PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-2118

JO HUSKEY; ALLEN HUSKEY,

Plaintiffs - Appellees,

v.

ETHICON, INC.; JOHNSON & JOHNSON,

Defendants - Appellants.

Appeal from the United States District Court for the Southern District of West Virginia, at Charleston. Joseph R. Goodwin, District Judge. (2:12-cv-05201; 2:12-md-02327)

Argued: December 8, 2016 Decided: January 26, 2017

Before MOTZ and DIAZ, Circuit Judges, and DAVIS, Senior Circuit Judge.

Affirmed by published opinion. Judge Motz wrote the opinion, in which Judge Diaz and Senior Judge Davis joined.

ARGUED: David B. Thomas, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia, for Appellants. Edward Anthony Wallace, WEXLER WALLACE LLP, Chicago, Illinois; Fidelma Louise Fitzpatrick, MOTLEY RICE LLC, Providence, Rhode Island, for Appellees. **ON BRIEF:** Charles C. Lifland, Los Angeles, California, Stephen D. Brody, David K. Roberts, O'MELVENY & MYERS LLP, Washington, D.C.; Philip J. Combs, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia; Christy D. Jones, BUTLER SNOW LLP, Ridgeland, Mississippi, for Appellants. Mark R. Miller, WEXLER WALLACE

LLP, Chicago, Illinois; Jeffrey Kuntz, Adam Davis, WAGSTAFF & CARTMELL LLP, Kansas City, Missouri, for Appellees.

DIANA GRIBBON MOTZ, Circuit Judge:

After Jo Huskey experienced complications from the implantation of a transvaginal mesh medical device, she and her husband Allen Huskey filed this products liability action against Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). Following a nine-day trial, the jury returned a general verdict for the Huskeys on their design defect, failure to warn, and loss of consortium claims. Ethicon now appeals the denial of its post-trial renewed motion for judgment as a matter of law or, in the alternative, for a new trial. The Huskeys offered sufficient evidence to sustain the jury's verdict and the district court committed no reversible error. Accordingly, we affirm.

I.

A.

In 2008, Mrs. Huskey began suffering symptoms of Stress Urinary Incontinence ("SUI"). In January 2011, after her condition had worsened, she discussed treatment options with her doctor, Dr. Gretchen Byrkit. By this time, Mrs. Huskey was regularly leaking urine while coughing, laughing, and sneezing, and she also experienced pain during intercourse. At Dr. Byrkit's suggestion, Mrs. Huskey agreed to have Dr. Byrkit

surgically implant a medical device called the Tension-Free Vaginal Tape-Obturator ("TVT-O").

The TVT-O is a mid-urethral sling that uses a heavy-weight laser-cut mesh. Ethicon received clearance from the Food and Drug Administration ("FDA") to market the TVT-O in December 2003. Ethicon uses polypropylene for the TVT-O's mesh. The TVT-O was not the first mid-urethral sling Ethicon had manufactured; rather, it was a second-generation version of an earlier Ethicon device called the Gynecare TVT and is one of multiple slings that Ethicon has manufactured and sold.

On February 23, 2011, Dr. Byrkit performed Mrs. Huskey's implantation surgery. A few weeks later, Mrs. Huskey visited Dr. Byrkit's office for a post-operative check-up. At this visit, Dr. Byrkit examined Mrs. Huskey and found that some mesh on her right side had eroded. This eroded mesh caused Mrs. Huskey to experience pelvic pain.

On June 24, 2011, after various alternative treatments that Dr. Byrkit had recommended failed, Mrs. Huskey agreed to have a second surgical operation to cover the exposed mesh. Dr. Byrkit performed this operation on June 29, 2011. Unfortunately, this operation was not successful and did not relieve Mrs. Huskey's pain. Dr. Byrkit then referred Mrs. Huskey to Dr. Sohail Siddique, a urogynecologist, for further treatment.

On November 18, 2011, Dr. Siddique performed surgery to excise Mrs. Huskey's mesh. He found that she had an infection and that the mesh on Mrs. Huskey's right side had completely eroded. He could not remove all the mesh because some had retracted behind Mrs. Huskey's pubic bone.

To this day, the remaining mesh and scar tissue from her operations cause Mrs. Huskey to experience severe pain, particularly when engaging in physical activity and sexual intercourse. Additionally, her SUI symptoms have returned. For the rest of her life, she will require medication for pain management; no surgical intervention can permanently cure her.

B.

On September 6, 2012, the Huskeys filed the operative Short Form Complaint in the Southern District of West Virginia in the instant multidistrict litigation, In Re Ethicon Inc., Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2327. The Huskeys, Illinois residents, brought all of their claims under Illinois law. After the district court granted Ethicon partial summary judgment, five claims remained for trial: strict liability and negligent design defect; strict liability and negligent failure to warn; and Mr. Huskey's loss of consortium. Beyond actual damages, Mrs. Huskey sought punitive damages for the substantive claims.

Trial began on August 22, 2014 and lasted nine days. The Huskeys presented their case, which consisted of testimony from thirteen witnesses and the introduction of numerous documents, over the first six trial days. At the conclusion of their case, Ethicon orally moved for judgment as a matter of law under Federal Rule of Civil Procedure 50(a). The court granted the motion as to Mrs. Huskey's claim for punitive damages but otherwise deferred ruling on the motion. Ethicon renewed its motion at the close of its case, and the court, again deferring a ruling, submitted the case to the jury.

The jury returned a unanimous general verdict for the Huskeys on all five claims. The jury awarded Mrs. Huskey $3.07 million in total damages, allocated between past expenses for medical care, previous pain and suffering, and future pain and suffering. The jury awarded Mr. Huskey an additional $200,000 for his loss of consortium.

After the jury returned its verdict, Ethicon again renewed its motion for judgment as a matter of law. In the alternative, Ethicon sought a new trial pursuant to Rule 59(a)(1)(A). The court issued a thorough written order denying the motion. Huskey v. Ethicon, Inc., No. 2:12-cv-05201, 2015 WL 4944339 (S.D. W. Va. Aug. 19, 2015). Ethicon subsequently noted this timely appeal.

II.

A.

Ethicon initially contends that the district court erred in denying it judgment as a matter of law. We review de novo the denial of Ethicon's motion. Durham v. Jones, 737 F.3d 291, 298 (4th Cir. 2013). A court "may grant judgment as a matter of law only if, viewing the evidence in a light most favorable to the non-moving party and drawing every legitimate inference in that party's favor, . . . the only conclusion a reasonable jury could have reached is one in favor of the moving party." Saunders v. Branch Banking & Tr. Co. of Va., 526 F.3d 142, 147 (4th Cir. 2008). If, upon the conclusion of a party's case, "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue," a court may grant a motion from the opposing party for judgment as a matter of law. Fed. R. Civ. P. 50(a). When the court defers ruling on such a motion, Rule 50(b) allows a party to renew it after the jury returns a verdict.

Ethicon moved for judgment as a matter of law on all five of the Huskeys' claims. As Ethicon's counsel conceded at oral argument, since the jury returned a general verdict, we can reverse the court's denial of Ethicon's motion only if the Huskeys failed, as a matter of law, to prove both their design defect and failure to warn claims. Given our resolution of the

Huskeys' design defect claims, we need not discuss their failure to warn claims. Moreover, because their negligent design defect claim relies on the same facts and arguments as their strict liability design defect claim, we address those claims together. Similarly, because it is wholly derivative of Mrs. Huskey's claims, we do not separately consider Mr. Huskey's loss of consortium claim. See Blagg v. Ill. F.W.D. Truck & Equip. Co., 572 N.E.2d 920, 926 (Ill. 1991).

B.

To prevail on their design defect claims, the Huskeys had to demonstrate: 1) that a certain condition of the TVT-O resulted from Ethicon's design, 2) that this condition made the product unreasonably dangerous, 3) that the dangerous condition existed when Mrs. Huskey's TVT-O left Ethicon's control, and 4) that the dangerous condition in the TVT-O proximately caused harm to Mrs. Huskey. See Mikolajczyk v. Ford Motor Co., 901 N.E.2d 329, 345 (Ill. 2008). Ethicon makes two arguments in support of its contention that the court erred in denying it judgment as a matter of law: 1) that the Huskeys failed to prove a specific flaw in the TVT-O's design -- as opposed to a general complication flowing from implantation, and 2) that comment k of the Restatement (Second) of Torts § 402A shields it from liability. We address these arguments in turn.

1.

The record belies Ethicon's assertion that the Huskeys failed to prove that a specific defect of the TVT-O's design caused harm to Mrs. Huskey. As the district court properly held, the Huskeys offered sufficient evidence for a reasonable jury to find that Ethicon's use of heavyweight polypropylene mesh in the TVT-O caused Mrs. Huskey's injuries.

First, Dr. Scott Guelcher, an associate professor of chemical engineering at Vanderbilt University and one of the Huskeys' expert witnesses, testified about the body's reaction to polypropylene and the consequences that ensue. He explained that "the body recognizes [the polypropylene mesh] as a foreign material, and . . . will continue to attack it in this way until it's removed or destroyed or it's gone." And Dr. Guelcher testified, based on his research, that "it's best to minimize the amount of polypropylene that's present in the mesh," because "the more polypropylene surface that's present, the greater those changes would be, [and] the more hazardous they could be."

Next, Dr. Bruce Rosenzweig, a urogynecologist and another of the Huskeys' expert witnesses, bolstered Dr. Guelcher's testimony. Dr. Rosenzweig testified that Ethicon used a heavyweight mesh and "[t]he more mesh there is in the pelvis, the more of a foreign body response." He explained that heavyweight mesh can lead to a foreign body response in an area

near the inner thigh called the obturator space, and that these foreign bodies can "irritate the nerve [that passes nearby] and lead to pain."

Additionally, Dr. Brigitte Hellhammer, a former Ethicon employee, testified that she had no reason to believe that lightweight mesh could not effectively treat SUI. Dr. Hellhammer explained that one risk of implanting mesh devices in patients was that the mesh would shrink, and that the weight of the mesh helps determine the likelihood of shrinkage. Dr. Hellhammer testified to a generally-recognized understanding that lightweight mesh "would help in reducing a foreign body response, inflammatory response, and would reduce the potentiation for scar plating."

Finally, Dr. Jerry Blaivas, a urologist and another expert witness for the Huskeys who had conducted a pelvic examination of Mrs. Huskey, testified that Mrs. Huskey had severe scarring and suffered from "chronic pelvic pain." Dr. Blaivas believed Mrs. Huskey's symptoms were "a reaction to the mesh" and that he did not "know of anything else that can cause . . . this particular constellation of symptoms."

Drawing all inferences in the Huskeys' favor, a reasonable jury could conclude from this expert testimony that Ethicon's use of a heavyweight quantity of polypropylene mesh in the TVT-O

constituted a design defect that caused Mrs. Huskey's inflammation and pelvic pain.

2.

Ethicon next argues that an exception to strict liability found in comment k to § 402A of the Restatement (Second) of Torts, on which Illinois courts rely, nevertheless shields it from liability. See Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 392 (Ill. 1987) (citing comment k in a recitation of applicable law).

Comment k, which is captioned "[u]navoidably unsafe products," recognizes that "some products . . . , in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965). Comment k recommends that such products, "with the qualification that they are properly prepared and marketed, and proper warning is given," not trigger strict liability. Id. This is because "the marketing and the use of [unavoidably unsafe products] are fully justified, notwithstanding the unavoidable high degree of risk which they involve." Id. Such products, it explains, are neither "defective, nor . . . unreasonably dangerous." Id.

Although comment k notes that unavoidably unsafe products "are especially common in the field of drugs," id., under Illinois law, courts determine "on a case by case basis" if a

particular product falls within comment k, Glassman v. Wyeth Labs., Inc., 606 N.E.2d 338, 342 (Ill. App. Ct. 1992). Whether a product is unavoidably unsafe is a question of fact on which the defendant bears the burden of proof. Id. at 343. If a reasonable jury could find that the TVT-O did not meet comment k's parameters, Ethicon's reliance on comment k fails.

Much of the trial evidence indicating that the use of heavyweight polypropylene mesh constituted a design defect also suggests that comment k provides Ethicon no defense. Specifically, the jury could reasonably infer from Dr. Guelcher's testimony that the greater quantity of mesh Ethicon used in the TVT-O, the greater the chance that a patient would experience an adverse foreign body response. The jury could also reasonably infer from Dr. Hellhammer's testimony that had Ethicon used lightweight mesh, the TVT-O would have remained effective and patients would have a reduced risk of an adverse foreign body response. Taken together, the expert testimony allowed the jury to infer that Ethicon could have designed the TVT-O with lightweight mesh without sacrificing any performance. Consequently, the jury could reasonably conclude that the TVT-O was not unavoidably unsafe. Comment k does not shield Ethicon from liability.

III.

We next address Ethicon's contention that the district court should have granted it a new trial. Federal Rule of Civil Procedure 59(a)(1)(A) allows a court to grant a party's motion for a new trial if the verdict is contrary to the clear weight of the evidence, rests upon false evidence, or will cause a miscarriage of justice. Minter v. Wells Fargo Bank, N.A., 762 F.3d 339, 346 (4th Cir. 2014).

We review a denial of a new trial for abuse of discretion. United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 375 (4th Cir. 2015). A court abuses its discretion if it relies on incorrect legal conclusions or clearly erroneous findings of fact. Belk, Inc. v. Meyer Corp., U.S., 679 F.3d 146, 161 (4th Cir. 2012). Moreover, we can reverse even without such errors "if we have 'a definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors.'" Id. (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999)).

Ethicon raises two grounds for a new trial. First, it contends that the district court improperly refused to instruct the jury on comment k. Next, it asserts that the court improperly excluded multiple pieces of evidence involving the FDA.

A.

We turn first to the comment k instruction. Ethicon argued at trial that comment k entitled it to "at a minimum, an appropriate jury instruction." After considering briefing and oral argument on the question, the district court declined to include the requested comment k instruction.[1] Instead, the court instructed the jury that it could find Ethicon liable on the design defect claim only if it found that the TVT-O was unreasonably dangerous. The court then defined an "unreasonably dangerous" product as one in which the "risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product."

[1] Ethicon titled the instruction it requested "Inherent Risks," and the proposed instruction read:

> Some useful products are inherently dangerous and cannot be made safe for their intended and ordinary use. An example is a prescription drug. A prescription drug is not defective simply because it . . . has unavoidable side effects.
>
> Products that contain inherent dangers are not defectively designed or unreasonably dangerous so long as they are accompanied by proper directions and warning.
>
> If you find that the risks that allegedly injured Mrs. Huskey . . . were unavoidable, inherent risks of the product, and that the product was accompanied by proper directions and warnings, you should find that the product is not defective.

We review the district court's refusal to provide Ethicon's proposed instruction for abuse of discretion. Rowland v. Am. Gen. Fin., Inc., 340 F.3d 187, 191 (4th Cir. 2003). We evaluate the jury charge as a whole, and an instructional error warrants a new trial only if it fails to inform the jury of the controlling legal principles. Id. Any lack of clarity must prejudice the challenging party. Id.

Again, to show that a product falls within comment k's protection, the defendant must prove that a product's "marketing and . . . use . . . are fully justified, notwithstanding the unavoidable high degree of risk which [it] involve[s]." Restatement (Second) of Torts § 402A cmt. k. We can discern only one difference between comment k and the jury instruction the court gave.[2] That difference is the burden of proof, which of course shifts to the defendant for comment k. Even assuming that Ethicon had produced sufficient evidence to justify the issuance of a comment k instruction, we cannot hold that it suffered prejudice from the absence of that instruction. As the district court correctly observed, the failure to provide an instruction that shifts the burden to Ethicon would not likely

[2] Ethicon argues that the district court's actual instruction did not capture "the policy rationale underlying comment k," namely, that of encouraging medical innovations. This argument fails however, given that defendants must prove comment k's applicability "on a case by case basis." Glassman, 606 N.E.2d at 342.

have provided Ethicon with a more favorable outcome. Without any prejudice, the district court did not abuse its discretion in denying Ethicon a new trial on that basis.

B.

We next address Ethicon's evidentiary contentions. Ethicon posits that the district court's exclusion of four pieces of FDA evidence warrants a new trial. Those four pieces of evidence are: evidence of the TVT-O's compliance with the FDA's Section 510(k) evaluation process; evidence that a 2011 FDA Advisory Committee deemed mesh slings, including the TVT-O, safe and effective; a 2013 published guidance, which reported the Advisory Committee's conclusions; and the regulatory history of the Prolene suture, an Ethicon product that contains the same polypropylene as the TVT-O's mesh.

The court relied on Federal Rule of Evidence 403 in excluding this evidence. That Rule allows a court to exclude relevant evidence when 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." Fed. R. Evid. 403. We review a decision to exclude evidence on this basis for abuse of discretion. United States v. Davis, 690 F.3d 226, 257 (4th Cir. 2012). Improper exclusion of evidence warrants a new trial only if it results in "a high

probability that the error . . . affect[ed] the judgment." Drakeford, 792 F.3d at 375.

We will address each exclusion in turn. But before doing so, we consider whether Ethicon has waived any challenge pertaining to the latter three pieces of evidence. The Huskeys argue that Ethicon never sought to introduce these three pieces of evidence, and that Ethicon thus cannot now rely on the exclusion of this evidence to gain a new trial. To the extent this accurately represents the proceedings below -- a notion Ethicon strongly contests -- the Huskeys have waived this argument.

Ethicon's memorandum in support of its post-trial motion contended that the exclusion of all of the evidence it invokes on appeal justified a new trial. The Huskeys' only response to this argument in their briefing was to incorporate by reference their pre-trial filing to exclude the 510(k) evidence. Nowhere did they contend that Ethicon had not sufficiently sought to introduce the other FDA evidence, or had otherwise waived its ability to assert that the exclusion of this evidence compelled a new trial. The Huskeys thus waived this argument by omitting it from their post-trial briefing. Cf. United States v. Carthorne, 726 F.3d 503, 509 n.5 (4th Cir. 2013) (holding that the Government "waived the waiver argument" when it failed to argue that plain error review applied to a particular appellate

challenge). Having resolved this issue, we now examine the evidence in question.

1.

We begin with the evidence of the TVT-O's compliance with the 510(k) process. Under the Federal Food, Drug, and Cosmetic Act, a manufacturer seeking to market a new medical device may attempt to bypass the FDA's normal premarket approval process by submitting a "§ 510(k) notification." Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996). The FDA then evaluates whether the new device is "'substantially equivalent' to a pre-existing device." Id. If the FDA finds substantial equivalence, the new device "can be marketed without further regulatory analysis." Id. The district court refused to permit Ethicon to introduce evidence that it had cleared the 510(k) process and evidence explaining that process.

We recently held in Cisson v. C.R. Bard, Inc. (In re C.R. Bard, Inc.), 810 F.3d 913, 919 (4th Cir. 2016), a bellwether case from a related MDL, that this same district judge did not abuse his discretion when he excluded evidence that the device in question had complied with the 510(k) process. We noted that the 510(k) process focuses mostly on the equivalence between the product in question and an older one, and only "tangentially" examines the safety of the product going through the process. Id. at 922 (emphasis added). We rejected the view that "[b]ald

assertions by the FDA" as to 510(k) compliance are highly probative of a product's safety. Id. at 921. Given its limited probative value and the risk of confusing the jury by, inter alia, causing a battle of the experts over the robustness of the 510(k) process's safety examinations, we held that exclusion of the 510(k) compliance evidence was not improper. Id. at 921-22.

We see no reason to distinguish Cisson here. The information Ethicon sought to introduce would, at best, have had "tangential[]" relevance to the case. This relative lack of probative value, especially given a possible battle of experts over the 510(k) process, underscores the risks of confusion and wasted time that would follow the introduction of this evidence. Ethicon's effort to distinguish Cisson on the ground that the TVT-O's 510(k) compliance process actually did focus heavily on safety would only amplify the risk, as the trial would then likely face a substantial diversion into just how rigorous those safety considerations were, how forthcoming Ethicon was to the FDA, and how robust the 510(k) process is. The district court did not abuse its discretion in excluding this evidence.

2.

We next address the FDA Advisory Committee evidence. In 2011, an Obstetrics and Gynecology Devices Advisory Committee (the "FDA Advisory Committee") conducted an examination of the "risks and benefits of surgical mesh . . . based on the

published literature and adverse event data from" an FDA database, and noted that "[a] substantial number of quality clinical trials, as well as systematic reviews, have been published for the first generation minimally invasive slings that provide evidence of safety and effectiveness of these devices." FDA Advisory Committee, Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence: FDA Executive Summary 1, 28 (2011). In 2013, the FDA issued a published guidance reiterating these conclusions.

While the district court did not permit Ethicon to present evidence as to the FDA's view of the underlying studies, it did permit Ethicon to introduce those studies themselves. The FDA did not use its own analysis of the TVT-O to reach a conclusion regarding the device's safety and efficacy. Rather, it simply opined on the work others had done. The underlying studies themselves enabled Ethicon to obtain most of the probative value from the FDA Advisory Committee evidence without risking a usurpation of the jury's essential role in determining if the Huskeys had adequately proven their claims.

Additionally, the FDA's use of the 510(k) process to approve the TVT-O layers on another risk of introducing the FDA Advisory Committee evidence. As discussed above, the 510(k) process focuses on a particular device's equivalence to an older device. Thus, the FDA's only original conclusion regarding the

TVT-O did not address its safety. This dynamic creates a potentially confusing disjunction for the jury between what the FDA deems other literature has to say about the TVT-O's safety and what the FDA itself found about the TVT-O's equivalence to an earlier device. This goes beyond the mere specter of too much jury deference to the FDA and tacks on the prospect of the jury misunderstanding the FDA Advisory Committee's actual conclusions. In these circumstances, therefore, the court did not abuse its discretion in excluding the FDA Advisory Committee evidence.

3.

Finally, we consider the evidence of the regulatory history of Prolene used in the Prolene sutures -- the same polypropylene used in the TVT-O's mesh also makes up part of the Prolene suture. Ethicon wanted to introduce evidence that the FDA had approved the Prolene suture not only in an initial application, but also in over thirty subsequent New Drug Applications. Ethicon also sought to introduce evidence that the "FDA approved language indicating that Prolene [in the suture] is not subject to degradation via tissue enzymes."

As the district court correctly explained, "evidence regarding the FDA process that the Prolene suture underwent . . . says little about the safety and effectiveness of the final product, the TVT-O." Huskey, 2015 WL 4944339, at

*13 (emphasis added). The jury ultimately had to make a determination about the entire device that Mrs. Huskey received, not just a component of it. Introducing the evidence regarding Prolene sutures alone could quite plausibly cause a diversion into how similar and integral the Prolene sutures are to the TVT-O end product and the role that other components of the TVT-O might play in triggering foreign body responses or interacting with the Prolene sutures to mitigate safeguards against such responses. And that is to say nothing of the risk, also present with the FDA Advisory Committee evidence, that the jury might draw too strong a conclusion from the fact that the evidence of Prolene's safety comes from the FDA. These drawbacks underscore that the court acted within its discretion.

Moreover, even without the evidence of the regulatory history of the Prolene sutures, the court permitted Ethicon to introduce evidence of their robust safety record. On cross-examination, Ethicon's counsel elicited testimony from Dr. Guelcher that Prolene sutures have an identical chemical composition to the Prolene Ethicon uses in both its hernia meshes and in its TVT meshes to treat SUI. In that same line of questioning, Dr. Guelcher also acknowledged that his research had uncovered no "problem[s] with polypropylene mesh." Ethicon was thus able to extract the same information that would have made up the core probative value of the Prolene suture's

regulatory history without bringing in the potential negative effects of introducing that evidence. The court did not abuse its discretion in excluding evidence of that other product's regulatory history.

IV.

Accordingly, for the reasons set forth above, the judgment of the district court is

AFFIRMED.