21-14397-BB

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

RAEANN BAYLESS,
Plaintiff-Appellee/Cross-Appellant

v.

COLOPLAST CORP.,
Defendant-Appellant/Cross-Appellee

Appeal from the United States District Court
for the Middle District of Florida, Orlando division

6:20-cv-00831-RBD-GJK

RAEANN BAYLESS'S PRINCIPAL AND RESPONSE BRIEF

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Defendant-Appellant/Cross-Appellee Coloplast Corp., a privately held corporation, is a wholly owned subsidiary of Coloplast A/S, a publicly held foreign corporation (COLO-B, Nasdaq Copenhagen).

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STATEMENT REGARDING ORAL ARGUMENT

Ms. Bayless does not request oral argument. Oral argument is unnecessary because the issues on appeal are simple: (1) whether the jury's verdict is supported by sufficient evidence of causation, (2) whether the jury's verdict is supported by sufficient evidence of a design defect, and (3) whether the district court erred in excluding evidence.

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STATEMENT OF THE ISSUES

Coloplast's appeal

I. The jury found that a defect in Coloplast's product, the Restorelle Y, was a legal cause of Ms. Bayless's injuries. Did the evidence of causation point so overwhelmingly in favor of Coloplast that the jury's verdict cannot stand?

II. The jury found that the Restorelle Y was defectively designed. Did the evidence of a design defect point so overwhelmingly in favor of Coloplast that the jury's verdict cannot stand?

Ms. Bayless's cross-appeal

III. At his deposition in the multidistrict litigation, Dr. Rosenzweig said he was not opining on the Restorelle Y. But at his later deposition in Ms. Bayless's case, Dr. Rosenzweig offered general-causation testimony that applied to the Restorelle Y. He also offered such testimony in his prior expert reports. Did the district court abuse its discretion in excluding such testimony on the grounds that it would be "unfair" even though Coloplast had notice of the testimony?

STATEMENT OF THE CASE

Raeann Bayless was implanted with a synthetic pelvic mesh designed by Coloplast Corp. Not long after the surgery, Ms. Bayless began experiencing pain, vaginal bleeding, and infections. She was diagnosed with mesh erosion and exposure of the mesh into her vagina.

Ms. Bayless sued Coloplast for products liability. After an eleven-day trial, the jury found that Coloplast's mesh was defectively designed and that the defect was a legal cause of Ms. Bayless's injuries. The district court denied Coloplast's renewed motion for judgment of law. Both parties appeal.

I. Course of proceedings

This case arises from a multidistrict litigation (MDL) of products-liability claims. Raeann Bayless filed her complaint directly in the MDL and sued the manufacturers of two synthetic pelvic meshes: Coloplast Corp. (manufacturer of the Restorelle Y), and Boston Scientific Corporation (manufacturer of the Advantage Fit).[1] Doc. 1. Both

[1] There were two MDLs: number 2326 (for Boston Scientific) and number 2387 (for Coloplast). Both MDLs (and multiple others) were assigned to the same district judge, who allowed plaintiffs implanted with multiple products to choose the MDL for their suit. Doc. 60-3 at 3. Ms. Bayless filed in the Boston Scientific MDL.

products were made of polypropylene—a type of plastic used to make fishing line and carpet backing. *See* Doc. 248 at 51:14–17, 132:3–22; Doc. 357 at 7:1–3, 14:21–15:2.

Ms. Bayless's case was later transferred to the Middle District of Florida for case-specific resolution. Doc. 52; Doc. 70. Coloplast then filed three motions that are relevant to this appeal.

First, Coloplast moved to exclude testimony by Ms. Bayless's expert polymer scientist, Dr. Jimmy Mays. Doc. 102. Coloplast argued that Dr. Mays was "not qualified to opine that Coloplast's surgical implants cause foreign body responses such as oxidation and degradation when implanted in humans" because he "is not a medical doctor, nor an expert in tissue response." *Id.* at 4. Ms. Bayless responded that other courts—including the MDL court—had rejected Coloplast's argument. Doc. 107 at 4; *see also Nunez v. Coloplast Corp.*, No. 19-cv-24000, 2020 WL 2315077, at *3 (S.D. Fla. May 11, 2020) ("The MDL Court found, among other things, Dr. Mays's forty years' experience in polymer science as a sufficient basis for him to offer opinions on the effect of polypropylene mesh in the human body. Here, too, the Court finds Dr. Mays qualified." (citation omitted)).

Next, Coloplast moved to exclude testimony by Ms. Bayless's expert urogynecologist, Dr. Bruce Rosenzweig. Doc. 113. Coloplast argued that Dr. Rosenzweig could not testify about "general causation"[2] for the Restorelle Y because he "never properly disclosed general causation opinions about Restorelle Y." *Id.* at 3. Coloplast further argued that Dr. Rosenzweig's "specific causation opinions"—which were based on his differential diagnosis[3]—were unreliable because he "presumed the existence of general causation, for which there is no evidence." *Id.* In other words, Coloplast argued that Dr. Rosenzweig "lack[ed] any basis by which he could 'rule in' Restorelle Y as a possible cause of [Ms. Bayless's] claimed injuries." *Id.* at 9.

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[2] General causation refers to "[t]he potential of an agent to produce the general occurrence of injuries in a population." *Causation*, *Black's Law Dictionary* (11th ed. 2019). By contrast, specific causation refers to "[t]he fact or implication that an agent produced a particular injury in a specific person." *Id.*

[3] "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) (cleaned up).

Ms. Bayless responded that, at his case-specific deposition, Dr. Rosenzweig "provide[d] admissible general causation evidence regarding the defective characteristics of polypropylene—which are the same across the board of all polypropylene meshes." *See* Doc. 124 at 3. She further explained that the MDL court had "expressly determined that Dr. Rosenzweig's general expert report can relate generally to all polypropylene mesh devices." *Id.* Nevertheless, Ms. Bayless also noted that Dr. Mays provided an expert report on general causation, so even if Dr. Rosenzweig did not testify about general causation, he could rely on Dr. Mays's opinion. *Id.* at 2–3.

Finally, Coloplast moved for summary judgment. Doc. 114. Coloplast argued that summary judgment was proper because Ms. Bayless could not offer any expert testimony on general causation and specific causation. *Id.* at 2. Ms. Bayless responded that she could prove causation through the testimony of Drs. Mays and Rosenzweig. Doc. 123 at 4–6.

The district court held a hearing on all three motions. Doc. 164. Coloplast told the court that, at his deposition in the MDL, Dr. Rosenzweig disavowed having any opinion on the Restorelle Y

(a transabdominal device) and "his opinions were strictly about transvaginal devices." *Id.* at 42:17–45:22. The district court questioned whether that distinction mattered given the MDL court's ruling that "the point of implantation is really not determinative of whether or not the product has a defect." *See id.* at 45:23–46:7. Coloplast responded that the distinction mattered because Dr. Rosenzweig's opinions were premised on transvaginal placement. *Id.* at 46:8–47:23.

Consistent with the district court's question, Ms. Bayless argued that the method of placement did not impact Dr. Rosenzweig's opinion on general causation. *Id.* at 48:3–22. Specifically, she explained that Dr. Rosenzweig "can testify to general causation…because it's the properties of the polypropylene that caused the injury, not the method…of placement." *Id.* at 48:7–9. Nevertheless, the court granted Coloplast's motion "with respect to Dr. Rosenzweig's ability to offer general causation testimony as it relates to the [Restorelle Y]." *Id.* at 53:15–17. The court "exclusively" based its ruling on Dr. Rosenzweig's disavowal of "any opinions with respect to [the Restorelle Y] or deficiencies in that product in the way that it was installed or inserted into Ms. Bayless." *Id.* at 53:17–23.

As for Dr. Mays, the district court ruled that although he could not testify "as to what the effect of the device is on the human body," Dr. Mays was "well qualified to testify about the properties of polypropylene and the fact that it undergoes oxidated degradation when it's implanted in vivo" and he could "certainly testify as to what the response is of the material to being placed inside the human body." *Id.* at 105:10–17. The court deferred ruling on Coloplast's motion for summary judgment. *Id.* at 183:12–14.

The district court entered a written order memorializing its oral rulings. Doc. 163. It said that "[a]llowing Dr. Rosenzweig to offer general expert testimony on the *design* of the Restorelle Y mesh at this late juncture would be unfair to Coloplast [and] would run contrary to Rule 26." *Id.* at 6 (emphasis added). The court therefore ruled that "Dr. Rosenzweig may not offer general opinion testimony as to causation, including on general causation opinions in his case specific expert report." *Id.* As an example, the court said "Dr. Rosenzweig may not testify that Bayless's injuries were the result of a *defect* in the Restorelle Y." *Id.* at 6 n.5 (emphasis added).

The district court explained that its ruling "d[id] not invalidate Dr. Rosenzweig's differential diagnosis." *Id.* at 6. To the contrary, Dr. Rosenzweig had solid grounds for "opting-in" the Restorelle Y as a cause of Ms. Bayless's injuries:

> First, Dr. Rosenzweig attributed the following injuries to the Restorelle Y…: mesh erosions/exposures, vaginal bleeding, and infection. As Coloplast notes in its motion for summary judgment, the Restorelle Y's instructions for use acknowledge the Restorelle Y can cause mesh erosion, mesh exposure, vaginal bleeding, and infection. Dr. Jones (Bayless's treating physician) also acknowledged that the Restorelle Y could cause these injuries. And Dr. Rosenzweig relied on his training and experience as well as the relevant scientific literature (including other expert reports) to conclude the mesh could be degrading in vivo and causing these injuries. So 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.

Id. at 7 (citations omitted).

The district court later denied Coloplast's motion for summary judgment. Doc. 169. The court ruled that the combination of Dr. Mays's testimony that the Restorelle Y "is defective because it is made from polypropylene" and Dr. Rosenzweig's testimony that the Restorelle Y "degraded in vivo and caused mesh erosions, vaginal bleeding, and infection" was sufficient to establish causation under Florida law. *Id.* at

11–12. In doing so, the court acknowledged its prior ruling that "Dr. Rosenzweig could not offer general causation opinions—e.g., the mesh is *defective*—but could offer case specific opinions on the injuries [Ms. Bayless] has suffered and their causes." *Id.* at 12 n.8 (emphasis added).

The case then proceeded to trial. Doc. 325. After Ms. Bayless presented her case-in-chief, Coloplast moved for judgment as a matter of law and argued that Ms. Bayless failed to prove general causation. Doc. 270 at 1. In its oral presentation (but not in its written motion), Coloplast also argued that Ms. Bayless failed to prove a design defect. Doc. 273 at 122:22–124:8. The district court rejected both arguments. *Id.* at 135:2–6; Doc. 327 at 2.

At the end of the eleven-day trial, the jury found that Coloplast's Restorelle Y was defectively designed and that the defect was a legal cause of Ms. Bayless's injuries. Doc. 311 at 3. The jury awarded $500,000 in damages to Ms. Bayless, and the district court entered judgment in her favor. *Id.* at 6; Doc. 331. The jury did not find Boston Scientific liable. Doc. 311 at 1–2. Ms. Bayless later settled with Boston Scientific and stipulated to a dismissal of her claims against it, which the district court granted. Doc. 366; Doc. 370.

Coloplast then filed a renewed motion for judgment as a matter of law. Doc. 346. It argued that the jury's verdict was not supported by evidence of a design defect because "no witness testified that the risks of the Restorelle Y outweighed its benefits." *Id.* at 18. Coloplast also rehashed its summary-judgment argument, maintaining that the jury's verdict was not supported by evidence of general causation. *Id.* at 19–28.

In response, Ms. Bayless said there was ample evidence of a design defect, including testimony by Drs. Mays and Rosenzweig, medical literature, and "internal communications" by Coloplast. Doc. 362 at 2–5. She argued that the task of evaluating this evidence and weighing the risks and benefits fell on the jury—not any particular expert. *See id.* at 3–5. Ms. Bayless further argued that the jury was presented with "plenty of evidence by way of expert testimony…, medical literature, and internal documents that showed that the Restorelle Y polypropylene mesh is capable of causing, and did cause, [her] injuries." *Id.* at 5.

The district court denied Coloplast's motion. Doc. 369. It ruled that there was sufficient evidence of design defect because Dr. Mays

testified "that polypropylene, the Restorelle Y mesh material, 'is unsuitable for permanent pelvic mesh implant' and defective" and Dr. Rosenzweig testified "that Restorelle Y mesh is unsuitable for implantation and causes erosion, discharge, vaginal bleeding, pain, and dyspareunia[4]." *Id.* at 4. The court rejected Coloplast's argument on general causation "for the same reasons" stated in its order denying summary judgment. *Id.* at 3–4.

Coloplast timely appealed. Doc. 373. Ms. Bayless timely cross-appealed. Doc. 377.

II. Statement of facts

A. Background facts

Raeann Bayless is a mother of five children. Doc. 266 at 37:6–16. After giving birth to her son in 1987, Ms. Bayless began experiencing symptoms of pelvic organ prolapse—a condition in which pelvic organs descend into the vagina. *Id.* at 55:24–56:3; Doc. 254 at 17:20–25. She also experienced symptoms of stress urinary incontinence—a condition in which a person involuntarily urinates when coughing, laughing, or making other abdominal movements. Doc. 266 at 57:3–11; Doc. 254 at

[4] Dyspareunia means "pain with sexual intercourse." Doc. 266 at 118:18–20.

18:4–8. Her symptoms gradually got worse, and she long hoped to get treatment. Doc. 266 at 56:4–57:15.

In 2012, Ms. Bayless was referred by her county medical clinic to Dr. Kathy Jones, an obstetrician-gynecologist. *See id.* at 53:22–24, 57:16–58:19; Doc. 254 at 13:9–24, 96:6–14. Dr. Jones diagnosed Ms. Bayless with stress urinary incontinence and moderate pelvic organ prolapse. Doc. 254 at 61:16–64:18. Dr. Jones also discussed potential treatments, including surgery. *Id.* at 64:19–67:2. Ms. Bayless said that she wanted definitive surgical correction. *Id.* at 73:9–11; Doc. 266 at 59:23–60:8.

Dr. Jones offered multiple surgical options to Ms. Bayless. Doc. 254 at 89:4–95:13. Ms. Bayless opted to have "robotic-assisted laparoscopic sacrocolpopexy with mesh, a possible sling, and cystocele repair and cystoscopy." *Id.* at 95:14–17. In simple terms, Dr. Jones would use a synthetic mesh manufactured by Coloplast, the Restorelle Y, to treat Ms. Bayless's pelvic organ prolapse. *See id.* at 42:20–22, 101:14–17. And she would use a synthetic mesh manufactured by Boston Scientific, the Advantage Fit, to treat Ms. Bayless's stress urinary incontinence. *See id.* at 101:14–17; Doc. 256 at 43:4–7.

Both meshes were made of polypropylene—a type of plastic used to make fishing line and carpet backing. *See* Doc. 248 at 51:14–17, 132:3–22; Doc. 357 at 7:1–3, 14:21–15:2. Coloplast's instructions for use list many "[a]dverse effects associated with the use of Restorelle Y." Doc. 319-15. Those adverse effects include "transient local wound irritation, foreign body inflammatory response, hematoma, adhesions, pain, infection, wound dehiscence, erosion, extrusion, exposure, fistula, nerve damage, contracture, urinary incontinence, voiding dysfunction, defecatory dysfunction, ileus or small bowel obstruction, dyspareunia[,] and procedure failure." *Id.*

Dr. Jones asked Ms. Bayless to sign multiple informed-consent forms, one of which warned about the use of synthetic mesh. *See* Doc. 254 at 96:15–96:23; Doc. 319-18. The form said that "[w]hen mesh is used in gynecological surgery, there is a 5 to 10 percent chance that this mesh can cause delayed healing and eventually erode into the vagina, requiring a second surgery to remove it." Doc. 254 at 110:8–13.

On August 9, 2013, Dr. Jones performed the surgery on Ms. Bayless. Doc. 319-18 at 29. There were no complications or difficulties during the surgery. *See* Doc. 256 at 8:9–23:1; Doc. 271 at 15:20–24.

Dr. Jones confirmed that the Restorelle Y was "not exposed" and was "completely covered" with peritoneum—the smooth surface that surrounds the abdominal cavity. Doc. 256 at 16:17–25; Doc. 266 at 217:23–24.

Six weeks after the surgery, Ms. Bayless returned to Dr. Jones for a post-operative visit. Doc. 256 at 27:6–12. Ms. Bayless was doing well overall. *Id.* at 27:17–20. However, a "foreign body" was visible at the top of her vagina. *Id.* at 31:24–32:6. Dr. Jones did not know whether the foreign body was the Restorelle Y or the absorbable sutures used during the surgery. *See id.* at 11:20–12:21, 32:9–15; 72:21–25, 108:19–21.

In 2014, Ms. Bayless started noticing blood spotting in her underwear and experiencing occasional pain. Doc. 266 at 89:12–90:4. She examined herself and felt something protruding into her vaginal canal from the top wall of her vagina. *Id.* at 90:5–10. In her words, it felt "[l]ike a piece of wire poking through," and "[t]he end of it was sharp like a needle." *Id.* at 91:23–24, 92:24–93:5.

Ms. Bayless's pain got progressively worse, the bleeding increased, and she experienced pain with sex. *Id.* at 93:20–94:22, 98:19–22. Although she had experienced abdominal pain before, the pain that

started in 2014 was "different," "more constant," and became more severe. *Id.* at 96:1–20. Ms. Bayless believed that her problems were "definitely" caused by the "perforation." *Id.* at 99:23–100:8.

In September 2014, Ms. Bayless sought medical treatment because she was having pain and vaginal bleeding. Doc. 271 at 31:10–25. A speculum exam revealed that mesh was exposed in her vagina. *Id.* at 33:5–14. In June 2015, Ms. Bayless again sought medical treatment and was diagnosed with "[v]aginal erosion due to surgical mesh." *See* Doc. 319-8 at 52. There was redness and discharge around the mesh, which indicated inflammation. Doc. 271 at 36:3–10. She was also diagnosed with vaginal infections. *Id.* at 36:18–37:10.

In October 2017, Ms. Bayless was referred to Dr. Lisa Rose for "[m]esh implant evaluation." Doc. 319-1 at 17; *see also* Doc. 266 at 103:21–104:5. Ms. Bayless reported discomfort, intermittent vaginal bleeding, and that she felt a wire perforating through the top of her vagina. Doc. 260 at 35:11–36:14. Dr. Rose performed a physical exam in which she both saw and felt a gray "very hard substance" protruding into Ms. Bayless's vagina. *Id.* at 38:1–25, 50:18–51:1. The hard

substance was located where the Restorelle Y was implanted. Doc. 271 at 51:4–8.

Dr. Rose diagnosed Ms. Bayless with mesh exposure and recommended that the mesh be removed as soon as possible. *See* Doc. 260 at 39:5–18. Dr. Rose also determined that Ms. Bayless was at "very high risk of infection" because of the mesh exposure. *See id.* at 39:5–40:8.

B. Expert testimony at trial

The jury heard testimony from several experts at trial, including Drs. Mays, Rosenzweig, Jones, Badylak, and Goldberg.[5] The relevant portions of their trial testimony are summarized below.

1. Dr. Jimmy Mays

Dr. Jimmy Mays is a polymer scientist who has worked in the field of polymer science his entire adult life. Doc. 248 at 31:18–19,

[5] Drs. Mays and Rosenzweig were disclosed as experts by Ms. Bayless. Doc. 218-5 at 9–10. The others—Drs. Jones, Badylak, and Goldberg—were disclosed as experts by Boston Scientific. Doc. 218-6 at 4. Nevertheless, their testimony can support the jury's verdict for Ms. Bayless. *Walden v. U.S. Steel Corp.*, 759 F.2d 834, 837 (11th Cir. 1985) ("In reviewing the denial of a motion for judgment n.o.v., this court is obligated to consider all the evidence, not just the evidence supporting the non-moving party's case, in the light most favorable to the non-moving party.").

34:17–22. He testified that polymers are long chain-like molecules and that polypropylene is a polymer. *Id.* at 31:20–25. He also explained that polypropylene reacts with oxygen in a process called "oxidation." *Id.* at 57:21–24.

Like a rusty nail, polypropylene crumbles when it reacts with oxygen or other oxygen-containing molecules. *Id.* at 58:6–15. Dr. Mays said this process is called "oxidative degradation." *See id.* at 57:25–58:21. It causes the polymer chain to break along its backbone. *Id.* at 58:19–21.

Antioxidants are often added to polypropylene to limit oxidative degradation. *Id.* at 57:6–24. But Dr. Mays explained that "[a]ntioxidants can't stabilize polypropylene forever. The best you can hope for with polypropylene, because of its high susceptibility to oxygen, is just to delay the process." *Id.* at 58:24–59:1. Polypropylene is particularly susceptible to oxidative degradation because of its chemical structure. *Id.* at 60:6–7. Moreover, Dr. Mays said that oxidative degradation specifically affects the parts of polypropylene that give it flexibility. *Id.* at 62:12–23.

When polypropylene enters the human body, the body detects it as a foreign substance and attacks it—a process called the foreign body response. *Id.* at 64:4–7. Dr. Mays testified that this process "generates very strong oxidizing agents…that catalyze oxidative degradation." *Id.* at 64:8–10. And he said it continues for as long as the implant is inside the body. *Id.* at 65:11–17, 102:11–14.

Although polypropylene is "initially flexible and can move with the body as an implant," Dr. Mays said "it becomes stiffer during this oxidation process because you're eating away the flexible part of the polypropylene." *Id.* at 65:25–66:3. The polypropylene also becomes brittle, contracts, can develop cracks, and pieces of it flake off. *Id.* at 66:3–4, 77:17–20, 104:23–105:1. Compared to a dense object, polypropylene mesh—including the Restorelle Y—undergoes oxidative degradation at a faster rate because of its large surface area. *Id.* at 77:21–78:17, 86:22–87:5. Dr. Mays explained that this degradation negatively affects the performance of the mesh by causing it to become stiffer and lose its flexibility. *Id.* at 103:23–104:1, 107:25–108:7. The Restorelle Y is supposed to be flexible so that it can move with soft tissue in the pelvic space. *Id.* at 108:18–109:14.

Dr. Mays testified that the foreign body response occurs regardless of where a polypropylene implant is placed, including the pelvic region. *Id.* at 69:22–70:15. He said this has been a "known scientific fact since around 1990." *Id.* at 70:16–18; *see also id.* at 87:13–21, 99:4–9. He further noted that, as of 2010, it was known that degradation occurred in all polypropylene pelvic meshes used at the time. *See id.* at 116:3–6, 121:4–10.

Dr. Mays testified about several studies concerning polypropylene mesh. He noted that one such study—a 2005 study of explanted hernia meshes—found that polypropylene meshes were "greatly damaged physically, independently of the implantation time," whereas meshes made of polyethylene terephthalate "were not damaged even after the long implantation periods." *Id.* at 88:18–92:13. A 2007 study of explanted hernia meshes similarly found that polypropylene meshes degrade in the body. *Id.* at 96:1–97:7, 107:7–16.

Dr. Mays said that a 2010 study of explanted pelvic meshes also found that polypropylene meshes degraded but polyethylene terephthalate meshes did not. *Id.* at 109:15–114:21. The authors of that

study further recognized that polypropylene pelvic meshes were associated with "high complication rates." *Id.* at 113:23–114:1.

Dr. Mays testified that there is "extensive" literature correlating oxidative degradation of an implant with clinical effects on a patient. Doc. 357 at 74:1–7. For example, he noted that several of the studies he discussed involved meshes that were removed because patients were having problems with them. *Id.* at 76:1–8, 77:19–22. Further, the 2007 study of explanted hernia meshes supports the connection between degradation of mesh and the resulting complications:

> This prolonged inflammatory response is thought to cause fibrosis and a rigid scar plate to form around the mesh material, particularly in the case of polypropylene meshes, leading to chronic pain and reduced mobility.
>
> ….
>
> Because of a susceptibility of polypropylene to oxidation and the evidence of embrittlement and reduced compliance of the material in vivo, it is our hypothesis that oxidation is responsible for some of the complications associated with polypropylene hernia repair materials.
>
> ….
>
> Our results supported our hypothesis and indicated that the explanted polypropylene meshes did undergo degradation while in vivo, most likely due to oxidation.

Doc. 248 at 102:18–21, 104:3–7, 107:9–11.

Dr. Mays explained that when polypropylene mesh stiffens due to oxidation, it causes a "mechanical mismatch leading to pain." Doc. 357 at 79:9–11. Specifically, he said "if there's mechanical mismatch created between the mesh and the surrounding tissue and the tissue grows into the mesh, there's nerves in there. That mechanical mismatch is going to cause pain when the patient moves." *Id.* at 79:14–18.

Dr. Mays also testified about several "material safety data sheets," which "tell you what to do with [a] material and what not to do with it." Doc. 248 at 140:12–18. He noted that the data sheet for the polypropylene used in Boston Scientific's Advantage Fit says not to use the material "in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." *Id.* at 139:21–140:1, 141:13–16. The data sheet for the polypropylene used in Coloplast's Restorelle Y similarly says to avoid strong oxidating agents, which includes oxidating agents known to be present in the human body. Doc. 357 at 6:20–8:23. Moreover, the data sheet for the resin used to make the polypropylene in the Restorelle Y says the material is "not intended for use as medical implant material for implantable medical devices." *Id.* at 18:10–21:15.

Dr. Mays opined that the antioxidants used in the Restorelle Y are not adequate for permanent implantation in humans—"[t]hey're the types of stabilizer package that you put into polypropylene fibers if you were stabilizing them for use as fishing line or carpet applications." *Id.* at 14:21–15:2. He explained that the antioxidants are not sufficient to prevent long-term degradation—"[t]hey can only delay the onset of oxidative degradation if you put this polypropylene in a strong oxidizing environment like the human body." *Id.* at 15:8–14.

Dr. Mays emphasized that the issues with polypropylene are the same for all polypropylene products: "the polypropylene is the same whether it's in the resin form,…whether it's in the fiber form, or whether it's in the finished product. The polypropylene chemistry is the same. Its reactivity is the same." *Id.* at 30:23–31:2. He testified that there is nothing unique about the Restorelle Y that makes it immune to the problem of oxidative degradation. *See id.* at 36:12–18.

Dr. Mays opined that oxidative degradation occurs with the Restorelle Y when it is placed in the human body. *Id.* at 38:25–39:6. As a result, he said, the Restorelle Y is not able to function and perform as intended because its properties change for the worse. *Id.* at 39:23–40:8.

Dr. Mays testified that if a polymer cannot maintain its physical properties in its intended application, it is not a suitable choice for a permanent implantation. *Id.* at 41:22–25. He further opined that the Restorelle Y was not suitable, fit, and appropriate for its intended use. *Id.* at 48:4–11. Dr. Mays therefore opined that the Restorelle Y is "defective." *Id.* at 48:18–23; *see also* Doc. 248 at 32:19–33:11.

Dr. Mays said he is not aware of any test results that confirm that the Restorelle Y degrades in the human body, but he underscored that "it's polypropylene and that's what polypropylene does." Doc. 357 at 104:12–17; *see also id.* at 102:2–10, 126:18–24. In other words, "all polypropylene degrades in the body," regardless of the manufacturer. *Id.* at 73:3–8. "Polypropylene is polypropylene." *Id.* at 138:14–19.

Dr. Mays explained that he did not need to see Ms. Bayless's mesh to form his opinions because the mesh was implanted in 2013, and "that's far longer than any induction time for any polypropylene on the market." *Id.* at 139:14–18. Dr. Mays had "[a]bsolutely no doubt" that the Restorelle Y has undergone oxidative degradation in Ms. Bayless. *Id.* at 139:19–22. He said there is no combination of antioxidants that could prevent or eliminate oxidative degradation in pelvic polypropylene

mesh implants. *Id.* at 141:14–20. He further noted that there is nothing magical or different about Coloplast polypropylene such that the laws of polymer chemistry do not apply to it. *Id.* at 145:19–23. Dr. Mays opined that degradation will occur in any permanent implantation. *Id.* at 106:20–25.

2. Dr. Bruce Rosenzweig

Dr. Bruce Rosenzweig is a urogynecologist who has practiced in that capacity for 30 years. Doc. 266 at 165:5–22. At trial, he testified that he has experience implanting polypropylene mesh to treat pelvic organ prolapse. *Id.* at 166:5–8. He also has experience treating mesh-related complications. *Id.* at 166:9–11. After reviewing Ms. Bayless's medical records, Dr. Rosenzweig opined that the Restorelle Y was causing or substantially contributing to Ms. Bayless's injuries. *Id.* at 166:12–167:7.

Dr. Rosenzweig said he started using polypropylene products to treat prolapse disorders in 2005. *Id.* at 171:25–172:2. Around 2008 or 2009, he stopped using polypropylene mesh to treat pelvic organ prolapse because "it was not worth using these products any more" in light of the "risks." *Id.* at 176:16–177:13. Specifically, Dr. Rosenzweig's

patients started having mesh complications such as pain, pain with sex, mesh erosion, and exposure of the mesh into the vagina. *See id.* at 177:15–22. Dr. Rosenzweig testified that these "risks" were a result of the properties of polypropylene mesh. *See id.* at 177:1–3.

Dr. Rosenzweig explained that when polypropylene mesh is in the human body, the foreign body response causes the body to form a scar plate around the mesh. *Id.* at 178:6–179:5. Nerves then get trapped in the scar, which is why polypropylene mesh causes pain. *Id.* at 179:6–16.

Dr. Rosenzweig has done surgery on approximately 350 patients that have had mesh-related injuries. *Id.* at 180:11–12. Although he has not implanted a mesh made by Coloplast, Dr. Rosenzweig testified that he did not need to implant a Coloplast mesh to form his opinions because "these are all made from polypropylene." *Id.* at 181:12–21. In other words, "[t]he polypropylene is the same," and regardless of whether a polypropylene product has different additives or components—including the Restorelle Y—"the body's reaction is the same." *Id.* at 182:15–183:2.

Dr. Rosenzweig explained that he used a process called "differential diagnosis" to form his opinions. *Id.* at 189:5–190:9. The

process involves reviewing the patient's history and test results to "get a list of factors or etiologies of what's causing their complaints." *Id.* at 189:17–20. After examining the patient and reviewing laboratory findings, Dr. Rosenzweig "whittle[s] down that list to come up with two or three of the most likely causes." *Id.* at 189:21–24. Finally, he "rule[s] in, out of that small list, what is the most likely cause of the complaint." *Id.* at 190:1–3.

Dr. Rosenzweig did not personally examine Ms. Bayless, so he relied on deposition testimony and medical records, which included results from examinations performed by other doctors. *Id.* at 190:4–9; Doc. 271 at 69:17–20. He ruled out multiple potential causes of Ms. Bayless's injuries, including pre-existing injury, cigarette smoking, drug use, sexually transmitted diseases, vaginal childbirth, past surgery, and failure to comply with post-operative instructions. *See* Doc. 266 at 190:10–191:8, 198:5–7, 212:15–213:1; Doc. 271 at 19:19–20:14, 73:24–74:20.

Dr. Rosenzweig opined that Ms. Bayless's mesh exposure beginning in 2014 was "due to a chronic foreign body reaction," and that the exposed mesh was the Restorelle Y. Doc. 271 at 33:17–18, 35:18–

36:2. He testified that pelvic pain and vaginal bleeding are symptoms of mesh exposure. *Id.* at 34:6–8. And he determined that Ms. Bayless's pain was caused by "chronic foreign body reaction from the mesh." *Id.* at 49:17–23. He further determined that Ms. Bayless's pain with sex was caused by exposure of the mesh. *Id.* at 50:7–9.

Dr. Rosenzweig noted that when a foreign substance was observed in Ms. Bayless's vagina in 2017, it was reported to be "gray" and "very hard." *Id.* at 50:10–51:6. Dr. Rosenzweig opined that it was the Restorelle Y that was protruding into Ms. Bayless's vagina. *Id.* at 59:18–19. The Restorelle Y is originally white, so for it to be gray and very hard is a sign that it underwent degradation, scarring, and contraction. *Id.* at 51:4–12, 58:14–59:7.

Dr. Rosenzweig opined that Ms. Bayless's Restorelle Y is causing pain and pain with sex, it is eroding, it is degrading, it is a cause of post-implant infections, it is a cause of bleeding, it is causing chronic inflammation and chronic foreign body reaction, it is causing scar plate formation and mesh encapsulation, and it is contracting. *Id.* at 67:25–69:6. Dr. Rosenzweig also testified that the Restorelle Y is not suitable for implantation in Ms. Bayless. *Id.* at 69:14–16.

Dr. Rosenzweig opined that but for the use of the Restorelle Y, Ms. Bayless would not have mesh erosion, pain, painful sex, and infections associated with the Restorelle Y. *Id.* at 70:8–18. Moreover, he opined that the Restorelle Y is causing more injuries than the Advantage Fit. *Id.* at 70:22–25. Specifically, "all the erosion is due to the Restorelle Y-mesh," "[t]he discharge [and] the bleeding is due to the Restorelle Y-mesh," and the "majority" of the pain and pain with sex is due to the Restorelle Y. *Id.* at 71:2–5.

Dr. Rosenzweig explained precisely how the foreign body reaction leads to a mesh causing pain to a patient: it results in the development of cells called macrophages that destroy the mesh, which leads to the vaginal tissue being injured, and that leads to the vaginal tissue dying and the mesh being exposed. *See id.* at 74:10–14. The mesh then degrades, scarring continues around the mesh, leading the mesh to contract. *See id.* at 74:15–17. Nerves grow through the mesh and become strangled as the mesh contracts, which leads to pain and pain with sex because of nerves trapped in the mesh. *See id.* at 74:17–18, 80:6–10.

If Ms. Bayless had presented to Dr. Rosenzweig in 2012, he would have done a "native tissue repair" using sutures to repair her prolapse, which would not have required polypropylene. *Id.* at 75:2–6, 15–23. Dr. Rosenzweig opined that this treatment is a safer alternative to using polypropylene mesh. *Id.* at 76:18–21.

Dr. Rosenzweig reviewed "[s]everal thousand" medical journal articles to form his opinions. Doc. 266 at 186:23–187:5. One such article noted that polypropylene meshes used to treat pelvic organ prolapse "are associated with significant complications,…most commonly mesh exposure and pain." Doc. 271 at 77:25–79:14. The article concluded that mesh degradation indeed occurs. *Id.* at 80:11–81:2. Dr. Rosenzweig said the article supports his opinions that the Restorelle Y undergoes degradation that leads to mesh exposure and that it undergoes fibrosis and scar plating, which leads to pain. *Id.* at 81:4–9. The article correlates with Dr. Rosenzweig's opinion that Ms. Bayless has mesh exposure from the Restorelle Y and is having pain and dyspareunia from it. *Id.* at 81:17–20.

Dr. Rosenzweig also reviewed several Coloplast and Boston Scientific "internal documents." Doc. 266 at 187:6–10. For example, he

testified about a white paper by a urogynecologist (and Boston Scientific consultant) who recognized that polypropylene mesh degrades. Doc. 271 at 85:6–87:5. Dr. Rosenzweig explained that the white paper reinforces his opinions that "mesh can cause erosion, infection, and pain," that "[m]esh can become stiffened, contracted, and folded," that "the patient's immune response is what leads to this," and that "mesh can degrade." *Id.* at 87:8–11.

The white paper also noted that, based on a "metanalysis" of 110 studies, the erosion rate for mesh is 10.3% and the dyspareunia rate is 9.8%. *Id.* at 87:16–19. Dr. Rosenzweig opined that these were not acceptable complication rates because they were "very high." *Id.* at 87:21–24.

Similarly, a 2008 internal Boston Scientific document found that "[a]ll mesh use increases complications, such as discharge, dyspareunia, erosion, and infection," compared to a surgery without mesh. *Id.* at 88:24–91:23. The document states that "the rate of 3.4 percent of postoperative synthetic mesh erosions has led to a search for alternative materials" from polypropylene. *Id.* at 92:3–18. Dr. Rosenzweig explained that the need to search for alternative materials was because

of "complications associated with polypropylene." *Id.* at 92:16–18. He also reiterated that Ms. Bayless has complications associated with polypropylene. *Id.* at 92:19–21.

Another internal document that Dr. Rosenzweig reviewed consisted of an email string between two Coloplast employees, which attached a white paper about mesh. Doc. 273 at 25:3–26:25. The paper said that "[a]ll current mesh and biological systems for reconstructive pelvic surgery available in the market today have dyspareunia and mesh exposure as problems." *Id.* at 27:7–27:9. The paper concluded that "inherent properties of the mesh contribute to dyspareunia." *Id.* at 27:20–21. This informed Dr. Rosenzweig's opinion that the inherent properties of mesh can lead to painful sex. *Id.* at 27:24–25. Dr. Rosenzweig further testified that the inherent properties of mesh in fact led to painful sex for Ms. Bayless. *Id.* at 28:1–3.

Dr. Rosenzweig also reviewed a different email string between Coloplast employees. *Id.* at 31:1–12. The emails attached an article that said "[t]here is data to suggest that once implanted, polypropylene mesh may exhibit different post-implantation biomechanical properties, specifically stiffness." *Id.* at 32:8–33:13. Dr. Rosenzweig testified that he

saw evidence in Ms. Bayless's medical records of mesh stiffness because the mesh was described as being hard. *Id.* at 33:14–18. Another article shared in the email string, which was printed in 2012, concluded that polypropylene is not inert after implantation. *Id.* at 34:6–35:5.

Dr. Rosenzweig testified that once polypropylene mesh "is in for a period of time, it becomes very difficult to remove." Doc. 266 at 178:1–2. And even with removal, "pain [i]s very difficult to make go away." *Id.* at 178:2–5. Dr. Rosenzweig said it would be difficult to remove the Restorelle Y in Ms. Bayless because it "would require a significant incision." Doc. 271 at 69:21–70:3; *see also id.* at 72:15–16 ("It's exceedingly difficult to remove all of the mesh associated with mesh products."). If all the mesh is not removed, the mesh will continue to degrade and undergo a chronic foreign body reaction. *Id.* at 72:17–21.

Dr. Rosenzweig testified that a 2008 report by a Boston Scientific consultant (and doctor) stated that "[s]ince mesh usually becomes adherent to the tissues, removing it involves…extensive dissection." *Id.* at 90:8–16, 93:21–23; *see also* Doc. 320-10 at 1, 4. Dr. Rosenzweig explained that this "means that removal procedures are difficult because of the amount of dissection that needs to be done." Doc. 271 at

93:25–94:1. Indeed, "nerves can grow through the opening or the pores of the mesh." Doc. 266 at 179:13–14. Further, the body causes a scar "that goes around each individual fiber" of the mesh and "then goes from individual fiber…to the next fiber and then completely surrounds the whole implant." *Id.* at 179:1–4.

3. Dr. Kathy Jones

Dr. Kathy Jones is an obstetrician-gynecologist. Doc. 254 at 13:9–24. She testified that "[t]he most common types of mesh-related complications is [sic] a mesh exposure and/or chronic vaginal discharge, vaginal bleeding, or pain with intercourse." *Id.* at 31:10–12. Dr. Jones also recognized that mesh erosions are a mesh-related complication, and she has given presentations on mesh erosion. *Id.* at 32:3–14, 37:6–20.

Dr. Jones explained that mesh is not supposed to erode or become exposed once it is implanted and that these are unwanted outcomes. *Id.* 42:2–8. She has observed exposures or erosions in women who have been implanted with mesh to treat pelvic organ prolapse. *Id.* at 42:16–19. She has also removed mesh because of pain associated with the mesh and because of chronic exposure associated with discharge or

bleeding. *Id.* at 43:17–22. Dr. Jones told Ms. Bayless that there was a 5 to 10 percent chance her mesh "can cause delayed healing and eventually erode into the vagina, requiring a second surgery to remove it." *Id.* at 110:8–24.

4. Dr. Steve Badylak

Dr. Steve Badylak is a medical doctor with a Ph.D. in anatomic pathology—"the discipline of examining tissues and determining the course and the cause of a problem or healing." Doc. 284 at 123:4–124:12. Dr. Badylak testified that "it's almost impossible to remove all mesh once it's implanted." Doc. 290 at 48:6–8.

5. Dr. Roger Goldberg

Dr. Roger Goldberg is a urogynecologist who has long served as a consultant for Boston Scientific. Doc. 281 at 18:9–22, 134:25–135:9. He testified that using mesh for surgeries "increases the mesh-specific risks of the procedure." Doc. 284 at 49:25–50:1. For example, Dr. Goldberg acknowledged that "mesh exposure…is a known complication…of any mesh repair." *Id.* at 84:25–85:2. He also acknowledged that a "risk" of pelvic mesh is that it will "erode through the tissue into the vagina and cause pain because of that." *See id.* at 90:20–91:4.

C. Facts relevant to cross-appeal

Before trial, Dr. Rosenzweig disclosed general-causation opinions in several forms. For instance, at his August 17, 2020 deposition in Ms. Bayless's individual case, he testified that "the mesh became exposed because of the characteristics of the mesh," which "make the vaginal epithelium break down." Doc. 113-9 at 51 (194:22–195:4); *see also id.* at 78 (302:23–303:3). He further explained that several of the opinions in his report could apply to "any mesh product"—namely, that "[m]esh products degrade, contract, deform, lead to chronic foreign body reaction, chronic inflammatory reaction, scar plate formation, [and] entrap nerves." *Id.* at 58 (223:18–224:3); *see also id.* at 60 (231:5–232:16), 63 (245:12–19); 64 (246:8–12), 74 (287:20–23), 75 (290:18–20), 75 (293:5–10). He also testified that "stiffness of the mesh is what leads to complications such as erosion, pain, dyspareunia, increased foreign body reaction, [and] increased inflammatory reaction." *Id.* at 63 (244:14–17); *see also id.* at 64 (246:17–19). And he confirmed that his opinions were based "on the properties of polypropylene mesh." *Id.* at 59 (226:24–227:3).

Dr. Rosenzweig's June 4, 2018 case-specific expert report likewise disclosed general causation opinions. Doc. 113-3. For example, the report states that Ms. Bayless injuries were "directly caused" by the "polypropylene mesh characteristics" of the Restorelle Y, which include:

> (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never meant to be implanted inside the human body and is incompatible with the naturally occurring condition of the vagina including peroxides and bacteria; (d) deformation, stiffness and rigidity of the mesh, fraying, roping, cording, curling and sharp edges of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices; (i) migration.

Id. at 10.

The case-specific report also states that Dr. Rosenzweig "relied upon [his] general causation Advantage Fit report in the MDL." *Id.* at 4; *see also id.* at 10 (referring to "general expert report"), 15 (referring to "general report"). In that June 4, 2018 report, Dr. Rosenzweig once again explained that the characteristics of polypropylene mesh cause degradation, chronic foreign body reaction, erosion, infection, pain, nerve entrapment in scar plates, and contraction. *See* Doc. 63-28 at 197–213.

Finally, Dr. Rosenzweig issued an expert report in the Coloplast MDL on March 10, 2019. Doc. 123-1. The report focused on Coloplast's transvaginal Restorelle products—not its transabdominal products such as the Restorelle Y. *See id.* at 9. Nevertheless, the report disclosed broad opinions that would apply equally to the Restorelle Y because it is made of the same polypropylene. *See id.* at 11 ("All Restorelle pelvic mesh products utilize Coloplast's Smartmesh polypropylene."); *id.* at 12 ("The following Restorelle Products use Coloplast's Smartmesh: Restorelle Y…."). Indeed, the report details the issues of degradation, chronic foreign body reaction, fibrotic bridging, and contraction caused by the characteristics of polypropylene. *Id.* at 13–35.

III. Standards of review and decision

This Court reviews de novo the district court's denial of a renewed motion for judgment as a matter of law. *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1298 (11th Cir. 2021). "Such a motion is to be granted 'only if the evidence is so overwhelmingly in favor of the moving party that a reasonable jury could not arrive at a contrary verdict.'" *Chmielewski v. City of St. Pete Beach*, 890 F.3d 942, 948 (11th Cir. 2018) (citation omitted). "All reasonable inferences are drawn in

favor of the nonmoving party, no credibility determinations may be made, the evidence may not be weighed, and evidence that the jury need not have believed is to be disregarded." *Id.* "[T]he 'proper analysis is squarely and narrowly focused on the sufficiency of evidence,' that is, whether the evidence is 'legally sufficient to find for the party on that issue.'" *Id.* (citation omitted)

This Court "review[s] evidentiary rulings for an abuse of discretion." *Johnson v. 27th Avenue Caraf, Inc.*, 9 F.4th 1300, 1310 (11th Cir. 2021).

SUMMARY OF ARGUMENT

The jury's verdict is supported by sufficient evidence of causation. Contrary to Coloplast's suggestion, Ms. Bayless was not required to prove general causation to meet her burden of proof under Florida law. But even if she was, there was ample evidence of general causation. Notably, both Drs. Mays and Rosenzweig testified in detail about how polypropylene mesh causes pain, erosion, and other complications.

The jury's verdict is also supported by sufficient evidence of a design defect. Ms. Bayless's experts were not required to specifically state that the risks of the Restorelle Y's design outweigh its benefits. Instead, the jury could draw that conclusion from its own evaluation of the evidence. The evidence in this case is materially identical to evidence this Court deemed sufficient in a similar case involving a defectively designed polypropylene mesh.

If this Court concludes that the evidence was insufficient to support the jury's verdict, this Court should reverse because the district court erred in excluding portions of Dr. Rosenzweig's testimony. The excluded testimony was disclosed to Coloplast, so it would not have been "unfair" for Dr. Rosenzweig to offer that testimony at trial.

ARGUMENT ON APPEAL

I. The jury's verdict on causation is supported by sufficient evidence.

Coloplast argues that this Court should set aside the jury's verdict because Ms. Bayless purportedly "did not offer any competent evidence of general causation." BlueBr. § I. Coloplast's argument suffers from two, independent flaws: (A) Ms. Bayless was not required to prove general causation, and (B) even if she were so required, Ms. Bayless presented sufficient evidence of general causation.

A. Ms. Bayless was not required to prove general causation.

Some jurisdictions require a plaintiff in a products-liability case to separately prove "general causation" and "specific causation." *E.g.*, *Wadley v. Mother Murphy's Labs.*, 850 S.E.2d 490, 494 (Ga. Ct. App. 2020). But Florida does not.[6] Instead, Florida "simply applies the general rules of causation, requiring the plaintiff to show that the defect caused the injury or harm alleged." *See Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 513 (Fla. 2015). In other words, the plaintiff is "merely required to show that the [defect] directly and in natural and

[6] The parties agree that "Florida substantive law applies." Doc. 218 at 10.

continuous sequence produced or contributed substantially to producing [her injury], so that it can reasonably be said that, but for the defect, the injury would not have occurred." *Id.*

Consistent with Florida law, the Florida standard jury instruction on causation in a products-liability case does not discuss—let alone mention—general causation and specific causation:

> [A defect in a product] [Negligence] is a legal cause of [loss] [injury] [or] [damage] if it directly and in natural and continuous sequence produces or contributes substantially to producing such [loss] [injury] [or] [damage], so that it can reasonably be said that, but for the [defect] [negligence], the [loss] [injury] [or] [damage] would not have occurred.

Fla. Std. Jury Instr. (Civ.) 403.12a (brackets in original).

Nor did the district court in this case instruct the jury on general causation and specific causation. Doc. 310. The jury's verdict form also does not include a special interrogatory for general causation and specific causation. Doc. 311.

As the Restatement of Torts explains, general causation and specific causation "are not 'elements' of a plaintiff's cause of action, and in some cases may not require separate proof." Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 28 cmt. c(1) (2010).

"These categories function as devices to organize a court's analysis, not as formal elements of the cause of action." *Id.*

Coloplast does not cite any contrary Florida authority. Indeed, the sole Florida case that Coloplast cites for causation is *Berry v. CSX Transportation, Inc.*, 709 So. 2d 552 (Fla. Dist. Ct. App. 1998). BlueBr. 29–38. And *Berry* did not hold that a plaintiff must *prove* general causation and specific causation. 709 So. 2d at 554–71. Rather, the issue on appeal was whether the trial court properly *excluded* expert testimony on those topics. *Id.*

Perhaps recognizing the absence of any Florida law to support its argument, Coloplast instead relies on this Court's caselaw. *See* BlueBr. 29–31. This Court, however, is not the final arbiter of Florida law—the Florida Supreme Court is. This Court may not usurp that court's power by adding elements of proof that the Florida courts never have required a plaintiff to prove. *Cf. Pier 1 Cruise Experts v. Revelex Corp.*, 929 F.3d 1334, 1349 (11th Cir. 2019) ("The Florida Supreme Court…is the ultimate arbiter of Florida law;...we…are bound by its determinations of state law.").

In any event, this Court has not held that general and specific causation are elements of proof required for a Florida products-liability claim. Instead, the cases cited by Coloplast dealt with the admissibility of expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

For example, Coloplast first cites *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183 (11th Cir. 2010). BlueBr. 29. But the only question presented in *Hendrix* was whether the district court "erred in finding unreliable under *Daubert*" certain expert testimony. *Id.* at 1191 & n.4. A court's holding is limited to "the parts of [its] decision that focus on the legal questions actually presented to and decided by the court." Bryan A. Garner et. al, *The Law of Judicial Precedent* § 4, at 44 (2016). To be a holding, a legal determination by the court must be "'pivotal to its decision.'" *Id.* (quoting *Black's Law Dictionary* 849 (10th ed. 2014)). Whatever *Hendrix* said about the elements of proof for a Florida products-liability action was not pivotal to its decision and thus was not a holding.

Coloplast next cites *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329 (11th Cir. 2010). BlueBr. 29. But *Kilpatrick* also dealt with "the exclusion of

[expert] testimony." 613 F.3d at 1333. To be sure, this Court said in a footnote that "to prevail on his products liability claims, [the plaintiff] must offer proof of both general causation…and proof of specific causation." *Id.* at 1334 n.4 (citing *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005)). However, that statement was unnecessary to deciding the case, which concerned only whether the district court erred in excluding expert testimony. *Id.* at 1333. The statement is therefore dictum. *United States v. Kaley*, 579 F.3d 1246, 1523 n.10 (11th Cir. 2009) ("[D]icta is defined as those portions of an opinion that are 'not necessary to deciding the case then before us.'" (citation omitted)). What's more, the dictum is not even persuasive because the sole authority cited to support it—*McClain*—says nothing about a plaintiff's burden of proof under Florida law. *See McClain*, 401 F.3d at 1236 (holding that, in a diversity case governed by Alabama substantive law, the district court "erroneously admitted Plaintiffs' experts' testimony").

Coloplast's remaining cases are likewise inapposite. *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005) (applying Colorado law); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d

1296 (11th Cir. 2014) (holding that the district court correctly excluded expert evidence); *Byrd v. Janssen Pharm., Inc.*, 333 F. Supp. 3d 111, 127 (N.D.N.Y. 2018) (applying New York law).

At bottom, Coloplast has not pointed this Court to any authority holding that, under Florida law, a plaintiff in a products-liability case must separately prove general causation and specific causation. Although Coloplast cites cases that address general and specific causation in the context of *Daubert* rulings, Coloplast has not appealed the district court's *Daubert* rulings. BlueBr. 13–51. Thus, the reliability of Ms. Bayless's expert testimony is not at issue. *Belize Telecom, Ltd v. Government of Belize*, 528 F.3d 1298, 1304 n.7 (11th Cir. 2008) ("Appellate courts generally do not entertain issues or claims not raised on appeal.").

Nor does this Court's review of the sufficiency of the evidence implicate a review of the reliability of Ms. Bayless's expert testimony (despite Coloplast's failure to raise the issue on appeal). Even if evidence—including expert testimony—is improperly admitted, it can support a jury's verdict. *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." (citation and emphasis omitted)); *accord* 1 Robert P. Mosteller et al., *McCormick on Evidence* § 54 (8th ed. 2020) ("[O]n appeal, the party may use the [inadmissible] evidence to uphold the legal sufficiency of the evidence to support a judgment….The principle applies to any ground of incompetency under the exclusionary rules. It is most often invoked with respect to hearsay, but it has also been applied to…opinions, evidence elicited from incompetent witnesses,…[and] expert qualification." (footnotes omitted)).

Simply put, the issue is whether—considering "the evidence *presented at trial*"—there was sufficient evidence to support the jury's verdict. *Moss v. City of Pembroke Pines*, 782 F.3d 613, 617 (11th Cir. 2015) (emphasis added). As discussed *infra* § I.B., at 46–56, there was.

B. Ms. Bayless presented sufficient evidence of general causation.

Even if Ms. Bayless were required to prove general causation and specific causation, she met her burden of proof at trial. Indeed, Coloplast does not dispute that Ms. Bayless presented sufficient

evidence of specific causation. BlueBr. 37 (acknowledging that Dr. Rosenzweig "offered specific causation evidence"); Doc. 346 at 7, 13–14, 24 (same). And notwithstanding the district court's pretrial rulings, both Drs. Mays and Rosenzweig testified to general causation. *See generally supra*, Statement of facts, §§ B.1–2, at 16–33.

Coloplast assumes that because of the pretrial *in limine* rulings, Drs. Mays and Rosenzweig necessarily did not testify to general causation. BlueBr. 25–26. But a district court's "[*in limine*] ruling is subject to change when the case unfolds." *Luce v. United States*, 469 U.S. 38, 41 (1984). "[T]he district judge is free [at trial], in the exercise of sound judicial discretion, to alter a previous *in limine* ruling." *Id.* at 41–42. If evidence presented at trial arguably cannot be squared with a pretrial order, then a party must object again at trial absent a "good reason" not to do so. *See Frederick v. Kirby Tankships, Inc.*, 205 F.3d 1277, 1285 (11th Cir. 2000). Such an objection gives the district court an opportunity to decide whether the pretrial order governs the evidence and whether that order should be reconsidered. *Cf. United States v. Hoffer*, 129 F.3d 1196, 1202 (11th Cir. 1997) (noting that an objection "allow[s] the trial court an opportunity to correct any arguable errors").

For example, Coloplast objected below that an exhibit introduced during Dr. Rosenzweig's testimony was evidence of general causation and thus should have been excluded under the pretrial order. Doc. 273 at 9:23–11:1, 12:22–23. The district court, however, admitted the exhibit.[7] *Id.* at 13:6–14:7; 26:3–8. Moreover, even though the district court ruled pretrial that Dr. Rosenzweig could not testify "whether the Restorelle Y mesh is defective," Doc. 163 at 5–6, the court observed at trial that Dr. Rosenzweig, in fact, had "testified that the product was defective and unreasonably dangerous," Doc. 273 at 8:7–9. Coloplast did not object to this testimony and cannot cite a "good reason" that would allow it to complain about such testimony now.[8] *See Frederick*, 205 F.3d at 1285.

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[7] This example illustrates that the lines between "general causation" evidence and other types of evidence are not so clear. All that Florida law requires is evidence of causation—not *general* and *specific* causation. *See supra* § I.A. at 40–46.

[8] Further, Coloplast has not appealed any of the district court's evidentiary rulings. BlueBr. 13–51. So even if Coloplast objected to the general-causation testimony at trial and the district court overruled those objections, it would be too late for Coloplast to challenge those rulings in its reply brief. *E.g.*, *Sapuppo v. Allstate Floridian Ins.*, 739 F.3d 678, 683 (11th Cir. 2014).

So, what was the evidence of general causation admitted at trial? As detailed in the statement of facts, Drs. Mays and Rosenzweig testified exactly how polypropylene mesh—including the Restorelle Y—causes pain, mesh erosion, and other complications. *Supra*, Statement of facts, §§ B.1–2, at 16–33. They linked the causal chain from the cellular level (macrophages attacking mesh as part of the foreign body response) all the way through to the erosion and pain that the patient experiences (because of nerves being trapped in scar plates). *Supra*, Statement of facts, §§ B.1–2, at 16–33. This is precisely what Coloplast claims that Ms. Bayless needed to prove. *See* BlueBr. 31 ("Plaintiff never presented competent expert testimony on the threshold question of whether the Restorelle Y is capable of causing the erosion and resulting pain Plaintiff alleged in this lawsuit.").

Not only did Drs. Mays and Rosenzweig testify to general causation, but so did other experts. Dr. Jones testified that "[t]he most common types of mesh-related complications is [sic] a mesh exposure and/or chronic vaginal discharge, vaginal bleeding, or pain with intercourse." Doc. 254 at 31:10–12. Dr. Jones also recognized that mesh

erosions are a mesh-related complication. *See id.* at 32:3–14. And Dr. Goldberg offered similar testimony. Doc. 284 at 84:25–85:2, 90:20–91:4.

Coloplast contends that Dr. Mays did not "testify about whether mesh products could cause Plaintiff's alleged erosion, abdominal pain, vaginal discharge and bleeding, and dyspareunia." BlueBr. 32. But he did just that: he testified without objection that there is "extensive" literature correlating oxidative degradation of an implant with clinical effects on a patient, and he explained that when polypropylene mesh stiffens due to oxidation, it causes a "mechanical mismatch leading to pain." Doc. 357 at 74:1–7, 79:9–11. Moreover, Dr. Mays testified without objection that "mechanical mismatch is going to cause pain when the patient moves." *Id.* at 79:17–18.

Dr. Rosenzweig offered the same testimony. He testified without objection that when polypropylene mesh is in the human body, the foreign body response causes the body to form a scar plate around the mesh. Doc. 266 at 178:6–179:5. Again without objection, he then testified that nerves get trapped in the scar, which is why polypropylene mesh causes pain. *Id.* at 179:6–16.

Coloplast's attempted distinction of *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017), proves Ms. Bayless's point. Specifically, Coloplast concedes that "two experts"—one of whom was Dr. Mays—"were permitted to discuss general causation in *Eghnayem*." BlueBr. 37 (citing *Eghnayem*, 873 F.3d at 1320). Yet, the referenced testimony is essentially identical to the testimony here. *See infra.* § II., at 59–63 (line-by-line comparison of the testimony).

Coloplast claims that the evidence in *Eghnayem* "was materially different" because Dr. Mays testified that "the mesh had a 'sawing effect' which ultimately 'cause[ed] some of the problems with the mesh" and "another expert testified that mesh had 'mesh-specific-risks' like pelvic pain and erosion." *See* BlueBr. 37. But the jury heard materially similar evidence in this case. Again, Dr. Mays testified that "mechanical mismatch is going to cause pain when the patient moves." Doc. 357 at 79:17–18. Dr. Rosenzweig repeatedly testified that the "risks" and complications he discussed were a result of the "properties of polypropylene mesh." Doc. 266 at 177:1–3; *see also* Doc. 273 at 27:24–25 (opining that "the *inherent properties* of the mesh…can lead to painful intercourse" (emphasis added)); *id.* at 94:1–3 ("[Ms. Bayless] developed

complications *from the characteristics* of the mesh devices that lead to harm." (emphasis added)). And Dr. Goldberg testified that using mesh for surgeries "increases the mesh-specific risks of the procedure," including pain and erosion. *See* Doc. 284 at 49:25–50:1, 84:25–85:2, 90:20–91:4.

Coloplast next argues that "Dr. Mays could discuss merely whether the mesh material changes inside human body—but he could not and did not opine that these changes cause any injury to any patient." BlueBr. 37. For starters, Coloplast's assumption is wrong because Dr. Mays *did* testify how mesh causes injury (i.e., pain) to patients. Doc. 357 at 79:9–18. In any event, the district judge in *Eghnayem* (the same judge who presided over the MDL) rejected a very similar argument. *Eghnayem v. Boston Scientific Corp.*, No. 1:14-cv-24061, Doc. 244 at 40 (S.D. Fla. Oct. 27, 2014) (rejecting argument that "Dr. Mays's opinions are a poor fit and would not be helpful to the jury because Dr. Mays was not able to correlate degradation to any clinical symptoms in an individual patient."). Yet, Coloplast still points to *Eghnayem* as an example of where general causation was shown.

Coloplast similarly suggests that Dr. Rosenzweig did not offer any opinion that the Restorelle Y "is generally capable of causing an erosion, lower abdominal pain, vaginal discharge and bleeding, or dyspareunia." BlueBr. 37. But he did offer such testimony. Again, he repeatedly testified that the "risks" and complications he discussed were a result of the "properties of polypropylene mesh." Doc. 266 at 177:1–3; *see also* Doc. 273 at 27:24–25 (opining that "the *inherent properties* of the mesh…can lead to painful intercourse" (emphasis added)); *id.* at 94:1–3 ("[Ms. Bayless] developed complications *from the characteristics* of the mesh devices that lead to harm." (emphasis added)). He testified that pelvic pain and vaginal bleeding are symptoms of mesh exposure. Doc. 271 at 34:6–8. He opined that the Restorelle Y undergoes degradation that leads to mesh exposure and that it undergoes fibrosis and scar plating, which leads to pain. *See id.* at 81:4–9. And he opined that "mesh can cause erosion, infection, and pain," that "[m]esh can become stiffened, contracted, and folded," that "the patient's immune response is what leads to this," and that "mesh can degrade." *Id.* at 87:8–11.

Finally, insofar as Coloplast argues that the testimony related only to polypropylene mesh generally, and not the Restorelle Y in

particular, that argument is flawed in two respects. First, both Drs. Mays and Rosenzweig tied their opinions directly to the Restorelle Y. *E.g.*, Doc. 271 at 81:4–20, Doc. 357 at 38:25–39:6, 139:19–22. Second, that argument would be equivalent to requiring a "dose-response relationship," which this Court has already rejected in this context. *See Taylor v. Mentor Worldwide LLC*, 940 F.3d 582, 596 (11th Cir. 2019) ("In this case, which is focused on the physiological response to a design defect in a medical device, the dose-response relation is not implicated….").

Taylor, like this case, was about a defectively designed polypropylene mesh (ObTape). *Id.* at 587. On appeal, the defendant argued that the district court erred in admitting an expert's general-causation testimony. *Id.* at 594. Specifically, the defendant argued that the expert's testimony "on the degradation and shedding of the ObTape mirrors testimony on substance toxicity and…it therefore was necessary for [the expert] to address the 'dose-response relationship' – that is, how much of the substance was necessary to create a risk of harm to [the plaintiff]." *Id.* at 595. The defendant cited this Court's decision in *McClain* as support. *Id.*

This Court held that the "[t]he dose-response relationship is not implicated" and "[t]he logic of *McClain* therefore is not transferrable." *Id.* As this Court explained, "[i]n *McClain*, the missing piece…was how much ephedrine and caffeine were required to start a chain reaction leading to a stroke or heart attack." *Id.* In *Taylor*, by contrast, the expert "testified that *all* ObTape degrades and that *any* polypropylene particles it sheds spark a response by the body's immune system, which leads to inflammation and erosion. There was no suggestion that there was a level of degradation that would not cause those harmful effects." *Id.*; *see also Eghnayem*, 873 F.3d at 1320–21 (rejecting a dose-response argument in the context of a polypropylene mesh because "there is no question of threshold; the [mesh] was either harmful or not").

Here, too, both Drs. Mays and Rosenzweig made clear that their opinions apply to any polypropylene mesh because of the inherent properties of polypropylene. *Supra*, Statement of facts, §§ B.1–2, at 16–33. For example, Dr. Mays testified that "the polypropylene is the same whether it's in the resin form,…whether it's in the fiber form, or whether it's in the finished product. The polypropylene chemistry is the same. Its reactivity is the same." Doc. 357 at 30:23–31:2. He further

testified that there is nothing unique about the Restorelle Y that makes it immune to the problem of oxidative degradation. *See id.* at 36:12–18. In other words, there is nothing magical or different about Coloplast polypropylene such that the laws of polymer chemistry do not apply to it. *Id.* at 145:19–23.

Dr. Rosenzweig similarly testified that although he has not implanted a mesh made by Coloplast, he did not need to implant a Coloplast mesh to form his opinions because "these are all made from polypropylene." Doc. 266 at 181:12–21. That is, "[t]he polypropylene is the same," and regardless of whether a polypropylene product has different additives or components—including the Restorelle Y—"the body's reaction is the same." *Id.* at 182:15–183:2. Accordingly, like in *Taylor* and *Eghnayem*, the dose-response relationship is not implicated in this case.

II. The jury's verdict on design defect is supported by sufficient evidence.

To prove that the Restorelle Y was defectively designed, Ms. Bayless had to show that "the risk of danger in the design outweighs the benefits." Fla. Std. Jury Instr. (Civ.) 403.7b; *accord* Doc. 310 at 8 (court's instructions to the jury). Ms. Bayless presented sufficient

evidence for the jury to make that finding. *See generally supra*, Statement of facts, § II.B., at 16–34.

Coloplast argues that the evidence was insufficient because Drs. Mays and Rosenzweig purportedly "did not offer any evidence about the risks and benefits of the Restorelle Y's design to any patient." BlueBr. 41. But they did offer such evidence. For his part, Dr. Mays testified about the pain and complications that a polypropylene mesh like the Restorelle Y causes. Doc. 357 at 74:1–7, 79:9–18. He also argued that Restorelle Y was not suitable, fit, and appropriate for its intended use, and that it was therefore "defective." Doc. 357 at 48:4–23; *see also* Doc. 248 at 32:19–33:11.

Dr. Rosenzweig offered similar testimony. Doc. 266 at 176:16–177:25; Doc. 271 at 34:6–8, 69:14–16, 81:4–9, 87:8–11; Doc. 273 at 27:24–25. And he even testified that it was "not worth using [polypropylene] meshes" in light of the "risks" of polypropylene mesh. Doc. 266 at 176:16–177:3.

Further, Dr. Jones told Ms. Bayless that there was up to a 10 percent change that her mesh "can cause delayed healing and eventually erode into the vagina, requiring a second surgery to remove

it." Doc. 254 at 110:8–24. Although Dr. Jones found that risk acceptable, the jury could independently determine it was not.

Coloplast suggests that either Dr. Mays or Rosenzweig had to explicitly state that "the risks of the Restorelle Y's design outweigh its benefits." BlueBr. 27. But an expert does not have to testify to the ultimate issue—the jury can reach that conclusion on its own. Indeed, as this Court held in *Eghnayem*, "[t]he ultimate question whether the[] risks outweigh[] the [product]'s benefits [i]s for a jury to decide." 873 F.3d at 1320.

In *Eghnayem*, like here, the defendant moved for judgment as a matter of law on the issue of whether, under Florida law, a polypropylene mesh was defectively designed. *Id.* at 1319. Moreover, like here, the plaintiff presented expert testimony on two defects: "the polypropylene material may experience oxidative degradation, which causes it to lose its physical and mechanical properties in a way that causes injury; and the crosshatched design of the mesh makes it very difficult, if not impossible, to remove if there is a problem with the mesh." *Id.* at 1319–20. The district court denied the defendant's motion, and this Court affirmed. *Id.* at 1311. Specifically, this Court explained

that "taken in concert, th[e] expert testimony provided a sufficient foundation for a reasonable jury to conclude that the design of the mesh increased both the potential for degradation and the difficulty of removal." *Id.* at 1320.

As the following line-by-line comparison shows, the testimony that this Court found sufficient in *Eghnayem* is materially identical to the testimony in this case:

Eghnayem	**This case**
"Dr. Mays…[testified] that polypropylene reacts with oxygen, and '[w]hen that oxidative process progresses enough, the material erodes away.'" 873 F.3d at 1320.	Dr. Mays testified that "[p]olypropylene reacts with oxygen…and that causes the polypropylene to crumble." Doc. 248 at 58:13–14.
"When this happens, the polypropylene 'stiffen[s]' and 'lose[s] [its] mechanical properties,' which 'is relevant to the proper or improper use of polypropylene in a medical device.'" *Id.*	"[P]olypropylene is unsuitable for a permanent pelvic mesh implant because it degrades inside the human body, and that changes its properties." Doc. 248 at 33:4–6; *see also id.* at 65:22–66:2 ("Its properties change, and they change for the worst….So polypropylene, which is initially flexible and can move with the body as an implant…becomes stiffer during this oxidation process…."); *id.* at 108:5–7 ("[I]t's designed to be a flexible mesh, but it's becoming stiffer. It loses its flexibility, can't perform the way it

	was designed to perform.").
"Mays further explained that 'if you increase the surface area of the material,…[y]ou're going to increase the rate at which that material undergoes degradation,' and that for polypropylene fibers—a category that the Pinnacle falls into—'physical properties deteriorate more rapidly upon oxidation.'" *Id.*	"[A] polypropylene fiber or a polypropylene mesh, because of its high surface area, will undergo oxidative degradation much faster in the same environment than a ball of polypropylene." Doc. 248 at 78:8–11; *see also id.* at 86:22–87:5 (explaining that the concept of surface area is significant to the Restorelle Y because it is "made of fibers, and those fibers have…very high surface area").
"Finally, Mays noted that degradation occurs in the body 'much more readily than it does in many other environments,' and once it occurs the material 'can no longer move with the body.'" *Id.*	"[P]olypropylene, which is initially flexible and can move with the body as an implant…becomes stiffer" Doc. 248 at 65:25–66:1; *id.* at 108:18–109:14 (testifying that the Restorelle Y is designed to be flexible, not hard and stiff, because it "ha[s] to move with soft tissue" in the pelvic space); *see also* Doc. 357 at 15:14 (referring to the "strong oxidizing environment [of] the human body"); *id.* at 21:24–25 ("[T]he human body contains strong oxidizing agents that attack the polypropylene"); *id.* at 29:20–22 ("[I]f you've got a product that's designed to be flexible and move with the body and that's becoming stiff, that is a problem.").
"Mays testified that there is evidence that polypropylene degrades 'when implanted in the	"[P]olypropylene is unsuitable for a permanent pelvic mesh implant because it degrades inside the

female pelvis,' and that such degradation may result in stiffness and ultimately 'a sawing effect' that Mays believed 'caus[ed] some of the problems with the mesh.'" *Id.*	human body, and that changes its properties." Doc. 248 at 33:4–6; *id.* at 70:10–15 (explaining that oxidizing agents are produced in the "the female pelvis" in response to polypropylene); Doc. 357 at 38:25–39:6 (confirming that oxidative degradation occurs with "polypropylene pelvic mesh that is put into the female body, including specifically [the Restorelle Y]"); *id.* at 79:9–18 (noting the "mechanical mismatch created by the stiffening of the mesh when it's oxidized" and explaining that "if there's mechanical mismatch created between the mesh and the surrounding tissue and the tissue grows into the mesh, there's nerves in there; [t]hat mechanical mismatch is going to cause pain when the patient moves")
"Another expert…testified that when treating pelvic organ prolapse with polypropylene mesh, there are 'mesh-specific risks' of pelvic pain, erosion, painful activity, and permanent tissue damage, along with a significant risk of subsequent surgery as compared to other prolapse surgical repairs—approximately a 'threefold' increase." *Id.*	Dr. Rosenzweig testified that there were "risks inherent in the product" that were a "result of the properties of polypropylene mesh," and that they were "different" than "the risks inherent in surgery." Doc. 266 at 176:19–177:3; *see also* Doc. 271 at 34:6–8 (confirming that "pelvic pain" and "vaginal bleeding" are "symptoms of a mesh exposure"); *id.* at 75:2–76:21 (discussing "safer alternative forms" of treatment compared to using polypropylene mesh); *id.* at 81:4–6 (opining that mesh

	degradation "leads to pain"); *id.* at 87:8–9 (opining that "mesh can cause erosion, infection, and pain"); *id.* at 90:20–23 (confirming that mesh "increase[s] the complications from a surgery without mesh"); Doc. 273 at 27:24–25 (opining that "the inherent properties of the mesh…can lead to painful intercourse"); Doc. 254 at 110:8–24 (Dr. Jones warned Ms. Bayless that "[w]hen mesh is used in gynecological surgery, there is a 5 to 10 percent chance that this mesh can cause healing and eventually erode into the vagina, requiring a second surgery to remove it"); Doc. 284 at 49:25–50:1, 84:25–85:2, 90:20–91:4 (Dr. Goldberg testified that using mesh for surgeries "increases the mesh-specific risks of the procedure," including pain and erosion.)
"[Another expert]…opined that the implantation of the mesh, which has a 'crosshatched' or 'window screen[ ]' pattern of holes, was 'irreversible" because '[s]car tissue, what are called fibroblasts, scar cells, move into the [holes in the] mesh and they cement the mesh into place.'" *Id.*	Dr. Rosenzweig testified that "nerves can grow through the opening or the pores of the mesh. And then once the scar starts happening, they get trapped." Doc. 266 at 179:13–15; *see also id.* at 179:1–4 (explaining that the scar "goes around each individual fiber…and then completely surrounds the whole implant")
"[T]his aspect of the mesh implantation makes it very difficult to treat mesh injuries,	Dr. Rosenzweig testified that once polypropylene mesh "is in for a period of time, it becomes very

complications, and erosions." *Id.*	difficult to remove." Doc. 266 at 178:1–2; *see also id.* at 178:2–5 ("even with removal,…pain [i]s very difficult to make go away"); Doc. 271 at 69:21–70:3 (explaining that it would be difficult to remove the Restorelle Y in Ms. Bayless because it "would require a significant incision"); *id.* at 72:15–16 ("It's exceedingly difficult to remove all of the mesh associated with mesh products."); *id.* at 93:25–94:1 ("[R]emoval procedures are difficult because of the amount of dissection that needs to be done"); Doc. 290 at 48:6–8 (Dr. Badylak testified that "it's almost impossible to remove all mesh once it's implanted")

Finally, Coloplast argues that the jury was not entitled to discount Dr. Jones's testimony that the benefits of the Restorelle Y outweighed its risks. BlueBr. 48. But this Court rejected that argument in *Eghnayem* as well. 873 F.3d at 1321 (deeming it irrelevant that the "implanting physician testified that polypropylene was safe and effective"). As this Court explained, "any testimony…that tend[s] to weaken [the plaintiff's] design defect claim is irrelevant to judgment as a matter of law; the weighing of conflicting evidence is properly for the jury." *Id.* Moreover, to evaluate Dr. Jones's credibility, the jury could

consider her seven-year history of consulting for a mesh manufacturer. *See* Doc. 254 at 21:5–22:7.

Coloplast contends that "a jury may reject an expert only if it has a reasonable basis for doing so, like when the expert's opinion has been refuted or severely impeached on cross-examination." BlueBr.48 (citing *Boyles v. A. & G Concrete Pools, Inc.*, 149 So. 3d 39, 48 (Fla. Dist. Ct. App. 2014)). But that "reasonable basis" can take a broad variety of forms. *See Boyles*, 149 So. 3d at 48 (noting that the "reasonable basis can include: conflicting medical evidence [and] evidence that impeaches the credibility or basis for an expert's opinion"); *see also Fell v. Carlin*, 6 So. 3d 119, 120 (Fla. Dist. Ct. App. 2009) (noting that even "conflicting lay testimony" can provide a reasonable basis to reject "uncontroverted expert medical testimony"). Here, based on the evidence at trial, the jury had a reasonable basis to reject Dr. Jones's testimony.

In sum, the district court correctly concluded that there was sufficient evidence of a design defect. Doc. 369 at 4. As the court explained, "Dr. Mays opined that polypropylene, the Restorelle Y mesh material, 'is unsuitable for a permanent pelvic mesh implant' and defective," and "Dr. Rosenzweig opined that Restorelle Y mesh is

unsuitable for implantation and causes erosion, discharge, vaginal bleeding, pain, and dyspareunia." *Id.* (citations omitted). This testimony "provided 'sufficient evidentiary basis for a reasonable jury to find for [Ms. Bayless].'" *Id.* (citation omitted).

ARGUMENT ON CROSS APPEAL

III. The district court abused its discretion in excluding portions of Dr. Rosenzweig's testimony.

The district court ruled that Dr. Rosenzweig could not testify about general causation because he purportedly disavowed such testimony at a deposition and it would therefore be "unfair to Coloplast [and] would run contrary to Rule 26" for him to offer such testimony at trial. Doc. 163 at 5–6. The district court abused its discretion for two reasons.

First, Dr. Rosenzweig did not forever disavow offering any testimony on general causation. At his May 2, 2019 deposition in the Coloplast MDL, he was asked whether he "intend[ed] to offer any opinions that the Restorelle Y mesh is *defective* in any way." Doc. 113-7 at 5:13–15 (emphasis added). Dr. Rosenzweig answered that he was "not offering opinions about the Restorelle Y mesh." *Id.* at 5:16–17. Counsel for the MDL plaintiffs explained that Dr. Rosenzweig had not

yet "reviewed the materials on Restorelle Y" or "written a report that has opinions on that." *Id.* at 6:14–19. Counsel further explained that "[w]hen [Dr. Rosenzweig] reviews the materials, if he does, about Restorelle Y, he will answer those questions." *Id.* at 7:17–19.

The district court seemed to recognize that Dr. Rosenzweig merely had not formed opinions about whether the Restorelle Y was *defectively designed*—not that he had no opinion about general causation. Indeed, in its order excluding portions of Dr. Rosenzweig's testimony, the court said that "[a]llowing Dr. Rosenzweig to offer general expert testimony on the *design* of the Restorelle Y mesh at this late juncture would be unfair." Doc. 163 at 6 (emphasis added). Then, when the court gave an example of what Dr. Rosenzweig could not do, it said "Dr. Rosenzweig may not testify that Bayless's injuries were the result of a *defect* in the Restorelle Y." *Id.* at 6 n.5 (emphasis added).

To be sure, the district court also ruled that "Dr. Rosenzweig may not offer general opinion testimony as to causation, including on general causation opinions in his case specific expert report." *Id.* at 6. But the district court seemed confused about what general causation is. As reflected in its summary-judgment order, the court apparently

understood general causation to refer to defect and not to whether a product is capable of causing injuries. *See* Doc. 169 at 12 n.8 ("Previously, the Court found Dr. Rosenzweig could not offer general causation opinions—e.g., the mesh is *defective*—but could offer case specific opinions on the injuries Plaintiff has suffered and their causes." (emphasis added)); *but cf. Causation, Black's Law Dictionary* (11th ed. 2019) (defining "general causation" as "[t]he potential of an agent to produce the general occurrence of injuries in a population").

Second, permitting Dr. Rosenzweig to testify about general causation would not have been unfair to Coloplast because he disclosed such testimony multiple times before trial. Specifically, he disclosed general-causation opinions at his August 17, 2020 deposition in Ms. Bayless's individual case, in his June 4, 2018 case-specific expert report, in his June 4, 2018 expert report in the Boston Scientific MDL, and in his March 10, 2019 expert report in the Coloplast MDL. *See generally supra*, Statement of facts, § II.C., at 35–37.

Although his March 10, 2019 report in the Coloplast MDL focused on Coloplast's transvaginal Restorelle products—not its transabdominal products such as the Restorelle Y—it still disclosed relevant general-

causation testimony. After all, Dr. Rosenzweig explained in the report that "[a]ll Restorelle pelvic mesh products" use the same polypropylene mesh, including the Restorelle Y. Doc. 123-1 at 11–12; *see also* Doc. 359 at 144:7–15. Thus, the general-causation opinions offered in the report—that the characteristics of the mesh cause degradation, chronic foreign body reaction, fibrotic bridging, and contraction, Doc. 123-1 at 13–35—apply equally to the Restorelle Y.

In short, Dr. Rosenzweig's general causation opinions were no surprise to Coloplast, and Coloplast had an opportunity to—and in fact did—depose Dr. Rosenzweig about those opinions. Accordingly, Coloplast would not have been harmed if Dr. Rosenzweig had been allowed to offer those opinions at trial. *See Taylor*, 940 F.3d at 592–93 (noting that any unfair surprise as to an expert's "evolved" opinion on an issue was "minimal" because the opinion "was a topic of extensive pretrial discovery" and was similar to what was disclosed in his Rule 26 report); *Crawford v. ITW Food Equip. Grp.*, 977 F.3d 1331, 1341–42 (11th Cir. 2020) (alleged violation of rule 26 was harmless where the other party was not "prejudiced by surprise or impairment of ability to prepare"). The district court thus abused its discretion in excluding

those opinions. *See Murphy v. Magnolia Elec. Power Ass'n*, 639 F.2d 232, 234–35 (5th Cir. Mar. 1981) (holding that, even though the "appellants breached their duty under [rule 26]," the district court abused its discretion in excluding their expert's testimony because of "the absence of prejudice and the essential nature of the evidence involved"); Fed. R. Civ. P. 37(c)(1) ("If a party fails to provide information…as required by Rule 26(a) or (e), the party is not allowed to use that information…unless the failure…is harmless.").

CONCLUSION

This Court should reject Coloplast's arguments and affirm the final judgment for Ms. Bayless. If this Court affirms the final judgment, then Ms. Bayless will abandon her cross appeal. On the other hand, if this Court concludes that Ms. Bayless did not present sufficient evidence to support the jury's verdict, this Court should reverse and remand for a new trial because the district court erred in excluding portions of Dr. Rosenzweig's testimony.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 28.1(e)(2)(B)(i) because it contains 13,909 words, not including items excluded under rule 32(f).

/s/ *Dimitrios A. Peteves*