

[DO NOT PUBLISH]

In the
United States Court of Appeals
For the Eleventh Circuit

No. 21-14397

RAEANN BAYLESS,

Plaintiff-Appellee-Cross-Appellant,

versus

BOSTON SCIENTIFIC CORPORATION,

Defendant,

COLOPLAST CORP,

Defendant-Appellant-Cross-Appellee.

Appeals from the United States District Court
for the Middle District of Florida
D.C. Docket No. 6:20-cv-00831-RBD-GJK

Before ROSENBAUM and LAGOA, Circuit Judges, and WETHERELL,^{*}
District Judge.

PER CURIAM:

After delivering four children, Raeann Bayless experienced symptoms of stress urinary incontinence and pelvic organ prolapse. To try to treat these conditions, she underwent a surgical operation in which two polypropylene meshes—including Coloplast Corp.’s Restorelle Y—were inserted into her pelvic region. But the surgery did not cure her ailments. Bayless continued to experience debilitating symptoms, and she was ultimately diagnosed with vaginal erosion.

Bayless attributed her post-operation injuries to the products inserted during surgery and brought suit against Coloplast and another manufacturer alleging, among other things, that Restorelle Y is defectively designed and that it caused her injuries. After an eleven-day trial, a jury agreed on these points and awarded her \$500,000 in compensatory damages.

^{*} The Honorable T. Kent Wetherell, II, United States District Judge for the Northern District of Florida, sitting by designation.

21-14397

Opinion of the Court

3

Coloplast now challenges the jury's verdict, arguing that Bayless did not present sufficient evidence to establish general causation and that Restorelle Y's risks outweighed its benefits. The district court rejected Coloplast's motions, finding that there was ample evidence to support the jury's verdict. After thorough review of the record, and with the benefit of oral argument, we affirm.

I. Background

Raeann Bayless is a mom. After giving birth to her youngest son in 1987, she began experiencing symptoms of stress urinary incontinence¹ and pelvic organ prolapse.² Bayless's symptoms worsened over time, and she had long sought medical treatment for them.

In 2012, Bayless was referred to Dr. Kathy Jones, an obstetrician-gynecologist. Dr. Jones offered Bayless multiple surgical options and Bayless selected a "robotic-assisted laparoscopic sacrocolpopexy with mesh, a possible sling, and cystocele repair and cystoscopy." More specifically, Dr. Jones was going to use two different

¹ Stress urinary incontinence is a condition in which involuntary urination occurs when a person makes abdominal movements such as coughing, laughing, or exercise.

² Pelvic organ prolapse is a condition that occurs when the natural supports of the female structures are broken or loosened such that the pelvic organs drop or even protrude out of the vaginal opening.

synthetic meshes made of polypropylene³ to treat Bayless’s conditions—Coloplast’s Restorelle Y to treat her pelvic organ prolapse, and Boston Scientific Corp.’s Advantage Fit to treat her stress urinary incontinence.

On August 9, 2013, Dr. Jones performed the surgery, which included inserting the Restorelle Y and Advantage Fit meshes and performing a hysterectomy. There were no complications or difficulties during the surgery. But six weeks after the operation, an examination revealed that there was a “foreign body” visible at the top of Bayless’s vagina.

In 2014, Bayless noticed blood spotting in her underwear and continued to experience pain. She “felt something protruding into [her] vagina canal from the top [wall] of [her] vagina,” and she described the feeling as a “piece of wire poking through,” and “[t]he end of it was sharp like a needle.” Her pain continued to worsen—in her words it was “different” and “more constant” than the pain she had experienced before the operation. A speculum exam revealed that mesh was exposed in her vagina. And she was eventually diagnosed with vaginal erosion due to surgical mesh and vaginal infections.

Bayless was later referred to Dr. Lisa Rose for a mesh implant evaluation. Dr. Rose saw and felt a hard, gray substance

³ Polypropylene is a type of plastic. Common examples of polypropylene include fishing line, bottle caps, and carpet backing.

21-14397

Opinion of the Court

5

protruding into Bayless's vagina from where the Restorelle Y was implanted. Dr. Rose recommended that the mesh be removed as soon as possible since there was a high risk of infection.

In 2016, Bayless filed this action against Coloplast and Boston Scientific Corp. She filed her complaint directly into a multi-district litigation about the synthetic pelvic meshes.⁴ Her complaint raised eight claims against each defendant, including, as relevant here, strict liability for defective design.

In May 2020, the case was transferred from the MDL court to the Middle District of Florida for case-specific resolution.⁵

Coloplast then moved to exclude testimony from Bayless's two expert witnesses: Dr. Jimmy Mays, a polymer scientist, and Dr. Bruce Rosenzweig, a urogynecologist. The district court granted those motions in part and denied them in part.

The district court concluded that Dr. Mays was "clearly qualified to testify on the oxidative degradation of a polymer, and his methodology is reliable." But because Dr. Mays is not a medical

⁴ There are two relevant multi-district litigations ("MDLs"): MDL 2326 (for Boston Scientific) and MDL 2387 (for Coloplast), which were both assigned to the Southern District of West Virginia. The MDL court allowed a plaintiff implanted with multiple products (like Bayless) to choose the MDL for her suit and bring claims against multiple defendants.

⁵ When this litigation began, Bayless lived in Florida. During its pendency, she moved to Georgia. We previously granted Bayless's motion to amend her complaint to now allege that she lives in Georgia.

doctor, the district court concluded he could not “testify as to the clinical implications of that degradation.”

As for Dr. Rosenzweig, the district court did not permit him “to offer any general expert testimony about whether the Restorelle Y mesh is defective” because he had represented in the MDL proceedings that he wouldn’t offer opinions about Restorelle Y. Nor did the district court allow Dr. Rosenzweig to offer “general opinion testimony as to causation, including on general causation opinions in his case specific expert report.” So he could not testify, for example, that “Bayless’s injuries were the result of a defect in the Restorelle Y” or that Restorelle Y is “defective because it contains polypropylene that degrades in vivo or that this defect [wa]s the cause of Bayless’s injuries.”

But the district court did allow Dr. Rosenzweig to testify about the differential diagnosis he made regarding Bayless’s ailments, which he disclosed in his case-specific expert report.⁶ And he was “permitted to testify that he believes the mesh caused Bayless’s injuries.” Under the district court’s ruling, Dr. Rosenzweig could also use his experience “to conclude the mesh could be

⁶ “Differential diagnosis is a term used to describe a process whereby medical doctors experienced in diagnostic techniques provide testimony countering other possible causes of the injuries at issue. It is well-settled that an expert’s use of differential diagnosis to arrive at a specific causation opinion is a methodology that is generally accepted in the relevant scientific community.” *Castillo v. E.I. Du Pont De Nemours & Co.*, 854 So. 2d 1264, 1270–71 (Fla. 2003) (citations and internal quotation marks omitted) (alteration adopted).

21-14397

Opinion of the Court

7

degrading in vivo and causing [Bayless's] injuries.” So ultimately, the district court concluded Dr. Rosenzweig “was justified in ‘opting-in’ the Restorelle Y device with his differential diagnosis when considering Bayless’s mesh erosions, vaginal bleeding, and infection.” In other words, there was a scientific basis for Dr. Rosenzweig’s conclusion that Restorelle Y caused Bayless’s injuries. The district court held that Dr. Rosenzweig “was thorough and used reliable methodology for excluding other possible causes,” as he “clearly explained his reasons for rejecting alternative explanations” and determining that “Restorelle Y was responsible.”

In May and June 2021, the parties conducted an eleven-day jury trial to determine whether Boston Scientific’s Advantage Fit and Coloplast’s Restorelle Y caused Bayless’s injuries. Several witnesses, including Bayless, Dr. Jones, Dr. Mays, and Dr. Rosenzweig, testified.

At trial, Dr. Mays testified about the properties of polypropylene, including oxidative degradation, a process in which polypropylene “crumble[s]” when it “reacts with oxygen or other oxygen-containing molecules.” He testified that, once polypropylene is implanted into the body, it is subject to a process known as foreign body response, in which the body “detects” and “attack[s]” a foreign substance. This process generates “very strong oxidizing agents” and “catalyze[s] oxidative degradation.” And the foreign body response occurs wherever the implant is placed in the body, including the pelvic region. He explained that a polypropylene

mesh—such as Restorelle Y—is “initially flexible” but “stiffe[ns] during th[e] oxidation process.”

Dr. Mays concluded that the oxidation issues in polypropylene would occur in all its forms because “[t]he polypropylene chemistry is the same” and “[i]ts reactivity is the same,” regardless of form. He testified there is nothing unique about the polypropylene that is in Restorelle Y and that Restorelle Y’s “properties change . . . for the worse” when it is inserted in the human body. Nor did Dr. Mays need to do specific tests on Restorelle Y because “[p]olypropylene is polypropylene,” and “eventually that polypropylene is going to degrade in vivo.” So, Dr. Mays told the jury, because Restorelle Y cannot hold its properties and functions, it is not a suitable choice for permanent implantation. He further testified that he believed Restorelle Y was “defective from a materials selection and design standpoint.” While Dr. Mays did not see or examine the mesh implanted in Bayless, he testified that he had “no doubt whatsoever” that it had gone through oxidative degradation.

The jury also heard testimony from Dr. Rosenzweig. As a practicing urogynecologist, Dr. Rosenzweig began using polypropylene to treat his patients in 2005. But a few years later, he stopped doing so because “it was not worth using these products any more” given their risks and complications. Those included symptoms like “pain, pain with intercourse, [and] difficulty urinating.” He explained that the complications from the mesh were “fairly significant,” as the mesh would “erod[e] or be[] exposed into the vagina.” Dr. Rosenzweig testified that he has surgically treated

21-14397

Opinion of the Court

9

around 350 patients for mesh-related injuries and roughly four times as many nonsurgically.

He further explained that these injuries were traceable to the foreign body response. Through that process, certain cells “try [to] destroy [the polypropylene] by releasing strong acids that will break it down.” The body then “send[s] little nerve roots to this area,” which can then “grow through the opening or the pores of the mesh.” These nerves “get trapped,” which ultimately causes pain. According to Dr. Rosenzweig, the “mesh undergoes degradation that leads to mesh exposure,” and that “mesh undergoes fibrosis and scar plating, and that leads to pain.”

As part of his testimony, Dr. Rosenzweig reviewed Bayless’s medical records in front of the jury. The records showed that she could “feel mesh in her vaginal wall” and that she had a “mesh exposure” that was “due to a chronic foreign body reaction.” She also experienced “pelvic pain,” “vaginal bleeding,” “persistent vaginal discharge,” “dysuria, which is pain during urination,” and “pain with sexual intercourse,” all of which are symptoms of mesh exposure.

Dr. Rosenzweig also observed that the records showed a hard, gray substance near Bayless’s vaginal cuff. He explained that Restorelle Y was the mesh located at the cuff and that the gray coloring was likely “a sign of degradation,” because Restorelle Y is white when it comes out of the box. The records revealed to Dr. Rosenzweig that Bayless “ha[d] a mesh exposure from the Restorelle Y mesh,” which was responsible for her pain.

In Dr. Rosenzweig's view, Restorelle Y was "eroding," "degrading," and "contracting" in Bayless. He concluded that was a cause of her "pain and pain with sex," "repeated infections," "bleeding," "chronic inflammation and chronic foreign body reaction," "fibrotic bridging," "scar plate formation," and "mesh encapsulation." Ultimately, Dr. Rosenzweig concluded that Restorelle Y was not suitable for implantation in Bayless.

Bayless's operating physician, Dr. Jones, also testified. Dr. Jones said that mesh can yield complications including "mesh exposure and/or chronic vaginal discharge, vaginal bleeding, or pain with intercourse." She said she had "observed exposures or erosions in women who have been implanted with mesh," and she had removed mesh because of "pain associated with mesh" and "chronic exposure associated with discharge or bleeding."

After receiving all the evidence, the jury concluded that Coloplast was liable because Restorelle Y was defectively designed, and the defect was a legal cause of Bayless's injuries.⁷ The jury awarded Bayless \$500,000 in compensatory damages.

At every opportunity, Coloplast has argued that it is entitled to judgment as a matter of law. Before trial, it sought summary judgment because, in its view, Bayless did not submit expert testimony on general causation and specific causation. During trial, it

⁷ The jury concluded that Boston Scientific was not liable for Bayless's injuries, so we do not discuss Boston Scientific further.

21-14397

Opinion of the Court

11

moved for judgment as a matter of law, arguing that Bayless had not met her burden to prove general causation or a design defect. And after trial, it renewed its motion for judgment as a matter of law, reiterating its arguments that there was no evidence of general causation and that no witness testified that Restorelle Y's risks outweighed its benefits.

The district court denied each motion. At the summary-judgment stage, it held that Bayless had presented enough admissible evidence to raise a triable issue of material fact on whether Restorelle Y was a defectively designed product that caused her injuries. And after Bayless's case-in-chief, the district court concluded that there was sufficient evidence to support a jury verdict in Bayless's favor. So it denied the motions for judgment as a matter of law.

Coloplast timely appealed the district court's judgment entering the jury's verdict. And Bayless cross-appealed the district court's decision to exclude Dr. Rosenzweig's testimony about general causation.⁸

II. Standard of Review

We review de novo a district court's order denying a defendant's renewed motion for judgment as a matter of law. *Yates v.*

⁸ Because we affirm the district court's judgment, we do not consider Bayless's cross-appeal. Appellee's Br. at 70 ("If this Court affirms the final judgment, then Ms. Bayless will abandon her cross appeal.").

Pinellas Hematology & Oncology, P.A., 21 F.4th 1288, 1298 (11th Cir. 2021). In conducting our review, we determine whether the record, viewed in the light most favorable to the prevailing party, “points so overwhelmingly in favor of the [moving party] that the jury’s verdict cannot stand.” *Id.*

We draw all reasonable inferences in favor of the nonmoving party, and we cannot make credibility determinations, weigh evidence, or consider evidence that the jury need not have believed. *Chmielewski v. City of St. Pete Beach*, 890 F.3d 942, 948 (11th Cir. 2018). Nor will we overturn a jury’s verdict “unless no rational trier of fact could have reached the same conclusion based upon the evidence in the record.” *Mamani v. Sanchez Bustamante*, 968 F.3d 1216, 1230 (11th Cir. 2020) (quoting *Nat’l Fire Ins. Co. of Hartford v. Fortune Constr. Co.*, 320 F.3d 1260, 1267 (11th Cir. 2003)).

III. Discussion

The central issue we must decide is whether sufficient evidence supported the jury’s verdict. After reviewing the record and our precedent, we conclude it did.

We divide our analysis in two parts. First, we address Coloplast’s argument that Bayless failed to present evidence about general causation—that is, as Coloplast defines it, whether Restorelle Y is even capable of causing the type of injuries that Bayless suffered. Second, we show why the testimony presented at trial,

21-14397

Opinion of the Court

13

along with our precedent, forecloses Coloplast's argument that the trial lacked evidence about Restorelle Y's risks.

A. A reasonable jury could find sufficient evidence of general causation.

The parties agree that Florida law governs their dispute. But they disagree about the controlling legal standard for causation in a products-liability action brought under Florida law.

Coloplast argues that causation must be divided into two separate and independent inquiries: general causation and specific causation. On its reading, general causation asks whether the product is capable of causing the type of injury that is alleged, while specific causation asks whether the particular unit of the product actually caused the specifically alleged injury.

Meanwhile, Bayless contends that causation in Florida is a single inquiry that asks whether the alleged defect "directly and in natural and continuous sequence produced or contributed substantially to producing [the plaintiff's injury], so that it can reasonably be said that, but for the defect, the injury would not have occurred." *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 513 (Fla. 2015).

For purposes of this appeal, we assume, without deciding, that Florida law mandates separate inquiries for general causation and specific causation. We do so because, even under Coloplast's preferred standard, Bayless presented sufficient evidence to allow a reasonable jury to find in her favor on both general and specific

causation. So we need not scrutinize the parties' competing interpretations of Florida law.

Coloplast does not dispute that Bayless presented sufficient evidence of specific causation. In other words, it effectively concedes that a jury could find that Restorelle Y caused Bayless's particular post-operation injuries. Coloplast contends only that Bayless did not present sufficient evidence of general causation—that is, that Restorelle Y is even capable of causing the type of injuries that Bayless suffered.

We cannot agree. The testimony presented at trial provided ample evidence for the jury to reasonably conclude that Restorelle Y is capable of causing Bayless's injuries. Because Restorelle Y is a polypropylene mesh, the jury could impute the evidence about polypropylene and its properties to Restorelle Y. And the jury heard testimony about the specific injuries Restorelle Y inflicted on Bayless. So it could have reasonably inferred that Restorelle Y was capable of causing those types of injuries.

Dr. Mays testified about polypropylene's physical properties. He told the jury that polypropylene undergoes oxidative degradation after it is inserted into a living organism (like a person) and how it is subsequently attacked through foreign body response. And Dr. Mays connected his testimony about polypropylene to Restorelle Y, explaining that, because Restorelle Y is a polypropylene mesh, it can be expected to experience the same degradation that occurs to all forms of polypropylene.

21-14397

Opinion of the Court

15

Dr. Rosenzweig followed with testimony about the body's clinical reactions to polypropylene degradation. He outlined the "fairly significant" complications he had observed in patients who had polypropylene mesh inserted. He explained that the mesh degradation can lead to mesh exposure, which causes many of the symptoms that Bayless experienced. And he explained that chronic foreign body reaction can cause nerves to grow through the mesh and lead to erosion, which also explains Bayless's symptoms.

All told, the record contains significant testimony about the potential harmful effects of polypropylene mesh. Based on Dr. Mays's testimony, the jury could have believed that, as a polypropylene product, Restorelle Y could undergo oxidative degradation after it is implanted in vivo. And based on Dr. Rosenzweig's testimony, the jury could have believed that oxidative degradation leads to injuries such as mesh exposure and vaginal erosion. Even though Dr. Rosenzweig did not testify about the general effects of Restorelle Y, he did testify about the general effects of polypropylene mesh, and a sufficient basis existed for the jury to connect them.

To put it another way, the jury could have relied on Dr. Rosenzweig's testimony about specific causation—combined with Dr. Mays's testimony about polypropylene—to infer that the general causation requirement was satisfied. Dr. Rosenzweig testified that the particular Restorelle Y mesh inside Bayless is degrading and causing her injuries. And Dr. Mays testified about the oxidative degradation process and that all polypropylene, including

Restorelle Y, will eventually experience this phenomenon after the polypropylene is implanted. So the jury reasonably could have inferred that, as a general matter, Restorelle Y experiences degradation and causes injuries when it does so.

Coloplast suggests that, under our precedent, evidence of specific causation cannot establish general causation because specific causation only assumes the existence of general causation. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329 (11th Cir. 2010); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233 (11th Cir. 2005); *see also Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296 (11th Cir. 2014); *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183 (11th Cir. 2010). In *Kilpatrick*, we reviewed a district court's decision to exclude an expert witness's testimony (rather than whether there was sufficient evidence to support a jury's verdict). 613 F.3d at 1333. We concluded that the district court did not abuse its discretion in finding that the expert used "flawed" and unreliable methodology to support his conclusions on general causation and on specific causation. *Id.* at 1341–43. Similarly, in *McClain*, we analyzed an expert witness's methodology and concluded that his differential diagnosis did not "offer[] a reliable explanation" for his conclusion because there was no "foundation" for his analysis. 401 F.3d at 1253; *see also Chapman*, 766 F.3d at 1309 (affirming decision to exclude expert's differential diagnosis because expert "did not follow" the "scientifically accepted methodology"); *Hendrix*, 609 F.3d at 1198–1201 (affirming decision to exclude expert's testimony after district court identified several errors in expert's analysis so expert's

21-14397

Opinion of the Court

17

“testimony is the type of ‘speculation, conjecture, or inference’” that should not be admitted (citation omitted)).

But here the district court affirmatively held that Dr. Rosenzweig used reliable methodology to prove specific causation. And Coloplast does not challenge that decision on appeal. The district court explained that because of Dr. Rosenzweig’s training and experience and the scientific literature, he had a valid, science-based explanation for his conclusion that Restorelle Y caused Bayless’s injuries. And it held that his differential diagnosis “was thorough and used reliable methodology for excluding other possible causes.” It does not follow, from our precedent on the admissibility of expert testimony, that the jury could not use Dr. Rosenzweig’s testimony about specific causation, in combination with Dr. Mays’s testimony on the oxidative degradation of polypropylene, to infer that Restorelle Y was capable of causing Bayless’s injuries.⁹

Coloplast also attempts to rebut the key expert testimony. Its efforts to do so for Dr. Mays’s testimony are unavailing.

⁹ Coloplast also cites *Byrd v. Janssen Pharmaceuticals, Inc.*, in which a district court applied New York law and awarded judgment as a matter of law because an expert witness’s differential-diagnosis opinions were speculative and therefore could not reliably establish general causation. 333 F. Supp. 3d 111, 130–31 (N.D.N.Y. 2018). But here, as we explained, the district court held that Dr. Rosenzweig’s differential diagnosis “was thorough and used reliable methodology for excluding other possible causes.” And again, Coloplast does not challenge that finding on appeal.

Coloplast makes several arguments, including that Dr. Mays improperly testified about pain, relied on irrelevant studies and materials, and offered some of his general-causation testimony during Boston Scientific's cross-examination. But Coloplast has no answer for Dr. Mays's key testimony about the oxidative degradation of polypropylene and the foreign body response that causes stiffening after implantation. From that testimony, the jury reasonably could have believed that Restorelle Y degrades in the body.

At bottom, many of Coloplast's critiques about the persuasive force of Dr. Mays's testimony are more relevant to the admissibility of his testimony than to its ability to support the jury's verdict. For example, Coloplast's argument that Dr. Mays relied on studies about products other than Restorelle Y closely mirrors a challenge to the reliability of Dr. Mays's methods and conclusions. But as we have explained, Coloplast has abandoned any admissibility challenges (and understandably so, as it failed to object to much of the testimony it now complains about). And because the district court admitted the evidence, the jury was entitled to credit it, and we cannot now disturb the jury's decision. *See Hastings v. Bonner*, 578 F.2d 136, 142 (5th Cir. 1978) ("If the evidence is received without objection, it becomes part of the evidence in the case, and is usable as proof to the extent of the rational persuasive power it may have. The incompetent evidence, alone or in part may support a verdict or finding." (quoting 1 McCormick on Evid. § 54 (2d ed. 1972) (alterations adopted))).

Coloplast's attempts to rebuff Dr. Rosenzweig's testimony fare no better. It suggests that his general-causation testimony about polypropylene mesh came in the context of Boston Scientific's Advantage Fit rather than Coloplast's Restorelle Y. But the record reveals otherwise. Dr. Rosenzweig testified that he stopped using both types of products because of the complications he observed from polypropylene mesh. His testimony did not purport to draw a distinction between the two products that were on trial together.

Coloplast next references the district court's directives, correctly observing that the district court instructed the jury to "disregard" Dr. Rosenzweig's testimony about Restorelle Y "at large," and instructing the jury to credit only his testimony about "the specific causation of the Coloplast product in Ms. Bayless." But that instruction does not mean that Dr. Rosenzweig could not make statements about the general effects of polypropylene mesh (like the ones Dr. Mays had already made) or that the jury could not connect the statements about polypropylene mesh to Restorelle Y and to the injuries that Bayless suffered.

In sum, between Dr. Mays's testimony about the properties of polypropylene mesh and Dr. Rosenzweig's testimony about the body's reaction to polypropylene mesh and the specific injuries that Bayless suffered from Restorelle Y, there was sufficient evidence for a reasonable jury to conclude that Restorelle Y could cause the type of injuries that Bayless suffered.

B. A reasonable jury could conclude that Restorelle Y's risks outweighed its benefits.

Coloplast next argues that Bayless failed to establish that Restorelle Y's risks outweigh its benefits such that it can be a defective product. We disagree.

A product is defectively designed “if the plaintiff proves that the design of the product proximately caused the plaintiff's injuries and the defendant fails to prove that on balance, the benefits of the design outweigh the risk of danger inherent in the design.” *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1319 (11th Cir. 2017) (quoting *Force v. Ford Motor Co.*, 879 So. 2d 103, 106 (Fla. Dist. Ct. App. 2004)); see also *In re Standard Jury Instructions in Civ. Cases—Rep. No. 13–01 (Prods. Liab.)*, 160 So. 3d 869, 873–74 (Fla. 2015).

We decided a similar challenge in *Eghnayem*. There, plaintiffs from a transvaginal mesh multi-district litigation argued that they suffered injuries from the defendant's pelvic floor repair kit. *Id.* at 1310–11. After a jury found for each plaintiff on all claims, the defendant argued, among other things, that the plaintiffs failed to present sufficient evidence to prove their design-defect claims. *Id.* at 1319.

We affirmed the jury's verdict. *Id.* We observed that the plaintiffs presented expert testimony that polypropylene may experience oxidative degradation, which can cause their injuries. *Id.* at

21-14397

Opinion of the Court

21

1319–20. Indeed, Dr. Mays was one of the experts who testified in that trial. *Id.* at 1320.

The record in *Eghnayem* included many statements that resemble those in the record here. For example, Dr. Mays testified in that case that the polypropylene “stiffens,” “loses its mechanical properties,” and “deteriorate[s]” after oxidation. *Id.* (alterations adopted). He also testified there that polypropylene’s degradation after insertion in the female pelvic area can cause “a sawing effect.” *Id.* And another expert in *Eghnayem* testified that there are “mesh-specific risks” of injuries including “pelvic pain, erosion, painful activity, and permanent tissue damage.” *Id.*

We determined that “[w]hen taken in concert, this expert testimony provided a sufficient foundation for a reasonable jury to conclude that the design of the mesh increased ... the potential for degradation.” *Id.* Therefore, we said that “[t]he ultimate question whether these risks outweighed the [product’s] benefits was for a jury to decide.” *Id.*

Our decision here follows directly from *Eghnayem*. As Bayless highlights in her brief, the key testimony in this case largely resembles the testimony in *Eghnayem*. Appellee’s Br. at 59–63. For example, in both cases, Dr. Mays testified about polypropylene’s reactions with oxygen, which can cause polypropylene to stiffen and lose flexibility. And in both cases, a medical doctor testified about mesh-specific risks, including pain, erosion, and the risk of subsequent surgery.

Coloplast argues that Dr. Mays's testimony here does not link the properties of polypropylene mesh to the risks and benefits of Restorelle Y. But Dr. Mays's testimony explained the risk that mesh will stiffen in the body and that the resulting loss in flexibility will affect its performance. And the jury could connect Dr. Mays's testimony about polypropylene mesh to Restorelle Y. And Dr. Rosenzweig's testimony about the medical risks of polypropylene mesh filled in any missing links to the medical risks of Restorelle Y.

Coloplast also rehashes its arguments that Dr. Rosenzweig could not testify about the risks of Restorelle Y. But as we've noted, Dr. Rosenzweig was permitted to (and did) testify about the medical risks of polypropylene mesh and explained that he had long stopped using it with his patients because he was uncomfortable with the risks. A reasonable jury could infer that the same risks associated with polypropylene mesh generally apply to Restorelle Y specifically.

Finally, Coloplast suggests that a decision endorsing Bayless's theory of liability means that mesh automatically equals defect. Coloplast overstates the implications of our decision. A jury observed eleven days' worth of evidence from several fact and expert witnesses. And it reasonably concluded that Restorelle Y's risks outweighed its benefits. Its decision neither obviates Florida's risk-utility test nor creates absolute liability for prescription-only products. The evidence presented at trial drove the outcome here.

21-14397

Opinion of the Court

23

IV. Conclusion

Based on the evidence presented at trial, a jury could reasonably conclude that sufficient evidence supported a finding of general causation and a finding that Restorelle Y's risks outweighed its benefits.

For these reasons, we affirm the district court's judgment and dismiss Bayless's cross-appeal as moot.

AFFIRMED.