under Federal Rule of Evidence 801, an out-of-court statement can constitute hearsay only if "a party offers [it] in evidence to prove the truth of the matter asserted." Here, the MSDS Caution was offered not to establish that the Caution was accurate, but instead to demonstrate that BSC had "notification . . . of the manufacturer's concerns about the safety of its product for permanent implantation" and to address BSC's "knowledge of potential safety concerns in its final product." J.A. 660–61. One need not assume that the Caution is true to find it relevant to BSC's state of mind at various times.

This conclusion is bolstered by our decision in *Cisson*, in which the plaintiffs similarly sought to introduce evidence of the manufacturer's MSDS Caution. As in this case, the Caution was introduced in *Cisson* to suggest that "the company should have further investigated the safety" of its medical device "rather than marketing the product immediately." *Cisson*, 810 F.3d at 926. A cloud, for example, may not bring rain, but it may certainly suggest the possibility of rain and the need to check the forecast. We approved that rationale for use of the MSDS evidence in *Cisson*, and we approve it here.

BSC argues that *Cisson* is distinguishable from this case because, in addition to using the MSDS evidence as the *Cisson* plaintiffs did, the plaintiffs here used the MSDS evidence inappropriately to support their warnings claims. Specifically, BSC notes that

the plaintiffs here suggested that a complete warning would have notified physicians of the MSDS Caution itself.

We are unpersuaded that this distinction requires a different result. BSC correctly notes that there is no duty to warn of a risk that does not exist. *See* BSC Opening Br. at 47. And of course, for the failure-to-warn claim to ultimately succeed, the plaintiffs needed to establish that there were risks from the Obtryx and that those risks injured them. But they did not rely on the MSDS evidence to establish those facts; they relied instead on expert testimony and medical evidence. The MSDS was used in a different way: The existence of the MSDS Caution, and the statements of various doctors that they would have used the Obtryx differently had they known about the warning, evinced not that the warning was correct, but rather that BSC reasonably could have provided the relevant information to physicians. Indeed, BSC could have done so even while explaining why it nonetheless believed the Obtryx to be safe. Providing both the Caution and their own data would have given physicians a clearer picture of what was and was not known regarding the Obtryx's safety. It is not unreasonable to expect manufacturers of medical devices to level with the physicians who are responsible for implanting their devices in who knows how many patients.

According to the plaintiffs and their experts, the MSDS Caution was later shown to reflect real risks, and the dangers of permanent implantation of Marlex polypropylene caused the plaintiffs' injuries. But because the plaintiffs offered evidence of the MSDS Caution not for its truth, but rather for the simple fact of the Caution's existence and

BSC's awareness of it, it was not hearsay. The district court thus did not abuse its discretion in admitting this evidence.

IV.

BSC next contends that it is entitled to judgment as a matter of law because the plaintiffs provided insufficient evidence to support their claims. Notably, because the plaintiffs' design-defect claims and failure-to-warn claims simply provide alternative bases to recover the same damages, overturning the verdicts on only one of these counts would not affect the damages awards themselves or necessitate a new trial. Thus, BSC must establish that there was insufficient evidence for both sets of claims in order to defeat the jury awards.

"A reviewing court may set aside the jury's verdict on the ground of insufficient evidence only if no rational trier of fact could have agreed with the jury." *Cavazos v. Smith*, 565 U.S. 1, 2 (2011) (per curiam). Thus, jury verdicts are set aside only in unusual circumstances. Those circumstances are not present here.

A.

We begin with the plaintiffs' design-defect claims. Under West Virginia law, a design-defect case requires the plaintiff to show that "the involved product is defective in the sense that it is not reasonably safe for its intended use" based on "what a reasonably prudent manufacturer's standards should have been at the time the product was made." *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 683 (W. Va. 1979). BSC argues that the evidence was insufficient for these claims because the plaintiffs did not

establish a specific design flaw, did not establish that the Obtryx differed from other polypropylene mesh slings, and did not provide evidence of a safer alternative design.

But the plaintiffs did identify several aspects of the Obtryx's design that allegedly contributed to its dangers. These included the difficulty of removing the Obtryx after implantation, the use of Marlex polypropylene, and the use of polypropylene generally. While BSC might dispute that any of these aspects of the Obtryx's design are "defects," the jury was entitled to conclude otherwise based on the evidence presented to it.

Similarly, the plaintiffs were not necessarily required to demonstrate that the Obtryx was different from other polypropylene mesh slings. It is possible for an entire class of products to suffer from the same or similar design defects. (In fact, several other sling manufacturers are facing their own product liability MDLs.) Even were they required to make this showing, however, the plaintiffs pointed out that the Obtryx, unlike other slings, was made from Marlex polypropylene, and that Marlex had an MSDS Caution against permanent implantation. At the least, the jury could have seen this as a difference in considering what a reasonable manufacturer would have done at the relevant times.

BSC's insufficient-evidence argument regarding a safer alternative design is also easily dealt with by reference to the trial record, which reveals that the plaintiffs did present evidence of safer alternatives. For example, one expert discussed a comparative study of the Obtryx and another BSC device that found no difference in cure rates between the two devices but more groin pain among women who received the Obtryx. *See* J.A. 2026–33.

BSC also claims that, even if there was sufficient evidence to support the jury's verdict, it is entitled to a new trial in which the jury receives an instruction that a safer alternative is an element of the plaintiffs' claims. This argument is made for the first time on appeal, however, and ordinarily we do not consider such arguments. *See Williams v. Professional Transp. Inc.*, 294 F.3d 607, 614 (4th Cir. 2002). BSC is correct that there are exceptions to this rule, but those apply "in very limited circumstances" where "the error is 'plain' and [] our refusal to consider [it] would result in the denial of fundamental justice." *Stewart v. Hall*, 770 F.2d 1267, 1271 (4th Cir. 1985). At the time of trial, the question whether West Virginia design-defect claims required evidence of a safer design was a disputed one. And while we have recently held that West Virginia law "require[s] the production of evidence on reasonable alternative design," *Nease v. Ford Motor Co.*, 848 F.3d 219, 234 (4th Cir. 2017), this does not necessarily establish that a reasonable alternative design is actually a separate element of a design-defect claim. We need not decide that issue today; it was not plain error to decline to instruct a jury on an element that may not be a part of the claim.

B.

Turning to the failure-to-warn claims, BSC argues that the plaintiffs did not introduce expert testimony establishing that the directions for use were inadequate, and that this dooms their claims. As noted earlier, the plaintiffs did provide expert testimony on the risks posed by the Obtryx, but they did not provide expert testimony on the adequacy of the Obtryx's directions for use. BSC's argument relies on the contention that expert testimony is required as a matter of law in West Virginia to establish a failure-to-

warn claim. Their sole citation for this proposition, however, is *Morningstar*, in which the West Virginia Supreme Court of Appeals stated that "[i]n a product liability case, the expert witness is ordinarily the critical witness" because he "serves to set the applicable manufacturing, design, labeling and warning standards based on his experience and expertise in a given product field." *Morningstar*, 253 S.E.2d at 682. This hardly establishes that expert testimony is *required* to establish a failure-to-warn claim.

BSC contends further that "[t]he adequacy of a manufacturer's warnings to physicians for a medical device is not within the 'common knowledge and experience of a lay juror.'" BSC Opening Br. at 54 (quoting *Watson v. Inco Alloys Int'l*, 545 S.E.2d 294, 303 (W. Va. 2001)). But whether this information is within the common knowledge of a juror goes to whether expert testimony would be helpful to a jury, and thus to whether the testimony is admissible. We agree that expert testimony on the adequacy of the Obtryx's instructions may well have been helpful in this case. But again, that does not mean that it was required. The jury heard evidence regarding the risks of the Obtryx, and also heard evidence concerning what risks the Obtryx's directions for use actually warned of. This evidence was largely introduced through the testimony of physicians, some of whom testified that there were significant risks not included in the Obtryx's directions for use. A jury could reasonably conclude based on this evidence that the Obtryx's instructions were inadequate.

V.

BSC's final challenge to the result below asserts that the district court instructed the jury on the wrong standard for punitive damages. According to BSC, punitive damages should have been governed by a clear-and-convincing-evidence standard.

We hold, however, that the district court's instruction was a correct statement of West Virginia law at the time of the trial. Various trial courts in West Virginia had applied the preponderance-of-the-evidence standard, and the West Virginia Supreme Court of Appeals had affirmed such decisions. *See, e.g., Goodwin v. Thomas*, 403 S.E.2d 13, 16–17 (W. Va. 1991). The West Virginia Supreme Court of Appeals had also specifically rejected the claim that clear and convincing evidence was required before a trial judge could give a jury instruction on punitive damages. *Coleman v. Sopher*, 499 S.E.2d 592, 606 n.21 (W. Va. 1997). Neither of these cases squarely confronted the question of the appropriate standard for evaluating punitive damages claims, but they do provide useful evidence regarding how the West Virginia Supreme Court of Appeals would most likely have decided this question.

BSC notes that after the trial in this case, the West Virginia legislature passed a statute establishing that punitive damages may be awarded only "if a plaintiff establishes by clear and convincing evidence" that he is entitled to such damages. W. Va. Code § 55-7-29. This statute was not in effect at the time of the trial, however, and thus provides little insight into the law at the relevant time.

Because the district court correctly instructed the jury regarding the standard for punitive damages in West Virginia as it existed at the time of the trial, we affirm the jury's punitive damages award.

VI.

Based on the foregoing, the judgments of the district court are

AFFIRMED.