No. 21-11768

In the United States Court of Appeals for the Eleventh Circuit

MICHELLE AREVALO,
Plaintiff-Appellant,

v.

MENTOR WORLDWIDE LLC, COLOPLAST MANUFACTURING US, LLC, COLOPLAST A/S, ETHICON, INC., AND PORGES, S.A.,
Defendants,

COLOPLAST CORP.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of Florida, Pensacola Division
Case No. 3:19-cv-3577, Hon. T. Kent Wetherell

APPELLANT'S BRIEF OF MICHELLE AREVALO

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Eleventh Circuit Rules 26.1-1 and 26.1-3, the following is an alphabetical list of the trial judges, attorneys, persons, and firms with any known interest in the outcome of this case.

1. Arevalo, Michelle – Plaintiff-Appellant;
2. Berg, Zane (of Schlesinger Law Offices, P.A. in Fort Lauderdale, Florida) – Trial counsel for Plaintiff-Appellant;
3. Burns, P.A. – Appellate counsel for Plaintiff-Appellant;
4. Burns, Thomas A. (of Burns, P.A. in Tampa, Florida) – Appellate counsel for Plaintiff-Appellant;
5. Carlton Fields, P.A. – Counsel for Defendant-Appellee;
6. Coloplast A/S (COLO-B, Nasdaq Copenhagen) – Defendant (dismissed) and parent corporation of Defendant-Appellee Coloplast Corp.;*
7. Coloplast Manufacturing US, LLC – Defendant (dismissed);*
8. Coloplast Corp. – Defendant-Appellee and sole member of Coloplast Manufacturing US, LLC;
9. Coloplast Manufacturing US, LLC – Defendant (dismissed);*
10. Davis, Christine R. (of Carlton Fields, P.A. in Tallahassee, Florida) – Counsel for Defendant-Appellee;
11. Ethicon, Inc. – Sole member of Defendant Mentor Worldwide LLC;*
12. Frank, Hon. Michael J. – United States Magistrate Judge for the Northern District of Florida;
13. Gdanski, Jonathan (of Schlesinger Law Offices, P.A. in Tampa, Florida) – Trial counsel for Plaintiff-Appellant;

14. Gerecke, Edward W. (of Carlton Fields, P.A. in Tampa, Florida) – Counsel for Defendant-Appellee;

15. Goodwin, Hon. Joseph R. – United States District Judge for the Southern District of West Virginia;

16. Haberman, Jeffrey L. (of Schlesinger Law Offices, P.A. in Fort Lauderdale, Florida) – trial counsel for Plaintiff-Appellant;

17. Hampton, Caycee D. (of Carlton Fields, P.A. in Tampa, Florida) – Counsel for Defendant-Appellee;

18. Howard, Heather M. (of King & Spalding, LLP in Atlanta, Georgia) – Counsel for Defendant-Appellee;

19. King & Spalding, LLP – Counsel for Defendant-Appellee;

20. Lang, Jr., Joseph H. (of Carlton Fields, P.A. in Tampa, Florida) – Counsel for Defendant-Appellee;

21. Leppert, Valentin (of King & Spalding, LLP in Atlanta, Georgia) – Counsel for Defendant-Appellee;

22. Mentor Worldwide LLC – Defendant (dismissed);*

23. Persons, Ray W. (of King & Spalding, LLP in Atlanta, Georgia) – Counsel for Defendant-Appellee;

24. Porges, S.A. – Defendant (dismissed);*

25. Reese, Shannon C. (of Burns, P.A. in Tampa, Florida) – Appellate counsel for Plaintiff-Appellant;

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* Arevalo voluntarily dismissed her claims against Mentor Worldwide LLC (including, therefore, those relating to its sole member, Ethicon, Inc.). *See* Doc. 80 at 1. On May 28, 2013, the MDL court entered PTO #28 MDL 2387, which terminated Porges S.A., Coloplast A/S and Coloplast Manufacturing US, LLC terminated pursuant to PTO #28 entered in MDL 2387. *See* Doc. 64.10 at 1–2.

26. Schlesinger Law Offices, P.A. – Trial counsel for Plaintiff-Appellant;

27. Schlesinger, Scott P. (of Schlesinger Law Offices, P.A. in Fort Lauderdale, Florida) – Trial counsel for Plaintiff-Appellant;

28. Schultz, Sarah (of Schlesinger Law Offices, P.A. in Fort Lauderdale, Florida) – Trial counsel for Plaintiff-Appellant;

29. Walz, David J. (of Carlton Fields, P.A. in Tampa, Florida) – Counsel for Defendant-Appellee;

30. Wetherell, Hon. T. Kent – United States District Judge for the Northern District of Florida.

CORPORATE DISCLOSURE STATEMENT

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

2. Defendant Coloplast Manufacturing US, LLC (dismissed) is a limited liability company whose principal member is Coloplast Corp.

3. Defendant Mentor Worldwide LLC (dismissed) is a limited liability company whose sole member is Ethicon, Inc. In turn, Ethicon, Inc. is a New Jersey corporation wholly owned by Johnson & Johnson (NYSE: JNJ). Johnson & Johnson has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

4. Defendant Porges, S.A. (dismissed) is a privately held foreign corporation in France; it's wholly owned by Mentor Corporation (Nasdaq: MNTR).

November 8, 2021

/s/ Thomas Burns
Thomas A. Burns

STATEMENT REGARDING ORAL ARGUMENT

Plaintiff-Appellant, Michelle Arevalo, requests oral argument. This products liability appeal concerns vaginal mesh. It began as one of thousands in the multi-district litigation court in the Southern District of West Virginia. After years of discovery and litigation, the MDL court transferred the case to the Northern District of Florida with instructions that it be set for trial. Instead, upon transfer, the district court entered orders that allowed Defendant-Appellee, Coloplast Corp., to file renewed *Daubert* motions that belatedly added a new argument, excluded several opinions of Dr. Rosenzweig (Arevalo's expert causation witness), struck the disclosure of Dr. Miklos (Arevalo's new treating physician), granted summary judgment to Coloplast Corp., and otherwise demonstrated clearly erroneous factual misunderstandings of Arevalo's medical history, the peer-reviewed medical support for Dr. Rosenzweig's general causation opinions, and the reliability of his differential etiology. The record is extensive, and oral argument will assist the Court.

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STATEMENT OF JURISDICTION

The district court had subject-matter jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity). After a limited remand, the district court made factual findings that confirmed the litigants' citizenship was diverse. Doc. 198 at 2–3; 65.14; *see also* 28 U.S.C. § 1332(c)(1) (corporations are citizens where incorporated and where they have their "principal place of business"); *Hertz Corp. v. Friend*, 559 U.S. 77, 80–81 (2010) ("the phrase 'principal place of business' refers to the place where the corporation's high level officers direct, control, and coordinate the corporation's activities," which "will typically be found at a corporation's headquarters"); *Taylor v. Appleton*, 30 F.3d 1365, 1367 (11th Cir. 1994) ("Citizenship, not residence, is the key fact that must be alleged in the complaint to establish diversity for a natural person.").

- Arevalo was a citizen, not a mere resident, of Georgia (Doc. 198 at 2–3);
- Mentor Worldwide LLC was a citizen of New Jersey, where its sole member, Ethicon, Inc., was incorporated and had its headquarters (Doc. 198 at 3);
- Coloplast Corp. was a citizen of Delaware (its place of incorporation) and Minnesota (where it maintains its principal place of business) (Doc. 198 at 3);

- Coloplast Manufacturing US, LLC was a citizen of Delaware and Minnesota because its sole member was Coloplast Corp. Doc. 198 at 3.

- Porges, S.A. was a foreign corporation with its principal place of busines in France (Doc. 198 at 2);

- Coloplast A/S was a foreign corporation with its principal place of business in Denmark (Doc. 198 at 2);

This Court has appellate jurisdiction under 28 U.S.C. § 1291 because the district court entered interlocutory orders excluding some of Dr. Rosenzweig's opinions (Doc. 119), denying reconsideration (Doc. 141), and striking the disclosure of Dr. Miklos (Doc. 171), after which it then entered summary judgment in Coloplast's favor due to a purported lack of causation evidence (Doc. 172). Judgment was entered on April 26, 2021. Doc. 173. Arevalo timely appealed on May 21, 2021. Doc. 177.

STATEMENT OF THE ISSUES

1. Did the district court abuse its discretion or commit clear error when it excluded Dr. Rosenzweig's specific causation opinion because his differential etiology was supposedly unreliable and his general causation opinion that degraded mesh causes pain because the peer-reviewed medical literature supposedly didn't support it?

2. Did Dr. Rosenzweig's erroneously excluded opinions, his additional non-excluded testimony, or the testimony of treating physicians (Dr. Kahn or Dr. Miklos) create genuine disputes of material fact about causation that precluded summary judgment?

3. Did the district court abuse its discretion when, under Rule 37, it excluded Dr. Miklos, Arevalo's later obtained treating physician?

STATEMENT OF THE CASE

This vaginal mesh product liability appeal concerns whether Arevalo marshaled enough causation evidence to try her case before a jury. Between 1994 and 2002, Arevalo birthed three children and had two pelvic surgeries. The first was to remove tissue from her cervix, and the second was a tubal ligation. In 2010, to address her heavy bleeding and pain during sex, she had a hysterectomy to remove her uterus and cervix.

That same day, to correct urinary incontinence, she was implanted with Coloplast's mesh product, the Aris. A few months later, to correct her bulging organs (bladder and rectum), she was implanted with another of Coloplast's mesh products, the Exair. After implantation of the Aris and Exair, she suffered extreme vaginal pain, pain during intercourse, and urinary and fecal incontinence. She then sued Coloplast.

After six years of multi-district litigation, Arevalo's case was transferred to the Northern District of Florida with instructions to set it for trial. Upon transfer, Coloplast convinced the transferee court to allow it to rebrief its MDL *Daubert* motions under Eleventh Circuit law. In that rebriefing, Coloplast then argued for the first time that Dr. Rosenzweig's differential etiology[2] was unreliable because he supposedly failed to reliably rule out what it described as Arevalo's extensive and complicated history of births and pelvic surgeries as potential alternative causes of her vaginal pain and incontinence. Dr. Rosenzweig, however, had repeatedly been allowed to testify in many similar vaginal mesh cases.

[2] Sometimes litigants mistakenly use the phrase "differential diagnosis" instead of "the more precise but rarely used term," which is "differential etiology." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005).

In reality, Arevalo's pelvic history wasn't all that complicated. Her hysterectomy (performed the same day the Aris was implanted) had removed her uterus and cervix. Those organs were the prior source of her complaints that were similar to her complaints from the mesh devices: vaginal pain; and pain during sex. Nevertheless, the district court allowed the new argument, excluded Dr. Rosenzweig, excluded Dr. Miklos, and granted summary judgment to Coloplast.

Course of proceedings

After Coloplast's mesh products caused her devastating and disruptive pain and incontinence, Arevalo sued Coloplast in MDL 2387, *In re Coloplast Corp., Pelvic Support Sys. Prods. Liab. Litig.*, No. 2:12-md-2387 (S.D. W. Va.). Docs. 1; 63; 65.13. Arevalo's operative claims were for negligent design and failure to warn, strict liability design defect, strict liability failure to warn, gross negligence, and punitive damages. Docs. 86; 142 at 4; 172 at 6–7.

On the deadline for filing dispositive and *Daubert* motions, Coloplast moved in the MDL litigation to exclude or limit Dr. Rosenzweig's opinions and for summary judgment. Docs. 44; 52; 53; 54. Despite challenging various opinions, Coloplast never attacked Dr.

Rosenzweig's differential etiology, which ruled out other potential causes of Arevalo's injuries.

Without ruling on those motions, the MDL court deemed the case ready for trial and transferred it to the Northern District of Florida. Doc. 63 at 1. Upon transfer, the MDL court stated discovery was "complete," noted the parties "have had time to file dispositive and *Daubert* motions, responses and replies," and "*urge[d] the receiving court to immediately set the[] case[] for trial*." Doc. 63 at 1 (emphasis in original).

Upon transfer, and over objection, the district court allowed Coloplast to rebrief its *Daubert* and summary judgment motions under Eleventh Circuit law. *See* Docs. 80 at 1–2; 118.2 at 26, 31–32. In its rebriefing—after the deadline for *Daubert* motions had expired—Coloplast added a new, untimely argument challenging Dr. Rosenzweig's differential etiology. Doc. 92 at 4, 26–30. Arevalo opposed. Doc. 103 at 16–19. The district court partially granted Coloplast's rebriefed *Daubert* motion; it excluded as unreliable Dr. Rosenzweig's differential etiology and his general causation opinion that mesh degradation causes pain. Doc. 119 at 29 (mesh causing pain), 34–36 (differential etiology).

Thereafter, Coloplast rebriefed summary judgment. Doc. 122. It argued Arevalo couldn't prove specific causation without the now excluded differential etiology of Dr. Rosenzweig. *Id.* at 5–9.

Meanwhile, Arevalo sought reconsideration of the *Daubert* order and attached Dr. Rosenzweig's full deposition transcript. Docs. 124; 124.1. That testimony flushed out his full reasoning—including his full differential etiology—for excluding Arevalo's other potential causes of pain and incontinence. Doc. 124.1 at 7, 10–32. Arevalo informed the district court that its ruling that Dr. Rosenzweig failed to exclude her bulging organs made no medical sense because the surgery was meant to correct some of the bulging organs, and the hysterectomy had removed her uterus. Doc. 124 at 11–14. Reconsideration was denied. Doc. 141.

Arevalo also supplemented her expert disclosures to add her new treating physician, Dr. Miklos. Docs. 157; 157.2. Like her prior treating physician (Dr. Kahn), Dr. Miklos also opined the mesh caused Arevalo's injuries. Doc. 157.2 at 7–10. Coloplast moved to strike Dr. Miklos and his case report as untimely. Doc. 163. Arevalo opposed. Doc. 166.

The district court struck Dr. Miklos. Doc. 171. Five days later, it granted summary judgment to Coloplast on the sole basis that Arevalo couldn't prove causation. Docs. 172; 173. This appeal followed. Doc. 177.

Statement of facts

A. Arevalo seeks gynecological treatment with Coloplast's mesh products

During her annual gynecological exam in August 2010, Arevalo complained of irregular periods, heavy bleeding, pain with intercourse (dyspareunia), and occasional urine leakage. Docs. 92.1; 124.1 at 55. She had given three vaginal births in 1994, 1997, and 2000. Docs. 92.1; 124.2 at 3, 46–47. She had gynecological LEEP surgery [3] in 1995 and a laporoscopic tubal ligation[4] in 2002. *Id.*; Docs. 124.1 at 31–32; 124.2. Her pelvic exam revealed a first-degree cystocele[5] (meaning her bladder was

[3] A large loop electrical excision procedure is where a hot wire is moved across the cervix to take off the transformation zone of the cervix.

[4] "Tubal ligation—also known as having your tubes tied or tubal sterilization—is a type of permanent birth control. During tubal ligation, the fallopian tubes are cut, tied or blocked to permanently prevent pregnancy." Mayo Clinic, *Tubal Ligation*, *at* https://tinyurl.com/yfte87ce.

[5] "Anterior vaginal prolapse, also known as a cystocele … or a prolapsed bladder, is when the bladder drops from its normal position in the pelvis and pushes on the wall of the vagina." Mayo Clinic, *Anterior Prolapse (Cystocele)*, *at* https://tinyurl.com/4xaxkdad.

descending), an enlarged uterus, and a second-degree uterine prolapse.[6] *Id.* Her pain during intercourse resulted from her enlarged and boggy uterus and her uterine prolapse. Doc. 124.1 at 55–56. Her gynecologist, Dr. Bankert, asked Arevalo to return after a pelvic ultrasound. Doc. 92.1.

In September 2010, Dr. Bankert performed a total vaginal hysterectomy,[7] which removed Arevalo's uterus, and treated her stress urinary incontinence by implanting Coloplast's Aris. Docs. 92.2; 124.1 at 63; 1 at 3. Seven weeks later, Dr. Bankert noted that Arevalo had second-degree cystocele, second-degree rectocele, and third-degree rectocele.[8] Doc. 124.1 at 77–78. In December 2010, Dr. Bankert treated Arevalo's cystocele and rectocele via a prolapse repair with Coloplast's Exair. *Id.* at

[6] Uterine prolapse occurs "when pelvic floor muscles and ligaments stretch and weaken and no longer provide enough support for the uterus. As a result, the uterus slips down into or protrudes out of the vagina." Mayo Clinic, *Uterine Prolapse*, *at* https://tinyurl.com/238aduf5.

[7] A vaginal hysterectomy is a procedure to remove the uterus through the vagina. Mayo Clinic, *Vaginal Hysterectomy*, *at* https://tinyurl.com/z4nzcx4j.

[8] Dr. Rosenzweig thought one of the "rectoceles" should have read enterocele, but he wasn't sure which one. Doc. 124.1 at 77–78. Enterocele occurs when the small intestine "descends into the lower pelvic cavity and pushes at the top part of the vagina, creating a bulge." Mayo Clinic, *Small Bowel Prolapse (Enterocele)*, *at* https://tinyurl.com/5c8j3n38.

79, 82, 103; Doc. 1 at 3. A month after implanting the Exair, Dr. Bankert noted Arevalo was healing well post-surgery. Doc. 103.9 at 8.

Arevalo first saw Dr. Kahn 3-1/2 years later. Doc. 103.3 at 23. She complained of incomplete bladder emptying, fecal incontinence since February 2011, urge incontinence, urinary tract infections ("UTIs"), dysuria (uncomfortable urination), and pelvic pain during intercourse. Doc. 103.3 at 24-29. Dr. Kahn examined Arevalo, noted she experienced pain when she touched her synthetic mesh, diagnosed her as having complications due to the mesh, noted her symptoms and pain were affecting her physically and emotionally, and recommended physical therapy and trigger point injections in the vagina. Doc. 103.3 at 32–33, 42–45. Over the next six months, Arevalo saw Dr. Kahn three more times. Doc. 103.9 at 8–9.

After the injections, Arevalo reported temporary improvement but was still having pain during sex. Docs. 103.3 at 48; 103.9 at 8. To relieve Arevalo's pain, Dr. Kahn recommended removal of Arevalo's mesh because it corresponded to her area of tenderness. Doc. 103.3 at 50, 52.

Dr. Kahn then performed a mesh graft removal, which removed a significant portion, but not all, of the mesh along with an anterior

colporrhaphy, cystoscopy, anal sphincteroplasty, and perineoplasty. Doc. 103.3 at 56. Because of extensive fibrosis between the graft and the vaginal wall, it was difficult to clearly identify the mesh. Dr. Kahn removed a good portion of the mesh and noted "appreciable decrease in the band," meaning she no longer felt the tautness. *Id.* at 62–63.

B. Dr. Rosenzweig opines that Coloplast's mesh products caused Arevalo's injuries

Dr. Rosenzweig, Arevalo's retained expert, was a highly successful pelvic-floor surgeon based in Chicago who also served as an assistant professor of obstetrics and gynecology at Rush University Medical Center. Doc. 103.1 at 1–2. He had performed more than 1,000 pelvic floor surgeries, including over 350 surgeries to address complications associated with synthetic mesh products. *Id.* He had published numerous articles and given numerous lectures on the treatments of urinary incontinence and pelvic organ prolapse. *Id.* He had sat for over 100 depositions and testified in roughly 18 mesh trials. Doc. 124 at 3.

Other than this case, he has served as a mesh expert in numerous other similar cases. *See infra* Argument I.B. Those district courts have always found his differential etiology reliable and have routinely

admitted his general causation opinions on the properties of polypropylene mesh. *See id.*

Here, Dr. Rosenzweig provided general causation reports on Coloplast's mesh sling products, including the Aris (Docs. 92.4; 103.1) and the pelvic organ prolapse mesh products, including the Exair (Doc. 92.5). He also provided a specific causation report about Arevalo. Doc. 103.9. His Aris Report opined "Coloplast has marketed and sold the Aris, [Supris and Altis] despite the fact that they contain numerous characteristics that make them unsuitable for implantation in a woman's vagina." Doc. 103.1 at 87. He explained that the problems with the mesh product include:

1. that the mesh degrades over time (Docs. 92.5 at 13; 103.1 at 15);
2. that the body reacts to the mesh with an inflammatory response or a chronic foreign body reaction (Docs. 92.5 at 22; 103.1 at 25);
3. that a slimy, protective biofilm formation results from the weave and design of the mesh and its implantation technique through the vagina, "which is not sterile and can never be completely sterilized" and allows for the "infiltration, harboring and protection of bacterial contaminants" (Doc. 103.1 at 28–31);
4. that the small pore size of the mesh leads to fibrotic bridging, which turns the mesh into a solid sheet of scar tissue (Doc. 103.1 at 31–37); and

5. that the small-pore, heavy polypropylene mesh contracts and shrinks leading to painful complications in women (Docs. 92.5 at 30; 103.1 at 39).

For those reasons, Dr. Rosenzweig opined that the Aris and Exair's polypropylene mesh "causes a multitude of injuries," including chronic pelvic and vaginal pain. Docs. 103.1 at 15; 92.5 at 31.

His specific causation report grounded his opinions upon his education and review of scientific literature, Arevalo's medical records, and his general causation reports. Doc. 103.9 at 2–3. In part, he opined the Aris and Exair "directly caused" Arevalo numerous permanent injuries, including "the need for mesh excision procedure, pelvic pain, vaginal pain, and dyspareunia, frequent UTIs, urinary and fecal incontinence." Doc. 103.9 at 12. Those permanent injuries resulted from "chronic inflammation, foreign body reaction, scarring, contraction, shrinkage, deformation and degradation of the mesh." *Id.* at 16.

He based those opinions on a "broad" differential etiology that "considered her medical and surgical history," including her three pregnancies and deliveries, her "Kidney stones, Asthma, Bipolar disorder, Headaches, rectocele, cystocele, uterine prolapse, Human papilloma virus and dysplasia of uterine cervix," along with her tubal

ligation and LEEP procedure. *Id.* at 13. But "[n]one of these conditions" caused her "current injuries." *Id.* He also "ruled out the hysterectomy as there are no findings of tenderness at the vaginal cuff." *Id.*

C. The district court strikes the disclosure of Dr. Miklos as untimely

At Arevalo's December 17, 2020 deposition, she disclosed that she had sought medical treatment from a new treating physician, Dr. Miklos, in July 2020. *See* Doc. 157. She found him after searching online for a doctor who specialized in urogynecology. *See* Docs. 157; 166.1.

On January 4, 2021, Arevalo's counsel first received Dr. Miklos's medical records and forwarded them to Coloplast three days later. Docs. 166 at 4; 166.2; 157. On January 24, 2021, Dr. Miklos wrote Arevalo's case report. Doc. 157.2. On January 26, 2021, Arevalo filed a Rule 26 supplemental expert disclosure, which attached Dr. Miklos's report. Docs. 157; 157.2.

Dr. Miklos examined Arevalo in July 2020, but waited to pursue treatment until after receiving and reviewing her medical records. Doc. 166.2 at 5. His report noted reproducible tenderness where Arevalo's mesh was located, which is "a diagnostic of a complication specific to a mesh placement." Doc. 157.2 at 10. He concluded the remaining mesh

(Doc. 124.2 at 6) was still causing Arevalo's pain and dyspareunia. *Id.* Essentially, he opined the same thing as Dr. Kahn. *See* Doc. 92.21 at 29.

On February 4, 2021, the court continued the pretrial conference until October 15, 2021 and the trial until November 1, 2021. Doc. 161. On February 12, 2021, Coloplast moved to strike Arevalo's disclosure of Dr. Miklos. Doc. 163; *see also* Docs. 166 (response); 170 (reply). On April 5, 2021—seven months before trial and before deciding Coloplast's summary judgment motion—the district court struck Dr. Miklos. Doc. 171. Thereafter, it granted summary judgment, finding no evidence of causation. Docs. 172; 173.

Standard of Review

1. *Daubert* rulings are reviewed for abuse of discretion. *Moore v. Intuitive Surgical, Inc.*, 995 F.3d 839, 850 (11th Cir. 2021).

2. Summary judgment rulings are reviewed de novo. *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1305 (11th Cir. 2014).

3. Rule 37 sanctions, like excluding Dr. Miklos as an expert, are reviewed for abuse of discretion. *OFS Fitel, LLC v. Epstein, Becker & Green, P.C.*, 549 F.3d 1344, 1360 (11th Cir. 2008).

SUMMARY OF THE ARGUMENT

1. The district court abused its discretion and committed clear error when it excluded Dr. Rosenzweig's causation opinions for three primary reasons, each of which independently requires reversal. First, its ruling—which stands alone among dozens of other courts' rulings—procedurally shouldn't have allowed the belated new argument in the first place. Second, it applied an incorrect legal standard by applying the wrong standard of proof for the causation element. Third, it committed clear error when it misunderstood the factual nature of Arevalo's medical conditions (such as the removal of her uterus) and otherwise misdescribed the record. For instance, the differential etiology did reliably consider and rule out Arevalo's potential alternative causes of pain, and the peer-reviewed medical literature—including *article abstracts*—clearly supported his general causation opinion that degraded mesh causes pain.

2. The district court erred in granting summary judgment. Dr. Rosenzweig's erroneously excluded testimony provided sufficient causation evidence. Even without it, sufficient causation testimony still

existed from Dr. Rosenzweig's remaining testimony and from Arevalo's treating physicians, Dr. Kahn and Dr. Miklos.

3. The district court abused its discretion when it excluded Arevalo's late retained physician expert, Dr. Miklos. His belated disclosure was substantially justified, in good faith, and harmless.

ARGUMENT AND CITATIONS OF AUTHORITY

I. The *Daubert* order excluding Dr. Rosenzweig was an abuse of discretion based on clearly erroneous factual mistakes

This Court should reverse the partial exclusion of Dr. Rosenzweig. *Daubert* rulings are manifestly erroneous when a district court applied an "incorrect legal standard, followed improper procedures, or made clearly erroneous findings of fact." *Crawford v. ITW Food Equip. Group, LLC*, 977 F.3d 1331, 1338 (11th Cir. 2020). Here, the district court followed improper procedures (by allowing a belated argument), applied an incorrect legal standard (by applying the wrong standard of proof for the causation element), and made clearly erroneous factual findings (by repeatedly overlooking Arevalo's medical history and misdescribing the basis for Dr. Rosenzweig's opinions). Thus, the *Daubert* ruling was manifestly erroneous.

A. To perform *Daubert*'s gatekeeping role, courts must focus on a methodology's reliability (which goes to admissibility), not the conclusion it produces (which goes to weight)

Rule 702 governs admission of expert testimony. *Guinn v. Astrazeneca, Pharm. LP*, 602 F.3d 1245, 1252 (11th Cir. 2010). But "after *Daubert*, the 'rejection of expert testimony is the exception rather than the rule.'" *Moore v. Intuitive Surgical, Inc.,* 995 F.3d 839, 843 (11th Cir. 2021) (quoting Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendments). Notwithstanding courts' "gatekeeper" role, Rule 702 isn't meant to replace the role of the jury in our adversarial system. *Adams v. Lab'y Corp. of Am.*, 760 F.3d 1322, 1334 (11th Cir. 2014). Rather, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 596 (1993).

In any event, this Court has "distilled from *Daubert*, *Kumho*, and Rule 702" three requirements to evaluate expert testimony:

> (1) whether the expert is "qualified to testify competently regarding the matter he or she intends to address";

> (2) whether the expert used a reliable methodology "as determined by a *Daubert* inquiry"; and
>
> (3) whether the expert's testimony assists the trier of fact "through the application of expertise to understand the evidence or determine a fact in issue."

Adams, 760 F.3d at 1328.

Under the second prong (reliable methodology), courts should focus solely on the expert's principles and methodology in forming his conclusions, not on the conclusions themselves. *Daubert*, 509 U.S. at 595 (courts must look at "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue"). "'The evidentiary requirement of reliability is lower than the merits standard of correctness.'" *Costa v. Wyeth, Inc.,* 2012 WL 1069189, at *2 (M.D. Fla. Mar. 29, 2012) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)). The reliability test is "a flexible one" that must be "tied to the facts." *Crawford*, 977 F.3d at 1337.

B. The district court's exclusion of Dr. Rosenzweig's specific and general causation opinions stands alone among dozens of contrary rulings

Other than this case, Dr. Rosenzweig has served as a mesh expert in numerous other vaginal mesh cases. Those district courts have always

found his differential etiology reliable. The MDL rulings from the Southern District of West Virginia include the following:

- *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *21 (Apr. 28, 2015);
- *Childress v. Johnson & Johnson*, 2017 WL 6350524, at *2 (Dec. 12, 2017);
- *Cooper v. Johnson & Johnson*, 2017 WL 6349092, at *2–3 (Dec. 12, 2017);
- *Corely-Davis v. C.R. Bard, Inc.*, 2018 WL 834944, at *2 (Feb. 12, 2018);
- *Edwards v. Ethicon, Inc.*, 2014 WL 336923, at *7 (July 8, 2014);
- *Flandro v. Boston Scientific Corp.*, 2016 WL 3282734, at *10 (June 14, 2016);
- *Foreman v. Boston Scientific Corp.*, 2016 WL 3039895, at *9–10 (May 27, 2016);
- *Mathison v. Boston Scientific Corp.*, 2015 WL 2124991, at *21 (May 6, 2015);
- *Priddy v. C.R. Bard, Inc.*, 2018 WL 662500, at *2 (Feb 1, 2018);
- *Sederholm v. Boston Scientific Corp.*, 2016 WL 3282587, at *10 (June 14, 2016);
- *Smith v. C.R. Bard, Inc.*, 2018 WL 715450, at *2 (Feb. 5, 2018);
- *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501 (2014).

The remand rulings include the following:

- *Armstead v. Coloplast Corp.*, 2020 WL 353576, at *3 (M.D.N.C. Jan. 21, 2020);

- *Bayless v. Boston Scientific Corp.*, 2020 WL 10058197 at *4–6 (M.D. Fla. Dec. 30, 2020);
- *Bell v. Ethicon, Inc.*, 2021 WL 1111071, at *10 (S.D. Tex. Mar. 23, 2021);
- *Chrastecky v. C.R. Bard, Inc.*, 2020 WL 748182, at *5 (W.D. Tex. Feb. 14, 2020);
- *Dorgan v. Ethicon, Inc.*, 2020 WL 5367062, at *2 (W.D. Mo. Sept. 8, 2020);
- *Gomez v. Am. Med. Sys., Inc.*, 2021 WL 1163087, at *15–16 (D. Ariz. Mar. 26, 2021);
- *Humleker v. Boston Scientific Corp.*, 2020 WL 6870852, at *20 (M.D. Fla. Oct. 2, 2020);
- *Messina v. Ethicon, Inc.*, 2020 WL 7419586, at *5 (M.D. Fla. Dec. 17, 2020);
- *Nunez v. Coloplast Corp.*, 2020 WL 2315077, at *7–8 (S.D. Fla. May 11, 2020);
- *Puldon v. Am. Med. Sys., Inc.*, No. 0:20-cv-60411, Doc. 127 at 2 (S.D. Fla. Oct. 22, 2020);
- *White v. Ethicon, Inc.*, 2021 WL 129818, at *3 (W.D. Wash. Jan. 14, 2021).

Similarly, other than this case, district courts have routinely admitted Dr. Rosenzweig's general causation opinions on the properties of polypropylene mesh. The MDL rulings from the Southern District of West Virginia include the following:

- *Flandro*, 2016 WL 3282734, at *9;

- *Foreman*, 2016 WL 3039895, at *7–8;
- *Griffin v. Boston Scientific Corp.*, 2016 WL 3031700, at *10–11 (May 25, 2016);
- *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2020 WL 774234, at *4 (Feb. 13, 2020);
- *Mathison v. Boston Scientific Corp.*, 2014 WL 5320566, at *19–20 (Oct. 17, 2014);
- *Sederholm*, 2016 WL 3282587, at *8–9;
- *Tyree*, 54 F. Supp. 3d at 565–66;
- *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *5–6 (May 5, 2015).

The remand rulings include the following:

- *Armstead*, 2020 WL 353576, at *3;
- *Bayless v. Boston Scientific Corp.*, 2020 WL 10058197, at *8;
- *Dorgan v. Ethicon, Inc.*, 2020 WL 5367062, at *2;
- *Gomez*, 2021 WL 1163087, at *11;
- *Hosbrook v. Ethicon, Inc.*, 2020 WL 5214644, at *5 (S.D. Ohio Sept. 1, 2020);
- *Humleker*, 2020 WL 6870852, at *20;
- *Messina*, 2020 WL 7419586, at *5;
- *Nunez*, 2020 WL 2315077, at *8;
- *Puldon*, *supra*, at 2;

- *Triant v. Am. Med. Sys. Inc.*, 2020 WL 4333645, at *2 (D. Ariz. July 28, 2020);
- *Wood v. Am. Med. Sys., Inc.*, 2021 WL 1178547, at *9 (D. Colo. Mar. 26, 2021).

C. The district court abused its discretion and committed clear error when it excluded Dr. Rosenzweig's specific causation opinions

The exclusion of Dr. Rosenzweig's specific and general causation opinions was an abuse of discretion grounded in clear factual errors.

1. The district court followed improper procedures when, after transfer from the MDL, it allowed Coloplast to rebrief its *Daubert* motion and inject an entirely new, untimely argument

The district court abused its discretion and procedurally erred in allowing Coloplast's belated differential etiology argument. In MDL litigation, district courts "should rarely reverse" MDL courts' orders "because any widespread overturning of [such] decisions would frustrate the principle aims of the MDL process and lessen the system's effectiveness." *In re Ford Motor Co.*, 591 F.3d 406, 411 (5th Cir. 2009). That's because the law of the case doctrine, as applied to MDL litigation, "'requires attention to the special authority granted to the multidistrict transferee judge' and ensures that transferor courts respect the transferee court's decisions." *Id.*; *accord Stevenson v. Four Winds Travel,*

Inc., 462 F.2d 899, 905 (5th Cir. 1972) (subsequent judge "should respect and not overrule" initial judge's rulings);[9] *Roeder v. Am. Med. Sys., Inc.*, 2021 WL 4819443, at *8 (D. Kan. Oct. 15, 2021) (denying motion to exclude one of Dr. Rosenzweig's opinions where defendant failed to raise issue in initial MDL briefing).

The district court acknowledged Coloplast's "critiques about Dr. Rosenzweig's differential etiology methodology were not previously included in the motion filed with the MDL court." Doc. 119 at 34; *see also* Doc. 118.2 at 26, 31–32. Nevertheless, it allowed Coloplast's new *Daubert* argument that Dr. Rosenzweig's differential etiology was unreliable, ruling it was a "natural corollary" to the reliability issue. *Id.* But that ruling didn't respect the MDL court's transfer order, which had ruled the case was ready for trial because the discovery and *Daubert* deadline had expired. Doc. 63 at 1.

[9] *See Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc).

2. The district court factually misunderstood Arevalo's medical conditions, including the removal of her uterus

The district court excluded Dr. Rosenzweig's differential etiology under *Daubert* because he supposedly failed to "systematically and scientifically" rule out "the other potential alternative causes for Arevalo's condition, such as her *rectocele, cystocele, or uterine prolapse*." Doc. 119 at 36 (emphasis added). But this factual finding was clear error: Arevalo no longer had a uterus after it was removed the same day the Aris was placed; and the Exair mesh was placed to correct her rectocele and cystocele conditions. *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233 (11th Cir. 2005) (*Daubert* rulings should be reversed "if the Court determines that the district court made a 'clear error of judgment'").

A differential etiology—which everyone agrees is a reliable methodology—"is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." *Guinn*, 602 F.3d at 1252. The expert "rules in" all of the things that could explain the patient's symptoms. *Costa*, 2012 WL 1069189, at *2. Then, the expert

"rules out" other potential causes. *Id.* at *3. Importantly, the expert needn't rule out *all* possible causes but should take serious account of other potential causes of a plaintiff's injury. *Guinn*, 602 F.3d at 1253. Of course, it logically follows that experts aren't required to rule out conditions that are unrelated or couldn't cause injury.

The district court's ruling that Dr. Rosenzweig failed to explain how he ruled out Arevalo's rectocele, cystocele, or uterine prolapse was a clearly erroneous misunderstanding of the facts because these conditions didn't need to be ruled out. Doc. 119 at 36. First, it was *impossible* for Arevalo to still have a uterine prolapse—a condition where the uterus slips down into or protrudes out of the vagina—because she no longer had a uterus.

Dr. Bankert had noted that Arevalo suffered from "uterine prolapse grade 2," but then Arevalo's uterus was removed during her total vaginal hysterectomy on the same day that the Aris sling was implanted. Docs. 92.1; 92.2. The district court was aware of and referenced Arevalo's hysterectomy in its *Daubert* order, but didn't appreciate that a "hysterectomy is the surgical removal of [a woman's] uterus." *Moore*, 995 F.3d at 843.

Coloplast had attached Arevalo's hysterectomy records to its *Daubert* motion. *See* Docs. 119 at 36; 92.2. Dr. Bankert's operative report confirmed that "the uterus was cross-clamped bilaterally and removed from the operative field." Docs. 92.2; 124.1 at 115 ("That was due to her uterus and her uterus was removed which would have treated that."); 123.1 at 116–17, 127 ("Correct. But that was resolved as we have been going over by her hysterectomy which took out the sources of pain prior to the Exair being placed."); 103.3 at 31–32 ("there's missing a D point because that only exists if she still has a uterus").

Two months after Dr. Bankert noted Arevalo had second-degree cystocele and rectocele (Doc. 103.9 at 7), he implanted the Exair to correct Arevalo's bulging organs (Docs. 103.9 at 7, 10; 124.1 at 81–82). Coloplast acknowledged the Exair "was placed to correct [Arevalo's] rectocele and cystocele." Doc. 54 at 1–2; *see also* Doc. 92 at 2.

Dr. Rosenzweig's report opined Dr. Bankert operated within the standard of care in performing *both* surgeries and there was no evidence of surgeon error,[10] which meant the Exair likely corrected Arevalo's

[10] Arevalo argued this in response to Coloplast's *Daubert* motion. *See* Doc. 103 at 17.

rectocele and cystocele. Doc. 103.9 at 10 Unfortunately, while the mesh implantations may have corrected Arevalo's organ bulges, they also caused unwanted side effects of vaginal pain and dyspareunia, among others—the subject of this lawsuit.

In short, Dr. Rosenzweig was not required to explain why or how these bulging organs could not be the cause of Arevalo's injuries because those conditions were addressed by the mesh placements. Dr. Rosenzweig had already attributed Arevalo's problems, before implantation with Coloplast's two mesh products, to her enlarged and boggy uterus.

The reason Arevalo's response to Coloplast's *Daubert* motion didn't address her rectocele, cystocele, or uterine prolapse is because Coloplast never argued Dr. Rosenzweig failed to properly exclude them (Doc. 92)—and for obvious good reason. The district court based its decision to exclude the differential etiology on Dr. Rosenzweig's failure to eliminate these conditions *sua sponte*. Because Dr. Rosenzweig wasn't required to eliminate conditions that couldn't have caused Arevalo's injuries, the district court's decision was clearly erroneous. *See Guinn*, 602 F.3d at 1253. And Arevalo's first opportunity to correct the district court's *sua sponte* error was her reconsideration motion. *See infra* Argument I.D.

3. Dr. Rosenzweig's differential etiology reliably considered and excluded Arevalo's *actual* potential alternative sources of injury

Even *if* Dr. Rosenzweig had failed in any manner to exclude any of the three conditions discussed above, a reliable differential etiology doesn't need to rule out *every* possible alternative cause. *Guinn*, 602 F.3d at 1253 (emphasis added). To the extent the district court found otherwise when ruling Dr. Rosenzweig didn't explain how he "systematically and scientifically ruled out *the other potential alternative causes*," its decision should be reversed for applying an incorrect legal standard. Doc. 119 at 36; *see Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999) (district court erred in requiring expert to "rule out *all* alternative possible causes").

Dr. Rosenzweig considered and excluded the *actual* potential alternative sources of Arevalo's injuries about which Coloplast's motion complained. *See* Doc. 92. Specifically, Coloplast argued Dr. Rosenzweig failed to eliminate alternative potential causes of Arevalo's injuries, such as her (1) prior pelvic surgeries, including her hysterectomy, (2) history of urinary tract infections and (3) delivery complications. *See* Doc. 92 at 28–30. But each argument misdescribed the record.

a. Dr. Rosenzweig considered and ruled out Arevalo's prior pelvic surgeries, including her hysterectomy

The district court acknowledged Dr. Rosenzweig properly ruled out the hysterectomy. Doc. 119 at 36. Arevalo still addresses it here because its implications are vital: namely, the hysterectomy removed Arevalo's prior source of pain, her uterus. Dr. Rosenzweig ruled out the hysterectomy as causing Arevalo's symptoms because there were "no findings of vaginal tenderness at the vaginal cuff." Doc. 103.9 at 12.

Coloplast argued Dr. Rosenzweig "cursorily dismisses Plaintiff's hysterectomy as a cause of her complaints." Doc. 92 at 28. Quite to the contrary, he repeatedly explained Arevalo's hysterectomy—performed on the same day the Aris was implanted to address her stress urinary incontinence—removed the source of many of her prior similar symptoms because they removed her uterus and cervix. *See* Doc. 124.1 at 115–17 (removal of uterus and cervix treated Arevalo's pelvic pain and dyspareunia, including gonorrhea, HPV, STDs, bacterial vaginosis, and chronic cervicitis that predated mesh implantation). Obviously, Arevalo's uterus and cervix could no longer be potential alternative sources of her

pain and dyspareunia because, after implanting Coloplast's mesh products, they no longer existed inside her body.

As for Arevalo's previous LEEP procedure, her cervix was removed during her hysterectomy. *See* Doc. 123.1 at 117. As for Arevalo's tubal ligation, Coloplast's *Daubert* motion represented to the district court that Dr. Rosenzweig "admits that all pelvic reconstructive surgeries, including those without mesh, can cause pelvic pain, dyspareunia, and infection." Doc. 92 at 28. But in the cited deposition testimony (which was from another case), when asked whether pelvic floor surgery carries the risk of having an increase in pelvic pain and dyspareunia, Dr. Rosenzweig actually responded, "In the postoperative period, correct." Doc. 92.18 at 73.

Coloplast then represented to the district court that Dr. Rosenzweig "offers no explanation as to how he can reliably rule out as a source of Plaintiff's claimed injuries the fact that she underwent numerous pelvic surgeries." Doc. 92 at 28. Actually, Dr. Rosenzweig testified about Arevalo's two (not numerous) other pelvic surgeries, her tubal ligation and LEEP procedure. Doc. 124.1 at 31–34. He also testified that pelvic floor surgery can cause pain and dyspareunia "in the postoperative

period, but not a delayed onset like we saw in Mrs. Arevalo's case." Doc. 124.1 at 129–30. That's because the medical literature had "very well documented" that "80 percent of mesh complications show up after one year." *Id.* Thus, he attributed Arevalo's current and future pain to the "characteristics of the mesh that lead to harm, in this case chronic inflammation, scar plate formation, mesh contraction, the mesh was under tension." *Id.*

Contrary to Coloplast's representation to the district court, Dr. Rosenzweig did, in fact, explain how he reliably considered and ruled out Arevalo's LEEP and tubal ligation surgeries as alternative potential causes of her pain, dyspareunia, and incontinence. Doc. 124.1 at 10. Although Coloplast may not have liked this explanation, cross-examination at trial was the appropriate remedy, not exclusion of Dr. Rosenzweig's testimony. *See Moore*, 995 F.3d at 857 ("district court improperly based its evidentiary determinations on the weight and persuasiveness of the evidence"); *Adams*, 760 F.3d at 1334 (district court "supplanted the jury's factfinding role" when it excluded expert who "had not sought to exclude the possibility of bias by conducting a blinded review" because "shakiness goes to the weight of her testimony, not its

admissibility"); *Costa,* 2012 WL 1069189, at *5 (denying *Daubert* motion because it went to weight, not admissibility, of expert's testimony).

b. Dr. Rosenzweig considered and ruled out Arevalo's history of childhood urinary tract infections

After her 2010 mesh implants, Arevalo reported consistent UTIs in 2013. Doc. 124.1 at 86–87. Dr. Rosenzweig explained these UTIs were unrelated to any history of childhood UTIs because she was "being assessed for incomplete bladder emptying." Doc. 124.1 at 87. That "would explain her recurrent urinary tract infections, four in the last year, which would be different from the condition that she might have had recurrent urinary tract infections as a child." Doc. 124.1 at 87.

Dr. Rosenzweig also testified that incomplete bladder emptying was one reason to justify a mesh removal procedure. *Id.* at 113. His testimony corresponds with Dr. Kahn's. Doc. 103.3 (Kahn Dep.) at 25–26 (bladder slings "cause an increased risk of urinary tract infections" "[m]ost likely because of impaired emptying").

Because Dr. Rosenzweig considered Arevalo's history of UTIs, any argument about his opinion would go to its weight, not its admissibility. *E.g.*, *Moore*, 995 F.3d at 857; *Adams*, 760 F.3d at 1334.

c. Dr. Rosenzweig considered and ruled out Arevalo's three childbirths

Coloplast questioned Dr. Rosenzweig about the specifics of Arevalo's three childbirths, including a large child who had a low forceps delivery and an episiotomy,[11] and whether they could've caused her vaginal pain, dyspareunia, and incontinence following her Aris and Exair mesh implantations in 2010. Doc. 124.1 at 35–43. Dr. Rosenzweig testified that having a larger baby doesn't necessarily increase one's risk for developing stress urinary incontinence, that any episiotomy pain would resolve within six weeks of the procedure, and that an episiotomy isn't a risk factor for pelvic organ prolapse, stress urinary incontinence, or sphincter damage. *Id.* at 38–40. Dr. Rosenzweig further testified that Arevalo's third-degree laceration wouldn't put her at greater risk of pelvic pain or dyspareunia and that any rectal damage would show up in the immediate postdelivery period if it didn't heal properly. *Id.* at 43.

Again, Dr. Rosenzweig properly addressed the fact that Arevalo was a mother who birthed three children, the last one 10 years before her

[11] An episiotomy is an incision made in the perineum (the tissue between the vaginal opening and the anus) during childbirth. Mayo Clinic, *Episiotomy: When It's Needed, When It's Not*, *at* https://tinyurl.com/cu2c7cdk.

mesh surgeries. He considered and ruled this out. So quibbles about his opinion would go to weight, not admissibility. *E.g.*, *Moore*, 995 F.3d at 857; *Adams*, 760 F.3d at 1334.

d. Dr. Rosenzweig "ruled in" the mesh as the most likely source of Arevalo's injuries

In *McClain*, although the expert ruled out other potential causes, he couldn't properly 'rule in' Metabolife as a potential cause of plaintiffs' serious medical problems. 401 F.3d at 1252. Here, in contrast, Dr. Rosenzweig did properly rule in the mesh as the most likely cause of Arevalo's vaginal pain and dyspareunia. Doc. 124.1 at 98–99, 115–16.[12]

[12] Like *McClain*, sister circuits' rulings support reversal here. In *Hardyman v. Norfolk & W. Ry. Co.*, the Sixth Circuit reversed a district court's exclusion of an expert's differential etiology and noted that "[a]fter careful review of the entire record, we are firmly convinced that the rationale of the district court did not justify exclusion of Plaintiff's expert testimony." 243 F.3d 255, 267 (6th Cir. 2001). Likewise, in *Messick v. Novartis Pharms. Corp.*, the Ninth Circuit reversed a district court's exclusion of a differential etiology where the expert "referred to his own extensive clinical experience as the basis for his differential diagnosis, as well as his examination of [the plaintiff]'s records, treatment, and history." 747 F.3d 1193, 1198 (9th Cir. 2014). *Messick* noted, "we do not require that an expert be able to identify the *sole* cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a *substantial causative factor*." *Id.* at 1199 (emphases added).

For instance, given the "severe" and "extensive" fibrosis found "between the graft and the anterior vaginal wall," he rejected the hypothesis that it reflected "a healing process that represents good tissue integration." *Id.* at 98–99. Instead, he inferred there was "scar plate formation due to the chronic foreign body reaction, chronic inflammatory reaction that's contracting the mesh, making the tight band which was causing her pain." *Id.* Additionally, he opined he had "ruled out every other possible cause of Ms. Arevalo's pelvic pain and dyspareunia even though she had pelvic pain and dyspareunia prior to receiving a Coloplast mesh device." *Id.* at 115–16.

Similarly, Dr. Kahn's testimony confirmed the mesh was the most likely cause of Arevalo's problems. Doc. 103.3 at 50, 52, 76. She proposed removing the mesh because it "seemed to correspond to her areas of tenderness." *Id.* at 50. For that reason, she thought it "more likely than not" that surgical removal would relieve her pain. *Id.* at 52. And she deemed the surgery successful in relieving Arevalo's pain. *Id.* at 76.

Notably, the MDL judge had already found Dr. Rosenzweig's similarly performed differential etiologies to be sufficiently reliable in many other vaginal mesh cases. *See supra* Argument I.B. For example,

in *Tyree*, 54 F. Supp. 3d at 566, the defendant similarly argued Dr. Rosenzweig's differential etiology wasn't reliable because he failed to properly exclude all alternative causes. *Tyree* found Dr. Rosenzweig's methods reliable because he acknowledged the plaintiff's prior pain, but explained that someone with preimplant pain could nevertheless experience an increase in pain after sling surgery. *Id*. at 566.

Similarly, in *Priddy v. C.R. Bard, Inc.*, 2018 WL 662500, *2 (S.D. W. Va. 2018), the MDL judge again ruled that Dr. Rosenzweig "conducted a detailed review of the plaintiff's medical records," "considered numerous alternative causes for the plaintiff's injuries," and "explained his reasons for ruling out those alternative causes." *Id.*; *accord Carlson,* 2015 WL 1931311, at *20–21; *Mathison*, 2015 WL 2124991, at *21; *Smith*, 2018 WL 715450, at *2; *Corley-Davis v. C.R. Bard, Inc.*, 2018 WL 834944, at *2 (S.D. W. Va. Feb. 12, 2018).

Other courts on remand also ruled Dr. Rosenzweig performed a reliable differential etiology. *See, e.g.*, *Bayless v. Boston Scientific Corp.,* 2020 WL 10058197, at *2 (M.D. Fla. Dec. 30, 2020); *Roeder,* 2021 WL 4819443, at *10 (D. Kan. Oct. 15, 2021). Typically, that was because the

defendant's arguments went to weight, not admissibility. *E.g.*, *Swintelski v. Am. Med. Sys., Inc.,* 2021 WL 4527451, at *4 (S.D. Fla. Aug. 6, 2021).

4. The district court abused its discretion when it excluded Dr. Rosenzweig's general causation opinion that degraded mesh causes pain

The district court ruled Dr. Rosenzweig couldn't offer his general causation opinion that polypropylene mesh degradation causes pelvic pain, vaginal pain, and dyspareunia (plus other conditions). Doc. 119 at 29. Despite agreeing that medical literature supported Dr. Rosenzweig's opinion that "polypropylene mesh degrades in vivo," the district court claimed it "did not see any that explained the mechanism by which degraded mesh causes the injuries alleged by Arevalo, *nor any that offered the ultimate conclusion that degradation of the mesh can cause these injuries in humans*." Doc. 119 at 9 (emphasis added). To the contrary, Dr. Rosenzweig's cited articles did, in fact, conclude that degraded mesh can cause pelvic pain, vaginal pain, and dyspareunia.

Dr. Rosenzweig's Rule 26 report stated, "In 2011, a group of similar researchers consisting of general surgeons, biological engineers and professors stated, polypropylene mesh materials 'are prone to degradation due to the body's aggressive foreign body reaction, which

may cause pain or complications, forcing mesh removal from the patient.'" Doc. 103.1 at 20 (emphasis added) (citing D.N. Grant *et al.*, *Conjugation of Gold Nanoparticles to Polypropylene Mesh for Enhanced Biocompatibility*, 22 J. MATERIALS SCIENCE: MATERIALS MED. 2803 (2011)).

He also cited and relied on Donald R. Ostergard, *Polypropylene Vaginal Mesh Grafts in Gynecology*, 116 OBSTETRIC GYNECOLOGY 962 (2010), *at* https://tinyurl.com/2x3br3p9. *See* Doc. 103.1 at 23 n.15. That article's abstract stated, "[t]he vagina is a clean-contaminated environment, and it is not possible to insert polypropylene mesh devices without bacterial contamination, despite standard antibiotic usage. Once inserted, the host tissue immediately attaches to the polypropylene and attempts to defend it from bacterial invasion." It further stated, "Noninert polypropylene *degrades* into potentially toxic compounds that would be expected to stimulate a greater inflammatory reaction leading to erosion." *Id.* And it concluded, "Scar tissue causes contraction to less than 50% of the implanted size, *which results in dyspareunia* and tension on the pelvic mesh attachments. Such contraction *may cause pelvic pain* and subsequent erosion into adjacent organs." *Id.* (emphasis added). Dr.

Rosenzweig reported that Coloplast had actual knowledge of this article and circulated it. Doc. 103.1 at 23.

Even the articles attached to Coloplast's own *Daubert* motion concluded mesh can cause pain. *See, e.g.*, Doc. 92.7 at 413 ("low but persistent rates of complications related to mesh, most commonly mesh exposure and pain, have hampered its use"), 413 ("Mesh complications include exposure through the vaginal wall, erosion into adjacent structures, infection, and pain prompting the [FDA] to issue two public statements—the first in 2008 warning of serious complications associated with the transvaginal placement of surgical mesh and a second in 2011 warning that mesh complications are not rare events"), 419 ("Current polypropylene prolapse meshes are associated with persistent rates of complications; particularly, mesh exposure and pain").

Because the district court's finding that no articles cited by Dr. Rosenzweig conclude that degraded mesh causes pain and dyspareunia was clearly erroneous, this decision should also be reversed. *See Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 84 (1st Cir. 1998) (articles supported reliability of expert's methodology).

D. The district court compounded its errors when it denied reconsideration

The district court denied Arevalo's motion to reconsider the *Daubert* order (Doc. 124) because it ruled Arevalo should've raised her arguments while the *Daubert* motion was still pending.[13] Doc. 141 at 4.

Although it might've been best practice to attach Dr. Rosenzweig's complete deposition to Arevalo's response to Coloplast's *Daubert* motion (*see* Doc. 92.8), the *Daubert* order—including its *sua sponte* errors—was the first instance in which Arevalo was on notice that the district court believed her uterine prolapse, rectocele and cystocele remained as potential alternative causes of her injuries. Doc. 119 at 35. Accordingly, when Arevalo notified the district court that the very purpose of the Exair mesh was to correct her bulging organs[14] and attached the full deposition

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[13] The district court cited *Wilchombe v. TeeVee Toons, Inc.*, 555 F.3d 949, 957 (11th Cir. 2009), for the proposition that "a motion for reconsideration cannot be used for 'new arguments that were previously available but not pressed.'" Doc. 119 at 4. But *Wilchombe* involved a motion to reconsider a summary judgment ruling *after* judgment had already been entered. *Id.* Thus, it arose under Rule 59 or Rule 60. In contrast, Arevalo asked the district court to reconsider its *Daubert* ruling on August 4, 2020, which was before she was even required to respond to Coloplast's July 28, 2020 summary judgment motion. *See* Docs. 122; 124.

[14] In response to Coloplast's *Daubert* motion, Arevalo did argue that Dr. Rosenzweig opined that Dr. Bankert operated within the standard of care. *See* Doc. 103 at 17.

testimony flushing out all of Dr. Rosenzweig's opinions, including his complete differential etiology, it should have reconsidered its ruling especially in light of this Court's "strong policy" for deciding cases on their merits. *Perez v. Wells Fargo N.A.*, 774 F.3d 1329, 1339 (11th Cir. 2014).

When deciding the motion for reconsideration, the district court labored under a misapprehension that it had less authority to reconsider its interlocutory *Daubert* order than it actually did. Because Arevalo was asking the district court to reconsider an interlocutory order, it actually had authority to revisit its decision pursuant to the inherent power of district courts. *See* Fed. R. Civ. P. 54(b) ("any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and *may be revised at any time before the entry of a judgment* adjudicating all the claims and all the parties' rights and liabilities" (emphasis added)); *see also Kolawole v. Sellers*, 863 F.3d 1361, 1368 (11th Cir. 2017) (relief under Rules 59(e) and 60(b) is available only when the court has already entered a final judgment.); *Finch v. City of Vernon*, 845 F.2d 256, 258 (11th Cir. 1988) ("Rule 59 applies to motions for reconsideration of matters encompassed in a

decision on the merits of the dispute, and not matters collateral to the merits); *Gallimore v. Missouri Pac. R. Co.,* 635 F.2d 1165, 1171 (5th Cir. 1981) (district courts have plenary power over interlocutory orders and their power to "reconsider, revise, alter or amend the interlocutory order is not subject to the limitations of Rule 59"); *Oliver v. Orange County, Fla.*, 456 Fed. App'x 815, 819 n.2 (11th Cir. 2012) (*Daubert* ruling was interlocutory order).

Here, the motion to reconsider the *Daubert* ruling did "not necessarily fall within any specific Federal Rule," but rather fell under "the inherent power of the rendering district court to afford such relief from interlocutory judgments ... as justice requires.'" *Greene v. Union Mut. Life Ins. Co. of Am.*, 764 F.2d 19, 22-23 (1st Cir. 1985). As such, there was no requirement that Arevalo demonstrate the unique or exceptional circumstances that Rule 59 or Rule 60(b) would ordinarily require; instead, the district court should have "applied an appropriate 'interests of justice' standard" and granted the request. *Id.* at 23.

In the "interests of justice," the Court should have granted Arevalo's motion for reconsideration once it was brought to its attention that it had misunderstood Arevalo's medical conditions and the purpose

of the mesh surgeries. *See* Doc. 124 at 11–14; *Greene*, 764 F.2d at 22–23. But even if the district court had properly proceeded under Rule 59 or Rule 60, the filing of the complete deposition of Dr. Rosenzweig coupled with notification of the nature of Arevalo's surgeries to correct her organ bulges, established clear error such that the motion should have been granted.[15]

II. Summary judgment was error

It was error to grant summary judgment. The district court imposed the wrong substantive law about causation (*see infra* Argument II.A), erroneously excluded Dr. Rosenzweig's causation testimony (*see infra* Argument II.B), and misconstrued Dr. Kahn's testimony (*see infra* Argument II.C).

A. The district court misconstrued Florida law about the standard of proof on the causation element

Summary judgment is proper only if the movant can establish that, viewing the evidence in the nonmovant's most favorable light, there's "no genuine dispute as to any material fact and the movant is entitled to

[15] Under Rule 59(e), three grounds justify reconsideration: (1) an intervening change in controlling law; (2) the availability of new evidence; and (3) the *need to correct clear error or prevent manifest injustice*. *SEC v. Radius Cap. Corp.*, 2013 WL 12155433, at *1 (M.D. Fla. Apr. 24, 2013) (emphasis added).

judgment as a matter of law." *Chapman*, 766 F.3d at 1312. The "substantive law will identify which facts are material," and district courts "must view the evidence presented through the prism of the substantive evidentiary burden." *Fernandez v. Bankers Nat. Life Ins. Co.,* 906 F.2d 559, 564 (11th Cir. 1990). "In this diversity case, the burden of proof regarding causation is governed by state law," and the federal law determining the reliability of an expert's report is "separate and distinct" from the question of proving causation under state law. *Cooper v. Marten Transp., Ltd.,* 539 Fed. App'x 963, 968 (11th Cir. 2013).

Further, this Court reviews the whole record when reviewing a district court's grant of summary judgment. *Id.* ("the issue on appeal from the grant of summary judgment for defendant is whether the record as a whole contains sufficient evidence" (citing *Sparks v. Pilot Freight Carriers, Inc.,* 830 F.2d 1554, 1562–63 (11th Cir. 1987)).

Arevalo's negligence, strict liability and gross negligence claims were brought under Florida law. In Florida, a defendant's conduct:

> need not be the only cause of a plaintiff's injuries, or even fifty-one percent of the cause; rather, the plaintiff must present evidence that the defendant's conduct was, more likely than not, a "substantial factor" in causing the injury. Thus, a plaintiff isn't required to prove that the defendant's conduct alone was more likely than not the sole proximate cause.

Whitney v. R.J. Reynolds Tobacco Co., 157 So. 3d 309, 312 (Fla. 1st DCA 2014).[16] Florida standard jury instructions confirm that a product's defect "need not be the only cause" of an injury; rather, it's sufficient if it "contributes substantially to producing" an injury. Fla. Std. Jury Instr. 403.12(a), (b); *accord Cohen v. Philip Morris USA, Inc.,* 203 So. 3d 942, 951 (Fla. 4th DCA 2016) (citing former version of jury instructions and reversing directed verdict for defendant on causation element).

First, the district court applied an incorrect legal standard when it ruled a jury couldn't infer that the mesh was "more likely than not *the* cause" of Arevalo's pain. Doc. 172 at 15 (emphasis added). In Florida, the standard for causation is merely that the mesh be more likely than not "a substantial factor" in causing Arevalo's injuries or pain. *Whitney*, 157 So. 3d at 312; *Guinn*, 602 F.3d at 1256) (Florida plaintiffs must introduce evidence that "more likely than not the conduct of the defendant was a substantial factor in bringing about the result"). Because summary

[16] *See also Costa,* 2012 WL 1069189, at *1 ("In order to be regarded as a legal cause of injury, the defect need not be the only cause. A defect may be a legal cause of injury even though it operates in combination with some natural cause (*i.e.,* a pre-existing physical condition) if the defect *contributes substantially* to producing such injury." (emphasis added)); *Bayless,* 2020 WL 10058197, at *3 (citing *Whitney*, 157 So. 3d at 312).

judgment was based an incorrect legal burden, it should be reversed on that basis alone. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986) ("in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden").

B. Dr. Rosenzweig's improperly excluded causation opinions provided sufficient causation evidence

Additionally, if this Court reverses the district court's exclusion of Dr. Rosenzweig's causation opinions, it must also reverse summary judgment, which was based solely on a lack of causation testimony. *Moore*, 995 F.3d at 843.

C. Even without Dr. Rosenzweig's opinions, factual disputes still existed whether Coloplast's mesh products "substantially contributed" to Arevalo's pain, dyspareunia, and incontinence

Even without excluding the differential etiology, summary judgment was still improper because Arevalo's remaining testimony from Dr. Rosenzweig, Dr. Kahn, Dr. Bankert, and Dr. Miklos (who was also improperly excluded) raised a sufficient jury issue on causation.

1. A differential etiology isn't always required

A differential etiology can be a valid way of establishing specific causation, but it isn't the only way. *See Hendrix ex rel. G.P. v. Evenflo*

Co., Inc., 609 F.3d 1183, 1195 (11th Cir. 2010) ("the differential etiology method *can* provide a valid basis for medical causation opinions" (emphasis added)); *see also Sampson v. Carnival Corp.*, 2016 WL 7377226, *4 (S.D. Fla. Dec. 16, 2016) ("Defendant's argument that the omission of a differential diagnosis analysis is fatal to Plaintiff's experts is unsupported as Defendant fails to cite to a single case—and the Court finds none—where the Eleventh Circuit has explicitly required this form of analysis.").

In *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, 2021 WL 830309, *5 (N.D. Fla. March 4, 2021), a district court ruled a defendant's expert's specific causation opinions regarding the cause of the plaintiffs' hearing problems were reliable even though they didn't "formally perform more traditional differential diagnoses." The experts had significant experience in their field, reviewed the plaintiffs' audiological and disability records, evaluated their noise exposure, and explained how the evidence supported their conclusions. *Id.*; *see also Campbell v. Chiles*, 2000 WL 730423, at *5 (N.D. Tex. May 18, 2000) (experts adequately supported opinion that airway obstruction caused death, not some other potential causes of death, even without employing a differential etiology).

Here, although the district court found that "simply citing experience does not deem an opinion reliable," Dr. Rosenzweig's extensive experience *was* an important factor for the district court to consider in determining the reliability of his methodology. Doc. 172 at 11. In *Adams,* this Court reversed the exclusion of an expert's testimony (and summary judgment) where the expert's "application of her extensive, relevant experience contributed to the reliability of her methodology." 760 F.3d at 1330; *accord Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.,* 388 F.3d 976, 982 (6th Cir. 2004) ("*Daubert*'s role of 'ensur[ing] that the courtroom door remains closed to junk science,' is not served by excluding testimony … that is supported by extensive relevant experience." (citing *Amorgianos v. Nat'l R.R. Passenger Corp*., 303 F.3d 256, 267 (2d Cir. 2002))); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1336 (11th Cir. 2010) ("there are instances in which a district court may determine the reliability prong under *Daubert* based primarily upon an expert's experience and general knowledge in the field"). Here, Dr. Rosenzweig's extensive experience with mesh informed his opinions regarding Arevalo.

2. Dr. Rosenzweig's unexcluded testimony and Dr. Kahn's specific causation testimony still created a genuine dispute of material fact about causation

In granting summary judgment, the district court ruled the treating physicians' testimony didn't create a factual dispute about causation. Doc. 172 at 13.[17] The district court ruled Dr. Kahn's testimony "is insufficient to establish specific causation." Doc. 172 at 14.

Dr. Kahn testified she partially removed the Exair mesh because she thought doing so would "resolve Plaintiff's pelvic issues." Docs. 103.3 at 50; 172 at 14. She thought the mesh was causing Arevalo's pain. *See* Doc. 103.3 at 50–52. Upon examination, when Dr. Kahn touched the mesh, Arevalo reported pain. *See* Doc. 103.3 at 29. Dr. Kahn determined that Arevalo "was having complications" due to the synthetic mesh grafts. Doc. 103.3 at 32–33. Arevalo had pain at the site of the mesh. Doc. 103.3 at 33–34. Arevalo's pain and tenderness were "more likely than

[17] The district court said it "need not consider" Coloplast's arguments that Arevalo's treating physicians' opinions weren't properly disclosed per Rule 26(a)(2)(C) or survivable under *Daubert*. *See* Doc. 172 at 13 n.17. Arevalo listed both Dr. Rosenzweig and Dr. Kahn as experts on September 5, 2017. *See* Doc. 122.1. On February 22, 2019, Arevalo added Dr. Bankert as an expert (along with four other additional doctors). *See* Doc. 122.2.

not" related to the mesh. Doc. 103.3 at 47–48. That's why Dr. Kahn recommended mesh removal. Doc. 103.3 at 52, 136.

The district court nevertheless ruled a jury "could not infer" from this testimony "that the mesh was more likely than not *the* cause of those issues because even Dr. Kahn was unable to make that inference." Doc. 172 at 15 (emphasis added). In support, the district court cited Dr. Kahn's subsequent testimony that she would have liked to have seen Arevalo again after her last appointment. *See* Doc. 103.3 at 75.

The district court didn't acknowledge that Dr. Kahn also testified that when removing the mesh, she encountered a "tight band consistent with mesh material," which she concluded was the cause of Arevalo's tenderness. Doc. 103.3 at 62–63. When she removed a good portion of the mesh, there was considerable "decrease in the band," meaning she didn't feel the tautness, and the tissue was more pliable. Doc. 103.3 at 61–62. Dr. Kahn felt that loosening the band of tightness would improve Arevalo's pain. Doc. 103.3 at 63–64.

Dr. Kahn also noted that during Arevalo's visit two months after her mesh removal, her notes made no mention of tenderness. Doc. 103.3

at 73–74. Although she couldn't be sure whether there was tenderness upon examination, Arevalo didn't report vaginal pain that day. *Id.*

As a general rule, "credibility determinations based on inconsistent statements of a witness are 'not appropriate at the summary judgment stage.'" *Rivera v. LeBron*, 824 Fed. App'x 838, 842 (11th Cir. 2020) (citing *Feliciano v. City of Miami Beach*, 707 F.3d 1244, 1253 (11th Cir. 2013)). Dr. Khan's testimony that she would've liked Arevalo to have followed up again wasn't inconsistent with her belief that the mesh removal would alleviate Arevalo's pain. And even if she qualified her testimony that the mesh caused Arevalo's pain in any way, that would go to her testimony's credibility, not its admissibility.

By deciding that *no* jury could make a reasonable inference of causation from Dr. Kahn's testimony as a whole, the district court made an impermissible credibility determination at summary judgment.[18] *See*

[18] The district court cited two cases in support of its assertion that this would require too much speculation from a jury: *Prieto v. Total Renal Care, Inc.*, 843 Fed. App'x 218, 224 (11th Cir. 2021); and *McCasland v. Pro Guard Coatings, Inc.,* 799 Fed. App'x 731, 734 (11th Cir. 2020). But both cases are easily distinguishable. They each involved plaintiffs who presented *no* causation evidence. In *Prieto*, the plaintiff presented no evidence that he would've fared any differently after a van accident if he had been on a stretcher instead of a wheelchair. In *McCasland*, a *pro se*

Anderson, 477 U.S. at 255 ("credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict"). Because the district court took on the jury's role, the summary judgment order (Doc. 172) should be reversed. *E.g., Waite v. AII Acquisition Corp.,* 194 F. Supp. 3d 1298, 1317 (S.D. Fla. 2016) ("the Court cannot conclude here, viewing the facts in the light most favorable to the Plaintiffs, that the evidence does not support an inference" that exposures "were a substantial factor leading to the development of his mesothelioma").

Additional testimony further creates a genuine issue of material fact as to causation. First, the district court ruled that Dr. Rosenzweig's testimony regarding the Aris's small pore size was reliable. *See* Doc. 119 at 30. Specifically, Dr. Rosenzweig opined that the mesh's small pore size leads to fibrotic bridging, which turns the mesh into a solid sheet of scar tissue, and that the small pore mesh contracts and shrinks, leading to painful complications in women. See Doc. 103.1 at 31-40.

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plaintiff presented *no* opinion as to what caused his oromandibular dystonia or other symptoms.

Even the scientific article attached to Coloplast's *Daubert* motion supported this opinion. It stated:

> Mesh pore size is also inversely related to bridging fibrosis (*i.e.*, as pore size increases, the incidence of bridging fibrosis decreases). Bridging fibrosis refers to a phenomenon that occurs when the foreign body response to a single mesh fiber overlaps or merges with that of a neighboring fiber resulting in a continuous fibrotic response or encapsulation of the mesh. The latter *can lead to pain*.

Doc. 92.7 at 414 (emphasis in original). Dr. Rosenzweig opined that this was one of the characteristics of Arevalo's mesh that caused her debilitating pain and other injuries. *See* Doc. 103.9 at 11. Dr. Rosenzweig also opined that the fibrosis Dr. Kahn found in Arevalo was due to her mesh. Doc. 124.1 at 98–99. When taken "in concert" with Dr. Kahn's testimony that she did, in fact, feel a tight band and thought this was the cause of Arevalo's tenderness and pain (Doc. 103.3 at 61–62), Arevalo has more than sufficient causal evidence to present her case to a jury. *See, e.g., Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304, 1320 (11th Cir. 2017) (three doctors' testimony, taken "in concert," provided requisite evidence for reasonable jury to find mesh design defective).

Even more, the district court didn't disturb Dr. Rosenzweig's opinions that the Aris and Exair's polypropylene mesh produces a chronic

inflammatory response by the body, localized near the implantation site. *See* Doc. 103.1 at 25–27. The smaller pore size of the mesh is associated with a greater inflammatory response. *Id.* at 26. In fact, chronic inflammation and fibrosis were found in a test performed by an outside laboratory on Coloplast's mesh products. *Id.*

The district court also ruled Dr. Rosenzweig could properly opine Arevalo's mesh did, in fact, degrade. Doc. 119 at 33. Of course, the district court's finding that Dr. Rosenzweig's general causation opinion that mesh degradation causes pain and other complications wasn't reliable was also clearly erroneous because the articles he relied upon did, in fact, say this. *See supra* Argument I.C.4. Accordingly, the testimony that Arevalo's mesh did, in fact, degrade coupled with the improperly excluded opinion that degraded mesh causes pain and dyspareunia, provided her with sufficient evidence of causation to withstand summary judgment.

III. The district court abused its discretion when it struck the testimony of Dr. Miklos as untimely

A district court's discretion regarding discovery sanctions "is not unbridled." *Wouters v. Martin County*, 9 F.3d 924, 933 (11th Cir. 1993). Although they have "broad powers under the rules to impose sanctions,"

a ruling that results in "dismissal is justified only in extreme circumstances and as a last resort." *Id.*

Thus, the "decision to exclude evidence is a drastic sanction." *Baratta v. City of Largo*, 2003 WL 25686843, at *2 (M.D. Fla. Mar. 18, 2003). "'Without a finding of bad faith or gamesmanship on the eve of trial, many courts are loathe to invoke the strong medicine of precluding expert testimony.'" *Collins v. United States*, 2010 WL 4643279, at *5 (M.D. Fla. Nov. 9, 2010) (quoting *McClain v. Metabolife Int'l, Inc.*, 193 F. Supp. 2d 1252, 1259 (N.D. Ala. 2002)). "In fact, the refusal to impose a lesser penalty can amount to an abuse of discretion." *Id.*

The district court ruled Dr. Miklos's disclosure wasn't "timely" under Rule 26(e)[19] because Arevalo should've disclosed him when she had her first appointment in July 2020, not when she was deposed five months later in December 2020.[20] Doc. 171 at 6. The district court ruled

[19] Notably, by this time, Arevalo's lawsuit had already been pending over seven years. In any event, Rule 26(e) provides that a party "who has made a disclosure under Rule 26(a) … must *supplement or correct its disclosure or response … in a timely manner* if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Fed. R. Civ. P. 26(e) (emphasis added).

[20] The district court noted Dr. Miklos appeared to be a nonretained expert subject to the provisions of Rule 26(a)(2)(C), although it determined that it didn't need to address Coloplast's argument that Dr.

the untimely disclosure wasn't substantially justified or harmless under Rule 37(c)(1).[21] But under Rule 37(c)(1), district courts "may impose other appropriate sanctions in addition to *or in lieu* of the evidentiary exclusion." *Prieto v. Malgor*, 361 F.3d 1313, 1318 (11th Cir. 2004).

District courts often utilize a five-factor test to determine substantial justification and harmlessness:[22] (1) the surprise to the party against whom the evidence is offered, (2) the ability of that party to cure the surprise, (3) the extent to which the evidence would disrupt trial, (4) the importance of the evidence and (5) the non-disclosing party's explanation for the failure to disclose. *See, e.g.*, *Mobile Shelter Sys. USA,*

Miklos was actually a retained expert, rather than a nonretained expert, subject to the requirements of Rule 26(a)(2)(B) because this affected only the disclosure's content, not its timeliness. *See* Doc. 163 at 7. "When a physician's opinion on causation is formed and based on observations made during the course of treatment, then no [Rule 26(a)(2)(B)] report is required." *Jones v. Disc. Auto Parts, LLC*, 2017 WL 1396477, at *9 (M.D. Fla. Apr. 19, 2017); *see also Caserto v. Metro-N. R.R. Co.,* 2016 WL 406390, at *1 (S.D.N.Y. Feb. 2, 2016).

[21] Rule 37(c)(1) provides that if a party "fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified *or* is harmless." Fed. R. Civ. P. 37(c)(1) (emphasis added).

[22] In *Circuitronix, LLC v. Kinwong Elec. (Hong Kong) Co.*, 993 F.3d 1299, 1307–08 (11th Cir. 2021), this Court left open the "the meaning of harmlessness under Rule 37 and, in particular, its relationship to prejudice."

Inc. v. Grate Pallet Sols., LLC, 845 F. Supp. 2d 1241, 1250 (M.D. Fla. 2012), *aff'd in part*, 505 Fed. App'x 928 (11th Cir. 2013).

Although Rule 37(c)(1) was adopted in 1993 "to provide explicit authority for excluding evidence and imposing other sanctions for failure to supplement disclosures and discovery responses," this Court still utilizes the test developed before 1993 in evaluating the harmlessness and substantial justification prongs: the explanation for the failure to disclose the witness; the importance of the testimony; and the prejudice to the opposing party. *See, e.g.*, *Rigby v. Philip Morris USA, Inc.*, 717 Fed. App'x 834, 835 (11th Cir. 2017) (citing *Fabrica Italiana Lavorazione Materie Organiche, S.A.S. v. Kaiser Aluminum & Chem. Corp.*, 684 F.2d 776, 780 (11th Cir. 1982)); Wright & Miller, 8A Fed. Prac. & Proc. Civ. § 2050 (3d ed. Apr. 2021); *see also* Doc. 171 at 9.

The district court abused its discretion in excluding Dr. Miklos because all these factors lean heavily in Arevalo's favor. Further, the decision ultimately amounted to the effective dismissal of Arevalo's case without finding any requisite showing of bad faith.

The late disclosure of Dr. Miklos was substantially justified because (1) the evidence was very important to Arevalo's case, and (2) Arevalo

couldn't have produced the evidence by the applicable expert disclosure date. Dr. Miklos's testimony went to "the heart" of Arevalo's case that Coloplast's mesh products caused her pain, dyspareunia, and other injuries. *See Goines v. Lee Mem. Health Sys.*, 2019 WL 968397, at *7 (M.D. Fla. Feb. 28, 2019) (late evidence went "directly to the heart" of plaintiff's case). Although Arevalo still had other sufficient causation evidence to withstand summary judgment, the district court disagreed and granted summary judgment due to a lack of causation evidence. Doc. 172. Accordingly, Dr. Miklos's testimony was extremely important.

Having researched treating urogynecologists in Alpharetta, Georgia in 2020, Arevalo couldn't possibly have disclosed Dr. Miklos by the expert deadline in September 2017. *See* Doc. 166 at 22 ("The MDL scheduling order called for case-specific disclosures in 2017."). Her injuries were ongoing. *See* Docs. 124.2; 157.2. In *Rigby,* 717 Fed. App'x at 835–36, cited by the district court (Doc. 171 at 9), there was *no* reason offered why the plaintiffs couldn't have produced the late affidavits earlier and, thus, the late disclosure wasn't substantially justified. Here, the district court acknowledged Arevalo "clearly could not have disclosed

Dr. Miklos' opinion by the disclosure deadlines established by the MDL Court because she had not yet seen him." Doc. 171 at 9.

Still, the district court ruled Arevalo should've disclosed Dr. Miklos immediately after her visit in July 2020, rather than December 2020 or January 2021. Doc. 171 at 9. But Dr. Miklos was unsure whether Arevalo had all her mesh removed, and he wanted to obtain her records before suggesting a course of treatment. Doc. 157.3 at 6. While the district court noted his records indicate he uploaded Arevalo's medical records shortly after her July appointment, Arevalo followed up periodically with his office to inquire about his recommendations and was told once he *reviewed* the notes he would recommend a plan. Doc. 166.1. Dr. Miklos wasn't a paid, retained expert; he's a busy, practicing physician. Under the circumstances, Arevalo's late disclosure was substantially justified.

Even if there wasn't substantial justification for the belated disclosure, it was harmless. Thus, the testimony shouldn't have been excluded. *See Hearn v. McKay*, 603 F.3d 897, 903 (11th Cir. 2010) (affirming district court that allowed late witness to testify where witness was disclosed in the pretrial stipulation, lessening degree of surprise).

First, Dr. Miklos' findings that Arevalo was tender where her mesh was and that the mesh was the most likely cause of Arevalo's pain mirrored the opinion of Dr. Kahn. In that sense, Coloplast wasn't surprised by the content of Dr. Miklos' opinion. *See, e.g.*, *Goines*, 2019 WL 968397, at *6 (there was no unfair surprise where the late disclosure addressed the same matters and came to the same conclusion as the initial opinion).

Next, courts have routinely found late disclosures to be harmless when the opposing side still has the opportunity to depose the individual with sufficient time before trial. *See, e.g.*, *Ellison v. Windt*, 2001 WL 118617, at *3 (M.D. Fla. Jan. 24, 2001) (despite no substantial justification, expert testimony was permitted where the belated disclosure was harmless, provided opponent was given opportunity to depose expert before trial). Notably, absent a stipulation or court order, the time to disclose expert testimony under Rule 26(2)(D) is 90 days before trial. While there was a court order here, Dr. Miklos was disclosed in January 2021, over 10 months before trial was scheduled.

"This is not the case of surprise witnesses revealed on the eve of trial in an effort to gain an unfair advantage." *Evanston Ins. Co. v.*

Premium Assignment Corp., 2013 WL 81997, at *4 (M.D. Fla. Jan. 7, 2013). The trial date was 10 months away, Dr. Miklos was opining the same thing that Dr. Kahn had already opined, and there was still sufficient time for Coloplast to prepare for trial. In *OFS Fitel, LLC v. Epstein, Becker & Green, P.C.*, 549 F.3d 1344, 1364 (11th Cir. 2008), this Court reversed the district court's decision to exclude expert testimony as sanctions for failing to timely provide a report where, "most importantly" no trial date "was imminent" and the other side had "ample time" to depose the expert; *see also Taylor v. Mentor Worldwide LLC*, 940 F.3d 582, 594 (11th Cir. 2019) (district court's decision to give opposing party additional time to prepare for cross-examination reflected its intention to preserve interests Rules 26 and 37 were designed to protect).

Finally, the district court acknowledged that options besides wholesale exclusion of Dr. Miklos' testimony were "possible," yet it still concluded exclusion was the "appropriate remedy." Doc. 171 at 12. Exclusion was not the appropriate remedy, however, because it amounted to a dismissal of Arevalo's entire case. For instance, the district court could've ordered Arevalo to pay for the expense of taking Dr. Miklos's deposition.

To enter a default judgment or dismissal, a finding of "willfulness or bad faith failure to comply" is required. *BankAtlantic v. Blythe Eastman Paine Webber, Inc.,* 12 F.3d 1045, 1048–49 (11th Cir. 1994). Here, the wholesale exclusion of Dr. Miklos's testimony effectively dismissed Arevalo's case; two weeks later, the district court ruled any remaining causation testimony was insufficient to withstand summary judgment. Doc. 172. Accordingly, this severe sanction was improper without the requisite finding of bad faith and should also be reversed.

CONCLUSION

This Court should vacate the judgment and remand for further proceedings.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with Federal Rule of Appellate Procedure 32(a)(7)(B)'s type-volume requirement. As determined by Microsoft Word 2010's word-count function, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and 11th Circuit Rule 32-4, this brief contains 12,325 words.

2. This brief further complies with Federal Rule of Appellate Procedure 32(a)(5)'s typeface requirements and with Federal Rule of Appellate Procedure 32(a)(6)'s type-style requirements. Its text has been prepared in a proportionally spaced serif typeface in roman style using Microsoft Word 2010's 14-point Century Schoolbook font.

November 8, 2021

/s/ Thomas Burns
Thomas A. Burns

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I filed the original and six copies of the foregoing brief with the Clerk of Court via CM/ECF and regular mail on this 8th day of November, 2021, to:

David J. Smith, Clerk of Court
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I FURTHER CERTIFY that I served a true and correct copy of the foregoing brief via CM/ECF on this 8th day of November, 2021, to:

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