PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-1102

In Re: C.R. BARD, INCORPORATED, MDL. No. 2187,
Pelvic Repair System Products Liability Litigation

DONNA CISSON; DAN CISSON,

Plaintiffs - Appellees,

v.

C.R. BARD, INCORPORATED,

Defendant – Appellant,

SAMUEL S. OLENS, Attorney General of the State of Georgia,

Intervenor.

FEDERATION OF DEFENSE & CORPORATE COUNSEL; PRODUCT LIABILITY ADVISORY COUNCIL, INCORPORATED; COOK BIOTECH INCORPORATED; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; COOK INCORPORATED; COOK MEDICAL LLC,

Amici Supporting Appellant,

PUBLIC JUSTICE; NATIONAL CENTER FOR HEALTH,

Amici Supporting Appellees.

No. 15-1137

In Re: C.R. BARD, INCORPORATED, MDL. No. 2187,
Pelvic Repair System Products Liability Litigation

DONNA CISSON; DAN CISSON,

Plaintiffs - Appellants,

v.

C.R. BARD, INCORPORATED,

Defendant – Appellee,

SAMUEL S. OLENS, Attorney General of the State of Georgia,

Intervenor.

FEDERATION OF DEFENSE & CORPORATE COUNSEL; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; PRODUCT LIABILITY ADVISORY COUNCIL, INCORPORATED,

Amici Supporting Appellee,

PUBLIC JUSTICE; NATIONAL CENTER FOR HEALTH,

Amici Supporting Appellants.

Appeals from the United States District Court for the Southern District of West Virginia, at Charleston. Joseph R. Goodwin, District Judge. (2:11-cv-00195)

Argued: September 16, 2015 Decided: January 14, 2016

Before GREGORY, AGEE, and DIAZ, Circuit Judges.

Affirmed by published opinion. Judge Gregory wrote the opinion, in which Judge Agee and Judge Diaz joined.

ARGUED: Elliot H. Scherker, GREENBERG TRAURIG, P.A., Miami, Florida, for Appellant/Cross-Appellee. Anthony J. Majestro, POWELL & MAJESTRO, PLLC, Charleston, West Virginia, for Appellees/Cross-Appellants. Julie Adams Jacobs, OFFICE OF THE ATTORNEY GENERAL OF GEORGIA, Atlanta, Georgia, for Intervenor. **ON BRIEF**: Lori G. Cohen, R. Clifton Merrell, II, Sean P. Jessee, Atlanta, Georgia, Daniel I.A. Smulian, GREENBERG TRAURIG, LLP, New York, New York; Brigid F. Cech Samole, Jay A. Yagoda, GREENBERG TRAURIG, P.A., Miami, Florida; Melissa Foster Bird, NELSON MULLINS RILEY & SCARBOROUGH, Huntington, West Virginia, for Appellant/Cross-Appellee. Allison Van Laningham, TURNING POINT LITIGATION, Greensboro, North Carolina; Henry G. Garrard, III, Josh B. Wages, BLASINGAME, BURCH, GARRARD, ASHLEY PC, Athens, Georgia, for Appellees/Cross-Appellants. Samuel S. Olens, Attorney General, W. Wright Banks, Jr., Deputy Attorney General, OFFICE OF THE ATTORNEY GENERAL OF GEORGIA, Atlanta, Georgia, for Intervenor. Debra Tedeschi Varner, MCNEER, HIGHLAND, MCMUNN & VARNER LC, Clarksburg, West Virginia; Stacy A. Broman, MEAGHER & GEER PLLP, Minneapolis, Minnesota, for Amicus Federation of Defense & Corporate Counsel. Chilton Davis Varner, Stephen B. Devereaux, Madison H. Kitchens, Atlanta, Georgia, Jeffrey S. Bucholtz, Paul Alessio Mezzina, KING & SPALDING LLP, Washington, D.C., for Amici Product Liability Advisory Council, Inc. and Chamber of Commerce of the United States; Hugh F. Young, Jr., PRODUCT LIABILITY ADVISORY COUNCIL, INC., Reston, Virginia, for Amicus Product Liability Advisory Council, Inc.; Kathryn Comerford Todd, Sheldon Gilbert, NATIONAL CHAMBER LITIGATION CENTER, INC., Washington, D.C., for Amicus Chamber of Commerce of the United States. Douglas B. King, WOODEN & MCLAUGHLIN LLP, Indianapolis, Indiana, for Amici Cook Incorporated, Cook Medical LLC, and Cook Biotech Incorporated. Michael J. Quirk, Esther E. Berezofsky, Joseph Alan Venti, WILLIAMS CUKER BEREZOFSKY, LLC, Philadelphia, Pennsylvania, for Amici Public Justice, P.C., and National Center for Health Research.

GREGORY, Circuit Judge:

On August 15, 2013, a jury awarded Donna Cisson $250,000 in compensatory damages on a design defect and failure to warn claim against C.R. Bard, Inc. ("Bard"), and awarded an additional $1,750,000 in punitive damages. The punitive damages award was split pursuant to a Georgia statute, with seventy-five percent going to the State of Georgia and twenty-five percent going to Cisson. This was the first jury verdict arising from multi-district litigation involving more than 70,000 cases against the proprietors of transvaginal mesh medical devices used to treat pelvic organ prolapse and other pelvic issues, of whom Bard is one.

We address several issues on appeal. The first issue raised by Bard is the district court's refusal to admit evidence relating to Bard's compliance with the Food and Drug Administration's ("FDA") Section 510(k) product safety process ("510(k) process"). Second, Bard challenges the denial of its motion in limine asking the district court to exclude evidence and argument pertaining to a material data safety sheet ("MSDS") produced for polypropylene, a key material in the Avaulta Plus surgical mesh. Bard argues that the MSDS relied on by Cisson was hearsay outside any exception. Third, Bard appeals the district court's jury instruction on causation, arguing that under controlling Georgia law the court should have told jurors

that causation must be demonstrated by expert testimony stated to a reasonable degree of medical probability. Bard also argues that, as a matter of law, the evidence Cisson presented to prove causation was insufficient to meet this more rigorous standard. Bard's final challenge on appeal is to the constitutionality of the punitive damages award, which it argues is excessive and in violation of the Due Process Clause. In a cross-appeal, Cisson argues that the district court committed constitutional error by failing to find that the Georgia split-recovery statute violates the Takings Clause. For the reasons that follow, we affirm the district court on all issues.

I.

Cisson was implanted with the Avaulta Plus, a transvaginal mesh medical device developed and marketed by Bard, on May 6, 2009, to address pelvic organ prolapse and stress urinary incontinence. The surgery was performed by Dr. Brian Raybon, a physician who had provided input to Bard during the development of the Avaulta Plus and who trained other physicians to use the device. Prior to her procedure, Cisson received warnings about a number of risks that could result from the surgical implant and signed a consent form acknowledging these warnings. Three months after the surgery, Cisson's doctor diagnosed "an adhesion band" of scar tissue running across her vagina that was taut

like a "banjo string" and was causing Cisson pain. Dr. Raybon resected the mesh, which involved cutting out a thick band of scar tissue and mesh encased in the tissue. Three weeks after the resection surgery, Cisson returned to Dr. Raybon who said she was healing well and should return in a year. Instead, a few months later, Cisson went to a different doctor who referred her to Dr. John Miklos. Dr. Miklos explanted the Avaulta Plus from Cisson's body, although complete removal of the mesh was not possible.

Complaining that the surgical mesh marketed by Bard caused ongoing "loss of sexual feeling" and "severe pain with intercourse and otherwise," Cisson filed a lawsuit against Bard in March 2011 in the Northern District of Georgia. Bard already faced suits from other claimants dating back to 2009, and the Judicial Panel for Multidistrict Litigation had begun transferring these cases to the Southern District of West Virginia in 2010. In re Avaulta Pelvic Support Sys. Prods. Liab. Litig., 746 F. Supp. 2d. 1362 (J.P.M.L 2010). Cisson's suit was added to these and would later become the first to reach a jury verdict.

On June 4, 2013, Bard won summary judgment on Cisson's claims for negligent inspection, marketing, packaging and selling, manufacturing defect, and breach of warranty. The district court allowed claims for design defect, failure to

warn, and loss of consortium to proceed to trial. During the trial, Cisson focused both her design defect and failure to warn claims on several alleged dangers presented by the Avaulta Plus. Expert witnesses were brought to testify that the design of the device's arms, used to anchor the Avaulta Plus inside a patient's body, resulted in ongoing pain to a patient as long as the device was implanted. Experts also testified that the pores in the mesh component of the Avaulta Plus were too small and that the mesh was subject to shrinking after implantation, with the result being a rigid scar plate and increasing tension on internal tissue. Cisson's experts further testified that polypropylene, from which the monofilament used in the Avaulta Plus mesh was made, may be attacked by the patient's body, causing inflammation of the tissue and degradation of the mesh. Slides were presented to the jury that Cisson's expert, Dr. Bernd Klosterhalfen, testified showed the polypropylene of the Avaulta Plus in Cisson's body was being attacked, causing a scar plate to form.

Beyond presenting evidence that the Avaulta Plus had caused her injuries, Cisson also painted a picture of Bard as ignoring, and at times hiding from others, the warning signs that its product could cause injuries. There was substantial argument regarding a MSDS Bard received from Phillips Sumika Polypropylene Company ("Phillips"), the corporation that

manufactured the polypropylene pellets used to extrude the Avaulta Plus mesh. The MSDS contained an explicit warning that polypropylene should not be used in short- or long-term human implantations. Internal e-mails showed that Bard executives knew about the MSDS, and that they sought to prevent their monofilament suppliers from learning of the warning. In addition to raising its hearsay objection to the MSDS, Bard countered that polypropylene had been used for decades in clinical settings and that the warning was with respect to polypropylene pellets, not to the extruded monofilament used in the Avaulta Plus.

Bard argued to the jury that its product was similar to the Avaulta Classic—a predecessor surgical mesh device that Bard contended had been safely used for years—and that it had taken appropriate steps to ensure biocompatibility and product safety. Bard argued to the judge (on evidentiary motions) that it was unfair to allow Cisson to attack its product's safety while Bard was prevented from presenting evidence that it complied with the FDA's 510(k) process.

The jury ultimately credited Cisson's evidence, awarding damages for the design defect and failure to warn claims. The jury returned a verdict for Bard on the consortium claim. Bard timely noted this appeal.

II.

Bard's first claim on appeal is that the district court abused its discretion by granting Cisson's motion in limine asking the court to exclude all evidence that Bard had complied with the FDA's 510(k) process. Bard sought to admit the evidence to show that its conduct was reasonable. Bard argued that this was relevant to its defense to the design defect claim under Georgia's product liability case law, as well as to the question of punitive damages. The district court excluded the evidence under Federal Rule of Evidence 402 for lack of relevance, and under Rule 403 for being substantially more prejudicial than probative. We affirm the court's ruling based on Rule 403 and therefore need not address its reliance on Rule 402.[1]

[1] We also need not address Bard's contention that state law, rather than federal, controls the question—at least not at any great length. Because this is a diversity case, the "general rule" is that federal courts apply state substantive law and federal procedural law. Hottle v. Beech Aircraft Corp., 47 F.3d 106, 109 (4th Cir. 1995). As procedural rules, the Federal Rules of Evidence control over conflicting state evidentiary rules in diversity cases. Id. Only where a state evidentiary rule is "bound-up" with substantive state policy will it control over the federal rule. Id. at 110. This is not such a case.

First, Bard fails to point to a state evidentiary rule contradicting Rule 403. Instead, Bard argues that regulatory compliance has been ruled relevant in numerous Georgia product liability cases. But the rulings Bard points to are just that—rulings, not rules. Bard does not demonstrate that Georgia law requires evidence of regulatory compliance to be admitted in all (Continued)

A.

Although Rule 403 will "generally favor admissibility," United States v. Wells, 163 F.3d 889, 896 (4th Cir. 1998), district courts are granted "broad discretion" to decide "whether the probative value of evidence is substantially outweighed by the danger of unfair prejudice, misleading the jury, or confusion of the issues," Minter v. Wells Fargo Bank, N.A., 762 F.3d 339, 349 (4th Cir. 2014). "[E]xcept under the most 'extraordinary' of circumstances, where that discretion has been plainly abused," this Court will not overturn a trial court's Rule 403 decision. United States v. Simpson, 910 F.2d 154, 157 (4th Cir. 1990) (quoting United States v. Heyward, 729 F.2d 297, 301 n.2 (4th Cir. 1984)) (internal quotation marks omitted).

Cisson's claim for design defect is controlled by Georgia product liability law. Georgia uses a "risk-utility" test for product liability claims, requiring the trial court to "evaluate

---

cases regardless of probative value or prejudicial effect, so there is no competing rule.

Second, Bard fails to demonstrate that the alleged rule is sufficiently "bound-up" with substantive state policy. Regulatory compliance is one of at least thirteen non-exclusive factors Georgia courts consider under the risk-utility test—hardly a cornerstone of the state's product liability jurisprudence. Ga. Suggested Pattern Jury Instruction, Vol. I: Civil Cases § 62.650 (5th ed. 2015).

design defectiveness under a test balancing the risks inherent in a product design against the utility of the product so designed." Banks v. ICI Americas, Inc., 450 S.E.2d 671, 674 (Ga. 1994). This test includes some reliance on "negligence principles," and "incorporates the concept of 'reasonableness,' i.e., whether the manufacturer acted reasonably in choosing a particular product design, given the probability and seriousness of the risk . . . , the usefulness of the product in that condition, and the burden on the manufacturer to . . . eliminate the risk." Id. at 673-74. Bard argues that compliance with the 510(k) process was important to its design defect defense because it shows that the company's conduct was reasonable.

Assuming without deciding that the 510(k) compliance evidence is relevant, under Georgia's risk-utility test the probative value of that evidence must depend on the extent to which the regulatory framework safeguards consumer safety. The 510(k) process allows some medical devices to avoid the strict safety testing requirements imposed by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act, so long as the device is "substantially equivalent" to a pre-1976 device already in use at that time. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996). Thus, devices approved under the 510(k) process "may be marketed without premarket approval" as would be required by the MDA, although they "are subject to

'special controls . . . that are necessary to provide adequate assurance of safety and effectiveness.'" Talley v. Danek Med., Inc., 179 F.3d 154, 160 (4th Cir. 1999) (quoting 21 U.S.C. § 360c(a)(1)(B)). In this respect, although the process is certainly not a rubber stamp program for device approval, it does operate to exempt devices from rigorous safety review procedures.

While some courts have found evidence of compliance with the 510(k) equivalence procedure admissible in product liability cases, the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value. The Supreme Court has regarded product clearance accomplished through the 510(k) process as "a qualification for an exemption rather than a requirement." Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008). This is in part because the "process impose[s] no requirements with respect to the design of the device." Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324, 329 (4th Cir. 1996). "Thus, even though the FDA may well examine 510(k) applications . . . with a concern for the safety and effectiveness of the device," the agency's clearance rests only on whether the device is "substantially equivalent to one that existed before 1976" before allowing it "to be marketed without running the gauntlet of the [MDA premarket approval] process." Lohr, 518 U.S. at 493-94.

Bard points out that much of this precedent stems from the Supreme Court's decision in Lohr, and argues that the case and its progeny should not be controlling here. Bard argues that because Lohr held only that state common law claims were not preempted by the MDA and the 510(k) process, id., and not that compliance with the 510(k) process was inadmissible as evidence to refute such claims, it is an inapposite precedent. However, the Supreme Court held that state law product liability claims were not preempted because the 510(k) does not amount to a safety regulation requiring device producers to meet any established design standards. Id. The entire analysis turned on the Court's finding that "the § 510(k) exemption process was intended to . . . maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents," not impose new regulatory requirements on devices. Id. at 494. Numerous courts, including this one, have relied on that reasoning in cases over the past two decades, and at a minimum the Supreme Court's statements about the 510(k) process (repeated most recently in 2008) are very persuasive as to whether and how compliance speaks to the relative safety of a device.

Nor is Bard helped by FDA statements claiming that "the principles of safety and effectiveness underlie the substantial equivalence determination" that is the heart of the 510(k)

review process. 2014 Guidance for Industry and Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 6. Such statements merely show that the FDA believes an equivalence determination is sufficient to "provide a reasonable assurance of safety and effectiveness," id. at 7, but this was also the case when the Supreme Court found the 510(k) process insufficiently tied-up with safety to preempt state tort actions, Lohr, 518 U.S. at 493-94, and again when the Court called the process an "exemption" and not a safety "requirement," Riegel, 552 U.S. at 322. Bald assertions by the FDA do little to alter the analysis of the basic question: How much information does 510(k) clearance provide a jury about the safety of the underlying product, and is the value of this information substantially outweighed by the possibility of prejudice in a particular case?

Turning, then, to the district court's ruling, it is clear that the court did not abuse its discretion by excluding Bard's evidence of 510(k) clearance. In one of several related rulings, the court stated that bringing in such evidence would result in a "mini-trial" about (1) the strengths and weaknesses of the process and (2) whether Bard had in fact made all of the disclosures it should have made during the process. Bard's evidence would have initiated a battle of experts: Bard was prepared to characterize the review process as "thorough" and

"robust" and the FDA's clearance of the Avaulta Plus as "an affirmative safety . . . decision" based on "specific safety and efficacy findings." JA 613-15. Cisson was prepared to argue, as she has done before this Court, that these characterizations wildly inflate the significance of the process, and that in any event Bard failed to make necessary disclosures to the FDA.

All of this, the district court reasoned, presented "the very substantial dangers of misleading the jury and confusing the issues." JA 1251. The court expressed concern that subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a "mini-trial" could easily inflate the perceived importance of compliance and distract the jury from the central question before it—whether Bard's design was unreasonable based on any dangers it posed versus the costs required to avoid them. While 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific. The vast majority of courts have said so, and having been thoroughly briefed not only by the parties but by several amici, we say so again today. As such, the district court did not abuse its discretion when it determined that allowing the 510(k) evidence

in on the question of design defect would be substantially more prejudicial than probative.

B.

Bard also argues that evidence of 510(k) compliance would have been particularly relevant on the question of punitive damages. Under Georgia law, punitive damages are available where there is "clear and convincing evidence" of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). And Georgia courts have noted that regulatory "compliance does tend to show" this high willfulness standard has not been met. Barger v. Garden Way, Inc., 499 S.E.2d 737, 743 (Ga. App. 1998).

Although the question remains one of federal, not state, evidentiary law, federal courts are not likely to disagree with the Georgia courts that evidence regarding regulatory compliance (or non-compliance) is often relevant to the willfulness inquiry. See Restatement (Third) of Torts, Prod. Liab. § 4. Nevertheless, Bard's argument is ultimately unpersuasive. While such evidence may be relevant, the compliance at issue in this case was, at most, minimally so. Again, the 510(k) process has been repeatedly characterized as something less than a safety requirement, gaining the applicant an exemption from regulation

rather than subjecting the applicant to regulation. Riegel, 552 U.S. at 322; see also Almy v. Sebelius, 679 F.3d 297, 308 (4th Cir. 2012); Rodriguez v. Stryker Corp., 680 F.3d 568, 574 (6th Cir. 2012) ("The 510(k) process does not comment on safety."). Thus, the decision to pursue 510(k) clearance was a choice to minimize the burden of compliance, potentially cutting in favor of punitive damages. See Anastasi v. Wright Med. Tech., Inc., 16 F. Supp. 3d. 1032, 1036-37 (E.D. Mo. 2014) (finding that defendant chose the FDA 510(k) process to "avoid the safety reviews, including clinical trials, required for pre-market approval under FDA regulations"). As such, the district court is entitled to put 510(k) evidence before the jury, but it is not obligated to do so. The court was within its discretion to determine that the value of putting the controversy over the 510(k) process, and Bard's compliance or non-compliance with that process, before the jury was substantially outweighed by the likelihood of confusing the issues and misleading the jury.

C.

This Court does not reach the district court's ruling that the 510(k) evidence could be excluded as irrelevant under Rule 402 because the evidence was properly excluded under Rule 403. The district court's Rule 403 ruling implicitly indicates that even if the evidence is relevant, it is insufficiently relevant to warrant admission. We agree that the district court was

within its discretion in denying admission of the evidence using the lower standard in Rule 403, and therefore decline to address the more difficult question presented by the Rule 402 ruling.

III.

The second issue on appeal is whether the district court erred when it overruled Bard's hearsay objections to the admission of a MSDS pertaining to polypropylene, a material used in the construction of the Avaulta Plus implanted in Cisson's body. There is, of course, a presumption that hearsay will not be admitted into evidence in federal courts. Fed. R. Evid. 802. The MSDS in question in this case read in pertinent part as follows:

> MEDICAL APPLICATION CAUTION: Do not use this . . . material in medical applications involving permanent implantation in the human body . . . . Do not use this . . . material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues, unless the material has been provided directly from [Phillips] under an agreement which expressly acknowledges the contemplated use.

JA 4826.

The district court accepted Cisson's argument that the MSDS could come in as non-hearsay for the limited purpose of showing that the statement was made and that Bard was aware of it. The court also ruled, sua sponte, that the MSDS was admissible for

its truth under the hearsay exceptions contained in Federal Rules of Evidence 803(17), 803(18), and 807.

We review the district court's applications of the hearsay rules, like applications of all Federal Rules of Evidence, for abuse of discretion, and its interpretations of such rules de novo. Precision Piping & Instruments, Inc. v. E.I. du Pont de Nemours & Co., 951 F.2d 613, 619 (4th Cir. 1991). Doing so, we reverse the district court's rulings as to the hearsay exceptions. However, we affirm the decision to admit the evidence as non-hearsay, finding that any use of the evidence by the plaintiff that went beyond the limited purpose for which it was admitted as non-hearsay resulted in harmless error and was not prejudicial to Bard's defense.[2]

A.

Rule 803(17), titled "Market Reports and Similar Commercial Publications," creates an exception to the prohibition on hearsay for "market quotations, lists, directories, or other

[2] Cisson argues that Bard waived its right to attack the MSDS rulings on appeal by failing to continually object. Bard, however, was relieved of this obligation by Rule 103(b) once the court had "definitively" ruled on the matter. Fed. R. Evid. 103(b). Cisson also argues that Bard waived this attack by introducing earlier versions of the MSDS for discussion by its witnesses, but this, of course, was in response to the district court overruling Bard's several objections to admission of the MSDS. Once a court has definitively decided evidence can come in, the opposing party must be allowed to defend against that evidence without losing its otherwise well-preserved objection.

compilations that are generally relied on by the public or by persons in particular occupations." Fed. R. Evid. 803(17). The district court ruled that the MSDS qualified as an "other compilation" within this exception. We disagree.

The district court's ruling relied on its interpretation of the term "other compilation" in Rule 803(17). A question of interpretation going to the scope of the rule is reviewed de novo. See Precision Piping, 951 F.2d at 619. Our analysis is guided by ejusdem generis, a statutory canon of interpretation holding that where a statute contains an exemplary list of objects to which it applies, a general term that follows specific ones will be limited in its meaning by the more specific terms that preceded it. Circuit City Stores, Inc. v. Adams, 532 U.S. 105, 114-15 (2001). The district court's reliance on the general term—"other compilations"—concluding Rule 803(17)'s exemplary list makes the canon applicable.

The narrower terms listed by the rule—"market quotations, lists, directories"—are items that recite established factual information. In general, a MSDS might contain similarly factual information. But in this case, Cisson sought to use a portion of the MSDS that was not factual but rather operated as a warning and disclaimer of liability for the self-interested issuing party. The warning from Phillips that polypropylene should not be used in human implants was an opinion the company

issued within the MSDS for self-interested reasons, and it therefore bears no resemblance to the factual, list-type documents enumerated in Rule 803(17).

An advisory note to Rule 803(17) states that "[t]he basis of trustworthiness" for evidence admitted under the exception should be "the motivation of the compiler to foster reliance by being accurate." Fed. R. Evid. 803(17), advisory comm. note (1972). Disclaimers of the sort in the MSDS are not typically so motivated, being intended instead to prevent any use of a product that might create a liability. Cisson has offered no proof or argument that the disclaimer warrants the same presumption of reliability afforded to market quotations and directories, and a disclaimer clearly lacks the hallmarks of reliability that make market reports an exception. The district court therefore erred in holding the MSDS admissible for its truth under Rule 803(17).

B.

Rule 803(18), titled "Statements in Learned Treatises, Periodicals, or Pamphlets," creates an exception to the prohibition on hearsay when a statement in such publications is (1) "called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination"; (2) the reliability of that statement is established "by the expert's admission or testimony, by another expert's testimony,

or by judicial notice"; and (3) the statement is read into evidence rather than being received as an exhibit. Fed. R. Evid. 803(18). The district court ruled, again sua sponte, that the MSDS could come in for the truth of the matter asserted as a "pamphlet" within the exception. Again, we disagree. We review this application of Rule 803(18) for abuse of discretion.

The MSDS, as used in this case, does not meet any of the rule's three facial requirements. First, it was not "relied on by [an] expert on direct examination," nor was it "called to the attention of an expert witness on cross-examination": Cisson's expert witnesses did not address the MSDS, and Bard's witnesses attacked the MSDS on direct examination. Second, the publication was not "established as a reliable authority" for the same reasons—because Cisson's witnesses did not address the MSDS and Bard's witnesses attacked it, no witness testifying at trial ever sought to demonstrate the reliability of the MSDS.[3] Finally, Cisson introduced the MSDS as an exhibit rather than having it read into evidence as required by the rule. Fed. R. Evid. 803(18). Therefore, without addressing whether the MSDS presented in this case could have qualified as a "pamphlet," we

[3] Nor did the district court invoke judicial notice to establish the reliability of the MSDS. The reliability of the MSDS warning was clearly in dispute at trial, and judicial notice would have been improper.

find that the district court abused its discretion by admitting it under Rule 803(18) because the reliability of the evidence was not established according to the rule's requirements.

C.

Rule 807, titled the "Residual Exception," creates a hearsay exception for certain statements not covered by any exceptions in Rule 803 or 804. Fed. R. Evid. 807. For a statement to come under this exception it must contain "circumstantial guarantees of trustworthiness," be used to prove "a material fact," and be "more probative on the point for which it is offered than any other evidence" available through "reasonable efforts." Id. We review the district court's application of the rule here for an abuse of discretion, noting however that the residual hearsay exception "was meant to be invoked sparingly." Heyward, 729 F.2d at 299 (quotation marks omitted).

As discussed in more detail below, the MSDS was hardly the best evidence available that polypropylene was potentially dangerous for human implantation. The relative dangers of polypropylene in pellet and monofilament form was an issue that received substantial attention from both parties' experts who themselves relied on studies, reports, empirical evidence, and tissue sample slides evidencing Ms. Cisson's particular pathology. The warning in the MSDS, on the other hand, was

nothing more than an assertion made by the self-interested manufacturer of polypropylene that the product should not be implanted in humans. The MSDS made no attempt to explain why polypropylene might be dangerous or how Phillips had come to this conclusion. Because there was ample other evidence available to address polypropylene's viability as a material for surgical implants, we find that the district court abused its discretion in finding, again sua sponte, that the MSDS could come in for its truth under Rule 807.

D.

Having reviewed and reversed the district court's several sua sponte rulings that the MSDS could come in for its truth under various hearsay exceptions, we now turn to Cisson's original rationale for offering the MSDS: that it was not offered as hearsay. Cisson argued, and the district court agreed, that the warning in the MSDS would not be hearsay if it was offered to show only that Phillips made, and Bard received, the warning statement. Bard does not dispute this on appeal, but argues instead that Cisson used the MSDS for its truth during the trial and that it was therefore offered as hearsay without an exception. Having thoroughly reviewed the record we have found no reversible error, and we therefore affirm the district court's admission of the MSDS.

"Out-of-court statements constitute hearsay only when offered in evidence to prove the truth of the matter asserted." Anderson v. United States, 417 U.S. 211, 219 (1974). A statement that would otherwise be hearsay may nevertheless be admissible if it is offered to prove something other than its truth, and this includes statements used to charge a party with knowledge of certain information. Gardner v. Q.H.S., Inc., 448 F.2d 238, 244 (4th Cir. 1971) (finding out-of-court statements admissible "to show defendants' knowledge of the harm their product could inflict, provided only that [the statements] were brought to the attention of the defendants"); see United States v. Macias-Farias, 706 F.3d 775, 781 (6th Cir. 2013). "[W]hether an out-of-court assertion is hearsay depends on its use" at trial. David F. Binder, Hearsay Handbook § 1:9 (4th ed. 2015).

Cisson originally sought to introduce the MSDS to show that Bard had received the warning from Phillips, one of many safety-related "red flags" she argued demonstrated Bard's knowledge that its product might be unsafe. This was used to support Cisson's argument that the company should have further investigated the safety of the Avaulta Plus rather than marketing the product immediately. Cisson insists that during the trial she did not rely on the MSDS to show that polypropylene was unsafe or to prove causation. Bard argues, however, that "[h]aving secured . . . a ruling that the MSDS was

admissible for its truth, Plaintiffs took full advantage of the rulings" by using the document to show that polypropylene was unsuitable for implantation and contributed to Cisson's injuries. Appellant's R. Br. 30. Cisson's position ultimately proves more convincing for two reasons. First, throughout the trial Cisson consistently limited use of the MSDS to establishing that Bard received the warning and then responded either by ignoring it or withholding it from other parties. Second, even if Cisson did at any time use the MSDS for its truth, she did so in a way that did not prejudice the defendant.

Roger Darois, Bard's Vice President of Research and Advanced Technology, was the key witness Cisson used to establish that Bard had received, and then ignored and withheld, the MSDS warning regarding human implantation. Throughout that testimony, Cisson's attorney pressed Darois on Bard's response to the warning, pointing out that (1) the company did not reach out to Phillips to clarify why the warning had been added to the MSDS in 2007 after decades of polypropylene production, (2) Bard's supplier of monofilament refused to continue supplying processed polypropylene for medical applications after it learned of the MSDS warning, and (3) Darois told Bard staff members to take steps that would prevent Phillips from learning that Bard was implanting medical devices made with polypropylene into human patients.

As Bard pointed out in its appeal on the 510(k) issue, Georgia product liability law incorporates reasonableness principles, ICI Americas, 450 S.E.2d at 673-74, and the punitive damages standard in Georgia requires a jury to find the defendant was willful and wanton in its disregard for the safety of others, Ga. Code Ann. § 51-12-5.1(b). It seems clear that Cisson used the MSDS, at least with regard to the Darois testimony (which again was the most significant exchange involving the MSDS), to show Bard's conduct was not only unreasonable but "would raise the presumption of conscious indifference to consequences." Id. None of the questions to Darois went to proving the actual truth of the MSDS warning, that is, the testimony did not address whether polypropylene was actually dangerous or could have caused Cisson's injuries.

Bard argues that Cisson relied on the MSDS as substantive evidence of causation not only during the Darois testimony, but throughout the trial, claiming that "Plaintiffs' counsel went so far as to tell the jury that it could . . . find for Plaintiffs based solely on the MSDS." Appellant's R. Br. 30. It is first worth noting that this assertion stands in stark contrast to Bard's characterization of the MSDS testimony in its closing argument at trial:

> The MSDS sheet. Think about it. Go back to your notes. Think about it. Not a single witness for the plaintiff talked about the MSDS sheet. Nobody[.]

> . . . . [T]heir experts, Dr. Brennan and Dr. Klosterhalfen and Dr. Hoyte, they didn't talk about it. Nobody linked it up. Nobody linked this issue up.

JA 6578. At that time, Bard apparently felt that the MSDS simply had not been used in a way that could support causation, but on appeal it argues Cisson ubiquitously abused the district court's mistaken ruling that the MSDS could be used for its truth, causing an incurable prejudice to Bard. At oral argument Bard's counsel called the MSDS the "centerpiece" of Cisson's case to the jury. Oral Argument 15:05. Having reviewed a great deal of the more than 7000 pages of record before us (not only the portions cited by Bard to support its contentions, but many more pages of testimony, transcripts, exhibits, and rulings), we find Bard's characterization generally overwrought. We tend to agree instead with their earlier statements to the jury that Cisson never sought to link the MSDS to the question of causation.

There is, however, one statement made by Cisson's counsel that has given us some pause. After bringing up the MSDS during closing arguments, Cisson's trial counsel said, "Now, the interesting thing about that is you can dismiss all the experts. You can say, well, this expert is biased and that expert is biased. But Phillips Sumika, they don't have a dog in the hunt." JA 6537. On its face, the statement appears to instruct

the jury that the MSDS is more reliable than the experts and can therefore establish causation. But we need not decide whether the statement was an attempt to use the MSDS to overcome adverse expert testimony on the question of causation, because that single stray comment was not enough to prejudice Bard and require a new trial. Federal courts of appeal review the fairness of district court proceedings "without regard to errors or defects which do not affect the substantial rights of the parties." 28 U.S.C. § 2111; McDonough Power Equip., Inc. v. Greenwood, 464 U.S. 548, 553-54 (1984). To find the alleged error harmless, "we need only be able to say 'with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the error.'" United States v. Heater, 63 F.3d 311, 325 (4th Cir. 1995) (quoting United States v. Nyman, 649 F.2d 208, 211 (4th Cir. 1980)).

The alleged error in this case was harmless for three reasons. First, Bard has pointed to only one actually problematic statement from Cisson's counsel over the course of a ten day trial. Although Bard cites several parts of the record it claims show the MSDS being used for its truth, the only one that is at all convincing is the "dismiss all the experts" statement. For example, Bard argues that the MSDS was used as substantive evidence of causation in Cisson's opening argument,

citing JA 2358-60. That portion of the transcript, however, shows Cisson's attorney explaining to jurors that the MSDS was produced by the polypropylene manufacturer, that it contained a warning that material should not be used in implants, that the MSDS (and its warning) was in Bard's possession, and that Bard should have taken the warning seriously by verifying that the material was safe for its medical device. None of that goes to causation, and all of it supports Cisson's contention that the MSDS was being used to show Bard was warned about potential dangers and acted irresponsibly in response to that warning. Bard cites other parts of the opening argument, but these show Cisson's attorney referring to the MSDS, not as scientific proof that polypropylene is unsafe, but rather as a "red flag" and a "safety alert" that should have put Bard on notice to investigate further.

Bard also points to a portion of the Darois testimony at JA 4424-27 (and a related exhibit at JA 4652-54), but the questions and answers on those pages demonstrate only that Bard was attempting to keep Phillips in the dark about polypropylene being used in the Avaulta Plus after Phillips added the implantation warning to the MSDS in 2007. Again, this evidence tended to show that Bard's reaction to the warning was unreasonable, not that polypropylene caused Cisson's injuries. The MSDS simply was not being used for its truth. The same is

true of all Bard's citations to the record on this point, with the exception of the one statement we have noted. The fact that there was only one such instance during ten days of evidence cuts strongly in favor of finding the alleged error harmless.

Second, Cisson presented substantive evidence showing that the polypropylene implanted in her body was degraded, providing the jury with a much more compelling reason to conclude that polypropylene contributed to her injuries than simple reliance on a warning in a MSDS. Had Cisson's "dismiss all the experts" statement been repeated, particularly on separate occasions and thereby developed into a theme, we might be more persuaded that there was error and that it was not harmless. After all, taken on its face and without context, the statement can be interpreted to tell the jurors that they can ignore both Cisson's experts, who testified that polypropylene can degrade in the body and cause injuries, and Bard's experts, who testified this was undemonstrated and unlikely.

However, the jury in this case heard substantial evidence to support the conclusion that the polypropylene in Cisson's Avaulta Plus degraded and harmed her. Cisson presented three separate experts who testified on this point: Dr. Anthony Brennan, a biomedical engineer; Dr. Bernd Klosterhalfen, a pathologist; and Dr. Brian Raybon, the physician who implanted the Avaulta Plus into Cisson's body. Dr. Brennan provided the

jury with an opinion that fluids in the human body can degrade polypropylene, Dr. Raybon testified that the polypropylene in Cisson's implant had degraded, and Dr. Klosterhalfen reviewed Cisson's pathology and told the jury she had an inflammatory reaction and scar plate, symptoms consistent with polypropylene degradation. In order for us to reverse the district court, Bard must show that its "substantial rights" were affected, Greenwood, 464 U.S. at 553-54, or that the jury was "substantially swayed by the error," Heater, 63 F.3d at 325, but the fact that the jury had substantial expert testimony on one side and a single stray comment by Cisson's attorney on the other again cuts strongly in favor of finding the alleged error harmless.

Finally, Cisson's causation evidence linked three other design defects to her injuries in addition to the alleged polypropylene defect. Bard therefore cannot meet its burden without some showing that the jury was unpersuaded by these alternative theories of causation, or at least that the polypropylene theory was sufficiently central to its damages award that Bard's substantial rights were affected. See id. (assuming an evidentiary ruling was erroneous and then considering all of the evidence adduced at trial to determine the likelihood of prejudice). Specifically, Cisson's evidence included expert testimony to the effect that the mesh in the

Avaulta Plus was subject to shrinking post-implantation, that the pores in the mesh were too small and therefore likely to result in the formation of rigid scar tissue, and that the arms used to hold the Avaulta Plus in place in the body were defectively designed and contributed to Cisson's pain. Bard fails to demonstrate, or even argue, that the jury based its conclusions on the polypropylene degradation evidence rather than these theories, which were central to her case. Cisson, on the other hand, presented multiple experts in support of each causation theory and linked them to her injuries.

Bard has failed to demonstrate that the one problematic statement regarding the MSDS it has managed to identify in the record had a significant effect on the jury's decision. Given the very significant evidence Cisson presented on causation, and given that the problematic statement was, at most, addressed to one of Cisson's four theories of causation, we cannot find that Bard's substantial rights were affected. We therefore find the alleged error harmless and affirm the district court's admission of the MSDS.

IV.

The third issue raised by Bard on appeal is whether the district court erred in its instruction to the jury on causation, as well as in its subsequent ruling upholding the

jury's causation finding pursuant to its denial of Bard's renewed motion for judgment as a matter of law. Bard charges that it was prejudiced because the court's causation instruction did not reflect Georgia law.

Rulings on jury instructions are reviewed for abuse of discretion, but where there is an error of law we review de novo. Emergency One, Inc. v. Am. Fireeagle, Ltd., 228 F.3d 531, 538 (4th Cir. 2000). We review to ensure that the "charge [was] accurate on the law and [did] not confuse or mislead the jury." Hardin v. Ski Ventures, Inc., 50 F.3d 1291, 1294 (4th Cir. 1995). Because the court's instruction met this standard, and because the jury had ample evidence on which to base its causation finding, we affirm the district court.

Bard's position is that Georgia law requires injury causation be proved by "expert testimony stated to a reasonable degree of medical probability or certainty," that the court was wrong to deny its request for an instruction reflecting that standard, and that Cisson failed to offer expert testimony on two alleged design defects sufficient under the standard to prove they caused her injuries. But Bard's characterization of Georgia law incorrectly states the standard of proof applicable here, inserting the standard for medical malpractice cases into this product liability case.

The district court charged the jury using Georgia's pattern jury instructions for strict liability tort cases, which defines the burden of proof for proximate cause as a preponderance of the evidence. See Ga. Suggested Pattern Jury Instructions, Vol. I: Civil Cases §§ 60.200 & 62.610 (5th ed. 2015). It is also established under Georgia law that plaintiffs in medical implant cases "may present medical as well as non-medical evidence to show causation." Allison v. McGhan Med. Corp., 184 F.3d 1300, 1320 (11th Cir. 1999).

Bard cannot point to a single Georgia case (or any case applying Georgia law) stating that the standard in the pattern jury instruction is incorrect. Instead, Bard points to an inapposite Georgia Supreme Court case, Zwiren v. Thompson, 578 S.E.2d 862 (Ga. 2003), a comparison that suffers from multiple problems. First, Zwiren was a medical malpractice case, not a product liability case. Second, while the Zwiren court did indeed adopt the "reasonable medical probability or certainty" standard Bard advocates, the thrust of the opinion was to reduce the standard from "reasonable medical certainty" to "reasonable medical probability." Id. at 867. This lower standard "is the functional equivalent of preponderance of the evidence"—the same standard expressed by the pattern jury instruction. Allison, 184 F.3d at 1320. Thus, even in malpractice cases, "Georgia case law requires only that an expert state an opinion regarding

proximate causation in terms stronger than that of medical possibility." Zwiren, 578 S.E.2d at 867. In medical implant cases the need for exclusively medical evidence is abrogated. Allison, 184 F.3d at 1320.

Cisson presented ample expert and non-expert testimony for a jury to find that the design defects caused her injuries. In addition to the evidence already described in Part III of this opinion, Cisson presented the following testimony to the jury: Dr. Lennox Hoyte, a urogynecologist, and Dr. John Miklos, one of Cisson's treating physicians, respectively testified that the arms on the Avaulta Plus constituted a design defect and caused Cisson's pain; Dr. Bernd Klosterhalfen, a pathologist, and Dr. Jim Ross testified that inadequate pore size can cause the implanted mesh to shrink and can lead to inflammatory reactions and rigid scarification inside the body; and Dr. Anthony Brennan, a professor and expert in material sciences and biomedical engineering, Dr. Klosterhalfen, and Dr. Brian Raybon, another of Cisson's treating physicians, testified that polypropylene can degrade in the human body, degradation can cause internal inflammation, and that Ms. Cisson's mesh was degraded. This and the other evidence presented at trial was more than enough for the jury to conclude that the alleged defects caused Cisson's injuries. Although Bard argues that Cisson's burden was to show precisely how each alleged defect

caused particular injuries, under Georgia product liability case law "it is not necessary for the plaintiff to specify precisely the nature of the defect"; a plaintiff need only show that "the device did not operate as intended and this was the proximate cause of [the plaintiff's] injuries." Trickett v. Advanced Neuromodulation Sys., Inc., 542 F. Supp. 2d 1338, 1345 (S.D. Ga. 2008) (emphasis removed) (quoting Williams v. Am. Med. Sys., 548 S.E.2d 371, 373 (2001)) (quotation marks omitted).

We therefore find that the district court did not err in giving the Georgia pattern jury instruction, in denying Bard's request for a modified instruction, or in upholding the jury's causation finding.

V.

The jury awarded Cisson $250,000 in compensatory damages and $1.75 million in punitive damages.[4] "The Due Process Clause of the Fourteenth Amendment prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor" in the form of punitive damages. State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 416 (2003). As such, Bard argues that

[4] The punitive damages were subject to a split-recovery statute, dividing the award between the plaintiff and the State of Georgia. As a result, Cisson only received twenty-five percent of the award, while Georgia received the remaining seventy-five percent. See Part VI. infra.

the punitive award in this case was constitutionally excessive. We review this constitutional question de novo, id. at 418, and affirm the award.

The Supreme Court has articulated three "guideposts" for reviewing the constitutionality of a punitive damages award: "(1) the degree or reprehensibility of the defendant's misconduct, (2) the disparity between the harm (or potential harm) suffered by the plaintiff and the punitive damages award, and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases." Cooper Indus., Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424, 440 (2001)) (citing BMW of N. Am., Inc. v. Gore, 517 U.S. 559, 574-75 (1996)). The Court also noted that the first of these factors, reprehensibility, is the most important. Campbell, 538 U.S. at 419 (quoting Gore, 517 U.S. at 575). Bard, however rests its challenge entirely on the second guidepost, asserting only that the punitive award "is constitutionally impermissible, as it is seven times the $250,000 compensatory damages award." Appellant's Br. 58.

Bard's argument is based principally on the Campbell Court's observation that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety." 538 U.S. at 425. However, Bard apparently failed to realize that the Court went on to say

"these ratios are not binding" and to conclude that "[s]ingle-digit multipliers are more likely to comport with due process . . . than awards with ratios in range of 500 to 1." Id.

Bard effectively urges this court to adopt a bright line rule against punitive damages exceeding a ratio of four-to-one, despite the Supreme Court itself "declin[ing] again to impose a bright-line ratio which a punitive damages award cannot exceed" in Campbell. Id. The district court found that "here, the compensatory damages and punitive damages against Bard both arose from its misconduct that resulted in Ms. Cisson's injuries," JA 7139-40 n.8, and grounded its refusal to overturn the award in reprehensibility of Bard's conduct, JA 7138-43. We therefore find that the seven-to-one ratio was not constitutionally excessive in this case and affirm the district court.

VI.

The final issue before us comes from Cisson who challenges, by cross-appeal, the district court's ruling that a Georgia split-recovery statute garnishing seventy-five percent of any punitive damages award arising from a product liability judgment, O.C.G.A. § 51-12-5.1(e), does not violate the Takings Clause of the Fifth Amendment of the United States Constitution.

Cisson asserts that Georgia created a property interest in such punitive damages awards when it codified them in O.C.G.A. § 51-12-5.1, and that enforcement of the state's subsequently enacted split-recovery statute violates the Takings Clause. The district court rejected that argument, and we review its decision de novo. To succeed, Cisson must first show she has "a constitutionally protected property interest" in the punitive damages award at issue. See Washlefske v. Winston, 234 F.3d 179, 184 (4th Cir. 2000). Cisson contends that she has a vested property interest in the entire punitive damages award, but, in the scant briefing she has provided to this Court on the issue, she has failed to articulate a viable theory in support of that contention.

Cisson makes no claim that her right to punitive damages arises from the common law or is otherwise fundamental, so we need not address the opinions of some courts which have found that no such right is cognizable under the Takings Clause. E.g. Enquist v. Oregon Dep't of Agric., 478 F.3d 985, 1002-04 (9th Cir. 2007). Instead she argues that her property interest was created by Georgia statute. Appellee's Br. 92. But Cisson does not explain how Georgia exceeds its authority by defining the contours of the right it has allegedly created. Washlefske, 234 F.3d at 184; see Cheatham v. Pohle, 789 N.E.2d 467, 473 (Ind. 2003) (holding that the legislature could define a plaintiff's

interest in a statutorily created property right). "[I]f a statute creates a property right . . . , the property interest so created is defined by the statute . . . ." Washlefske, 234 F.3d at 184. As such, under Cisson's own theory "the legislature may lawfully regulate the amount of punitive damages which can be awarded," Mack Trucks, Inc. v. Conkle, 436 S.E.2d 635, 639 (Ga. 1993), and she has therefore provided no basis for us to find the state's actions unconstitutional.

As such, we affirm the judgment of the district court.

VII.

For the foregoing reasons, the judgment of the district court on all issues raised in this appeal is

AFFIRMED.