

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 16-17147

D.C. Docket Nos. 4:08-md-02004-CDL,
4:12-cv-00176-CDL

TERESA TAYLOR,

Plaintiff – Appellee,

versus

MENTOR WORLDWIDE LLC,
MENTOR CORPORATION,

Defendants – Appellants.

No. 16-17245

D.C. Docket Nos. 4:08-md-02004-CDL
4:12-cv-00176-CDL

In re: MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS
LIABILITY LITIGATION.

TERESA TAYLOR,

Plaintiff – Appellant,

versus

MENTOR WORLDWIDE LLC,
MENTOR CORPORATION,

Defendants – Appellees.

Appeals from the United States District Court
for the Middle District of Georgia

(October 8, 2019)

Before TJOFLAT and JULIE CARNES, Circuit Judges, and KAPLAN,* District Judge.

KAPLAN, District Judge:

Teresa Taylor here sues Mentor Worldwide LLC (“Mentor”) and Mentor Corporation¹ for compensatory and punitive damages for injuries she suffered as a result of the surgical implantation of a polypropylene mesh sling manufactured by Mentor to treat her stress urinary incontinence. The jury found Mentor liable to Taylor for failure to warn both before and after implantation, defective design, and negligence. It awarded \$400,000 in compensatory and \$4 million in punitive

* The Honorable Lewis A. Kaplan, of the United States District Court for the Southern District of New York, sitting by designation.

¹ Mentor Corporation merged into Mentor Worldwide LLC and consequently ceased to exist prior to the filing of the complaint.

damages. Mentor moved for judgment as a matter of law or, in the alternative, for a new trial or to reduce the punitive damages award. The district court upheld the jury's verdict with respect to liability and compensatory damages, but concluded that the punitive damages award exceeded Florida's statutory cap and consequently reduced the punitive damages award to \$2 million.

Mentor now appeals. It contends that it is entitled to judgment as a matter of law because the district court erred in (1) receiving certain expert testimony on the issue of specific causation and (2) applying an incorrect causation standard to Taylor's failure to warn claims. Mentor argues, in the alternative, that it is entitled to a new trial on the basis of various evidentiary rulings by the district court or to an amended judgment eliminating or further reducing the punitive damages award. Taylor cross appeals, arguing that the district court erred in reducing the punitive damages awarded by the jury. We find no error in the judgment and therefore affirm.

I. BACKGROUND

This is one of more than 800 cases that were consolidated by the Judicial Panel on Multidistrict Litigation into the multidistrict proceeding known as *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, No. 4:08-MD-2004 (CDL). The cases arise from claims of medical complications allegedly associated with a polypropylene mesh sling manufactured by Mentor called ObTape.

One such case, brought by Taylor, who was surgically implanted with ObTape in 2004 to treat stress urinary incontinence, was selected to go to trial as a bellwether.

Taylor claimed defective design, negligence, and failure to warn both before and after implantation of the ObTape. She contended that her ObTape implant caused her to suffer from a thinning of her urethral wall and from chronic bladder inflammation (also called cystitis). At trial, she endeavored to prove that her injuries resulted from two design defects in the ObTape, namely, a small pore size, which allegedly did not allow adequate tissue ingrowth, and an alleged propensity to degrade and shed polypropylene particles in the body. She relied at trial on several expert witnesses to establish both general causation – that is, that ObTape was capable of causing the types of injuries from which she suffered – and specific causation – that is, that the ObTape implanted in her in fact caused her injuries.

We begin with an overview of the evidence offered and objections made at trial to the extent such evidence and objections are relevant on appeal.

A. General Causation

1. Porosity of ObTape

Several witnesses testified, in their respective expert opinions, that ObTape's small pore size did not allow adequate tissue ingrowth, which in turn led to inflammation, erosion, and infection.

One such witness was Dr. William Hyman, a professor emeritus of biomedical engineering at Texas A&M University. Dr. Hyman testified that large pores are better than small pores in a mesh sling implant such as ObTape. He explained that the goal is for the tissue to grow into the implant and to “stabilize it and hold it in place” in order to prevent the implant from “moving relative to the tissue.” According to Dr. Hyman, if an implant has “big holes and relatively little material,” the “[t]issue can grow through the holes, find other tissue on the other side, and anchor it all in place, and that helps control erosion.”² He testified also about the ObTape sling in particular and opined that it had a “uniquely bad” design in part because it had a small pore size as well as smaller numbers of pores. In other words, according to Dr. Hyman, the small pore size of ObTape prevented adequate tissue ingrowth, which then permitted the ObTape to move around the implant area and cause erosion.³

Dr. Andrew Siegel, a urologist, testified along similar lines, saying that, in his experience with his patients, ObTape “didn’t develop the typical tissue ingrowth and incorporation that [he] had come to expect with some of the previous generation

² Dr. Hyman explained that erosion occurred when tissue was “essentially . . . rubbed through by [a] foreign object.”

³ He explained also that the small pores in ObTape trapped bacteria and prevented the body from fighting infection.

sling materials” and that the implant’s pores were not big enough to allow adequate tissue ingrowth.

2. Tendency to Degrade

Dr. Ahmed El-Ghannam, a professor of biomaterials at the University of North Carolina, testified on the degradation theory. He said that he had conducted a series of scientific experiments on ObTape, including an electron microscope examination of the product after immersing it in a physiological solution, a Fourier Transform Infrared Spectroscopy, a gas chromatography/mass spectrometry analysis of a physiological solution after the ObTape had been immersed in it, a differential scanning calorimetry, and an x-ray diffraction analysis. Each analysis, he said, confirmed that ObTape, although intended to be an inert, permanent material, had a propensity to degrade and shed polypropylene particles in the body. He testified that this degradation and shedding of particles sparked a reaction by the body’s immune system, causing the body continuously to release hydrogen peroxide – a strongly acidic fluid – in order to destroy the implant. The response by the body’s immune system caused tissue inflammation, erosion of tissue and, in some cases, infection. If the ObTape were inert, he testified, it still would stimulate the body’s immune system, but because of the size of the sling, the body would form a fibrous capsule around the implant to encase it which, in turn, would cause the immune system to stop attacking the foreign object.

Dr. El-Ghannam testified further that it was not a matter of *whether* degradation would occur, but *when*. He opined that any patient implanted with ObTape would suffer the effects of degradation because, after an initial incubation period during which the rate of degradation would be slow, the rate of degradation would increase dramatically, necessitating the removal of the ObTape.

B. Specific Causation

On the question of specific causation, Taylor proffered Dr. William Porter, a urogynecologist, as an expert witness to show that ObTape in fact caused the chronic inflammation and pain she claimed to have suffered. In order to explain the significance of Dr. Porter's testimony at trial, it is useful first to explain the opinions given in both his expert report and deposition.

Taylor disclosed Dr. Porter as a causation expert and provided an expert report prior to trial as required by Rule 26. In his Rule 26 report, Dr. Porter opined "to a reasonable degree of medical and scientific probability that [Taylor's] injuries were caused by complications attributable to the Mentor ObTape product at issue in this case." In support of that opinion, he noted that medical literature indicated the ObTape had a higher incidence of erosion than did other such slings. Moreover, that same literature revealed that ObTape had a smaller pore size than did competing products, which increased the likelihood of infection. Dr. Porter noted that

complications generally associated with implantation of ObTape included, among other things, “chronic inflammation of tissue” and “erosion of mesh into tissues.” The resulting injuries included vaginal and pelvic pain, inflammation, and bladder problems.

In summary, the report indicated that Dr. Porter had concluded, based on his physical examination of Taylor and a review of her medical records, that she suffered pain and chronic inflammation that was primarily attributable to ObTape’s small pore size and to a “tightening/contraction” process that resulted from ObTape’s faulty design. Dr. Porter reached his conclusion that ObTape was the culprit largely through a process of elimination. He considered other possible causes for Taylor’s maladies but, upon examining her, was largely “able to rule out these other potential causes (except Arias Sling)” because Taylor’s symptoms started after placement of the ObTape. He therefore concluded “within a reasonable degree of medical certainty, that the most likely cause of her . . . chronic inflammation is the ObTape.”

In his deposition, Dr. Porter expressed less confidence in the opinions described above. In response to questions by defense counsel, he conceded that none of Taylor’s medical records showed an erosion of her ObTape. He conceded also that there could be causes other than ObTape for Taylor’s chronic bladder inflammation. Indeed, at one point in his deposition, Dr. Porter stated that he could not say “to a reasonable degree of medical probability” that her ObTape caused her

chronic inflammation. Further, Dr. Porter expressed skepticism about Dr. El-Ghannam's degradation theory.

At trial, Taylor's counsel asked Dr. Porter to assume that ObTape does degrade, as Dr. El-Ghannam had opined and testified. Mentor objected that the assumption would pose an improper hypothetical, but the district court overruled the objection. It ruled that Dr. Porter could answer questions based on the assumption he had been asked to make and that the jury ultimately could decide whether to credit Dr. El-Ghannam's degradation theory. Assuming Dr. El-Ghannam's theory was valid, and based also on the absence of anything else in Taylor's medical history that could explain her chronic bladder inflammation, Dr. Porter testified that the inflammation of her bladder most likely was caused by ObTape.

Later in his trial testimony, Dr. Porter stated his opinion that ObTape caused a thinning of Taylor's urethral tissue, which he described as an "erosion" of the urethra. Dr. Porter had not opined on Taylor's urethral thinning in his report or deposition, but he had noted that her medical history indicated that her urethra had thinned near the site of the ObTape and that relevant literature had indicated a greater incidence of erosion of the mesh into tissues and of bladder problems as a result of using ObTape. Dr. Porter conceded that his opinions had "evolved and changed" in this respect as a result of his having gone over Taylor's medical records "with a fine-

tooth comb” and answering some of the questions Taylor’s attorneys had posed to him after his deposition.

At the conclusion of Dr. Porter’s direct examination, Mentor moved to strike his testimony. It argued that the opinions offered by Dr. Porter at trial were not disclosed in his Rule 26 report and that they differed from his deposition testimony. Specifically, Mentor noted that Dr. Porter had said during his deposition that he didn’t believe in degradation. In addition, Mentor pointed out that Dr. Porter never had mentioned “urethral erosion” prior to trial and that he had said in his deposition that Taylor’s bladder inflammation was not caused by ObTape. It stated also that if the court were unwilling to strike the testimony, counsel would like an overnight continuance to prepare its cross-examination of Dr. Porter. It never asked for a mistrial.

The district court denied Mentor’s motion to strike Dr. Porter’s testimony, but granted the alternative relief it requested: the opportunity to prepare overnight for Dr. Porter’s cross-examination. Defense counsel cross-examined Dr. Porter the following day. Mentor’s attorney pointed out the inconsistencies between the doctor’s deposition testimony and his trial testimony and probed also the urethral erosion issue. Specifically, in response to Mentor’s questions, Dr. Porter admitted that he could not rule out the surgical injection of Durasphere as a potential cause of Taylor’s urethral thinning and acknowledged that the surgeon who actually had

observed Taylor's urethra had opined that it was the Durasphere that caused this problem.

Notably, in his Rule 26 report, his deposition, and his trial testimony, Dr. Porter based his conclusion that the ObTape had caused Taylor's injuries on the fact that he had ruled out all other potential causes. On cross, however, Mentor was able to elicit a concession from the doctor that not only was Durasphere a possible culprit, but also that there were other possible causes, including Taylor's hysterectomy and corresponding post-menopausal state as well as the subsequent surgical insertion of an Aris sling.

Mentor's counsel also elicited from Dr. Porter an admission that he had not personally seen any evidence to support Dr. El-Ghannam's degradation theory. Dr. Porter even stated that he did not believe in the theory that the mesh sling shed polypropylene particles. More than that, defense counsel prompted Dr. Porter to admit that he himself had inserted into hundreds of patients non-ObTape mesh-type slings that Dr. El-Ghannam likewise had decried as degradable: an admission that suggested that Dr. Porter remained skeptical of the theory.

Mentor renewed its motion to strike Dr. Porter's testimony, arguing that the opportunity to prepare for cross overnight had failed to alleviate the prejudice resulting from Dr. Porter's previously undisclosed opinions. The district court

denied the motion, concluding that Mentor had done “a fine job in that cross-examination” such that it was “clear . . . there was no prejudice.”

C. The Jury Verdict

At the conclusion of the nine-day trial, Mentor moved pursuant to Rule 50(a) of the Federal Rules of Civil Procedure for judgment as a matter of law. The district court reserved. The jury then returned a verdict with the following specific findings:

1. The ObTape implanted in Taylor had a design defect that was a legal cause of her injuries.
2. Mentor failed to provide Taylor’s physician with an adequate warning about ObTape prior to her implant surgery, and the failure to provide that adequate pre-implant warning was a legal cause of Taylor’s injuries.
3. Mentor failed to provide Taylor’s physician with an adequate warning about ObTape after her implantation surgery, and the failure to provide that adequate post-implant warning was a legal cause of the injuries.
4. Mentor was negligent with respect to the ObTape used in Taylor’s implantation surgery, and that negligence was a legal cause of her injuries.
5. Taylor proved by clear and convincing evidence that punitive damages should be awarded against Mentor; that Mentor had a specific intent to harm her at the time of Taylor’s injuries and did in fact harm her; and that

Mentor was motivated solely by unreasonable financial gain and actually knew about both the unreasonable danger of the conduct and the high likelihood of injury resulting from the conduct.

The jury awarded Taylor \$400,000 in compensatory and \$4 million in punitive damages.

D. Mentor's Post-Trial Motions

Following trial, Mentor renewed its motion for judgment as a matter of law under Rule 50(b) and moved in the alternative for a new trial under Rule 59 or to amend the judgment to reduce the punitive damage award to no more than \$1.2 million.

The district court issued a thorough opinion in which it denied Mentor's motions for judgment as a matter of law and for a new trial but reduced the punitive damage award to \$2 million (and thus the total judgment to \$2.4 million) after concluding that the evidence at trial was insufficient to support the jury's finding that Mentor had the requisite "specific intent." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004 (CDL), 4:12-cv-176 (Taylor), 2016 WL 6138253 (M.D. Ga. Oct. 20, 2016).

Mentor and Taylor each appealed. Mentor argues that it is entitled to:

(1) Judgment as a matter of law both because the district court (A) erred in failing to strike Dr. Porter's testimony insofar as it expressed previously undisclosed opinions, and (B) applied an incorrect causation standard to Taylor's failure to warn claims;

(2) A new trial because the district court erred in:

A. admitting (i) testimony by Dr. El-Ghannam on degradation theory absent evidence of the dose-response relationship, (ii) evidence of vaginal erosion injuries experienced by other women who were implanted with ObTape, (iii) evidence of Mentor's decision to take ObTape off the market in violation of the district court's *in limine* ruling and remedying that violation with a curative instruction, and (iv) evidence of foreign regulatory action related to ObTape, and

B. excluding evidence of the Food and Drug Administration's 510(k) clearance of ObTape; and

(3) An amended judgment eliminating the punitive damage award or reducing it pursuant to Florida statutory limits.

Taylor argues that the jury verdict of \$4 million should be reinstated because the district court erred in concluding that the evidence offered at trial was insufficient to support the jury's finding that Mentor had a specific intent to harm her.

II. DISCUSSION

A. Motion for Judgment as a Matter of Law

We review *de novo* a district court's ruling on a motion for judgment as a matter of law, considering the evidence and the reasonable inferences drawn therefrom in the light most favorable to the non-moving party. *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304, 1313 (11th Cir. 2017) (citing *Middlebrooks v. Hillcrest Foods, Inc.*, 256 F.3d 1241, 1246 (11th Cir. 2001)). Judgment as a matter of law is "appropriate only if the evidence is so overwhelmingly in favor of the moving party that a reasonable jury could not arrive at a contrary verdict." *Id.* (quoting *Middlebrooks*, 256 F.3d at 1246) (internal quotation marks omitted). A district court's evidentiary rulings, however, are reviewed "only for a clear abuse of discretion" and must be affirmed "unless we find that the district court has made a clear error of judgment, or has applied the wrong legal standard." *Id.* (quoting *United States v. Brannan*, 562 F.3d 1300, 1306 (11th Cir. 2009)) (internal quotation marks omitted).

Mentor asserts that it is entitled to judgment as a matter of law or, alternatively, to a new trial because the district court failed to strike Dr. Porter's testimony to the extent he offered opinions at trial that had not been disclosed in his Rule 26 report. Notably, Mentor does not argue that it was entitled to judgment as

a matter of law if the testimony properly was admitted. Because Mentor's motion is based entirely on the district court's evidentiary ruling, we review for abuse of discretion.⁴

Mentor's argument is based on Rule 26 of the Federal Rules of Civil Procedure, pursuant to which parties are obliged for any expert witness they plan to call at trial to provide a written report containing, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Rule 26 imposes a duty to supplement an expert report that is "incomplete or incorrect." Fed. R. Civ. P. 26(e). Mentor argues that Taylor violated this duty with respect to Dr. Porter because of the inconsistencies between his trial testimony and his Rule 26 report.

⁴ We assume without deciding that Mentor properly preserved its objection to the admission of Dr. Porter's testimony. Rule 103(a) of the Federal Rules of Evidence provides:

"A party may claim error in a ruling to admit . . . evidence only if the error affects a substantial right of the party and . . . a party, on the record: (A) timely objects or moves to strike; and (B) states the specific ground, unless it was apparent from the context . . ."

Fed. R. Evid. 103(a); *see also United States v. Hawkins*, 905 F.2d 1489, 1493 (11th Cir. 1990) ("A defendant must specifically and timely object at trial to claimed errors.").

Mentor's only objections during the course of Dr. Porter's testimony were with respect to his testimony that, based on the assumption that the polypropylene degrades, Taylor's inflammation was caused by the ObTape. When that question initially was posed to Dr. Porter, Mentor objected first on the ground that the question was an improper hypothetical and then on the ground that Dr. Porter was "just taking the assumption to now a medical diagnosis from a materials man." The question of a deviation from Dr. Porter's expert report was not raised until after the direct examination was completed, when Mentor first moved to strike. While it might be argued that Mentor waived the point by failing to timely and specifically object, we need not reach this question because we conclude that the district court did not abuse its discretion in admitting Dr. Porter's testimony.

We hold that the district court did not abuse its discretion in not striking Dr. Porter's testimony.

As an initial matter, we note that the only true inconsistency between Dr. Porter's Rule 26 report and his trial testimony had to do with the "urethral erosion" issue. Although Dr. Porter expressed doubt about Dr. El-Ghannam's degradation theory during his deposition, it was not inconsistent either with Dr. Porter's Rule 26 report or with his deposition testimony for him to (a) assume that Dr. El-Ghannam's theory was valid and then (b) respond to a hypothetical question based on that assumption. Further, Dr. Porter clearly opined in his Rule 26 report that ObTape caused or at least contributed to Taylor's chronic bladder inflammation. His deposition testimony on that point was more equivocal, offering a prime opportunity for impeachment at trial. But Dr. Porter's trial testimony as to causation was not inconsistent with his Rule 26 report, which was the basis for Mentor's motion to strike.

As to the urethral erosion issue, we have no doubt that Dr. Porter's Rule 26 report should have been supplemented prior to trial to flesh out his "evolved" opinion on that issue. We do not condone Taylor's conduct in failing to make that

required disclosure. But striking Dr. Porter's testimony was not the only viable response under the circumstances.⁵

Rule 37 gives a trial court discretion to decide how best to respond to a litigant's failure to make a required disclosure under Rule 26. *See* Fed. R. Civ. P. 37(c)(1) (stating that "[i]n addition to or instead of [the] sanction [of exclusion]" the court may: (1) order payment of the expenses caused by the failure, (2) "inform the jury of the party's failure," and (3) "impose other appropriate sanctions"). The district court's decision to allow Mentor additional time to prepare for Dr. Porter's cross-examination, rather than striking his testimony entirely, was not an abuse of that discretion.

An abuse of discretion occurs only when the district court relies on a clearly erroneous finding of fact or an errant conclusion of law, or improperly applies the law to the facts. *Adams v. Austal U.S.A., LLC*, 754 F.3d 1240, 1248 (11th Cir. 2014). The district judge here correctly stated and properly applied the governing legal principles. His decision on the motion to strike was based on his factual finding that

⁵ We acknowledge our dissenting brother's concern with the possibility that failing to make the required disclosure was part of a deliberate strategy to employ "ambush tactics" at trial. In fact, the dissent goes so far as to say that "Porter's reversal was almost certainly fraudulent—and Taylor's counsel helped to induce it." Dis. Op. at Part II.B. The district court, however, made no such finding, and it is not for us so to determine in the first instance. The district court acted well within the bounds of its discretion by analyzing the specific Rule 26 violation at issue—and to the extent necessary for its harmlessness analysis, the motivations for such violation—and determining that exclusion was not warranted in this instance. We do not agree that our failure to upset the trial judge's permissible exercise of discretion in this respect "invites the procedural abuse that [Rule 37(c)(1)] is meant to discourage."

the nondisclosure at issue was “harmless” given the additional time Mentor had to prepare for Dr. Porter’s cross-examination.⁶ *In re Mentor Corp.*, 2016 WL 6138253, at *6 n.3. That finding was not clearly erroneous. Again, the only previously undisclosed part of Dr. Porter’s opinion was his statement that Taylor had a “urethral erosion” – a term that he clarified in his cross-examination referred to a “thinning” of her urethral tissues. Any unfair surprise as to that issue was minimal because “erosion” generally was a topic of extensive pretrial discovery and Dr. Porter specifically disclosed in his Rule 26 report his belief that ObTape could cause “erosion of mesh into tissues or organs.”⁷ Further, Dr. Porter indicated in his Rule

⁶ The district court’s use of the word “prejudice” rather than “harmless” does not warrant a different result. Mentor points to the district court’s conclusion during trial that because Mentor had additional time to prepare and then conducted a “Clarence Darrow”-like cross examination of Dr. Porter, “[i]t was clear . . . there was no prejudice.” Mentor maintains that the district court applied the wrong legal standard – prejudice rather than harmlessness – and thereby abused its discretion. This argument is unavailing. As an initial matter, the district court in fact tracked the language of Rule 37 in its post-trial order, concluding that any failure to disclose by Taylor was “harmless” given Mentor’s receipt of extra time and effective cross examination. *In re Mentor Corp.*, 2016 WL 6138253, at *6 n.3. In any event, we do not find that the district court applied the wrong standard at trial. We have said in the past that the importance of compliance with the disclosure rules in Rule 26 is grounded in the need “to allow both sides in a case to prepare their cases adequately and to prevent surprise.” *Reese v. Herbert*, 527 F.3d 1253, 1266 (11th Cir. 2008) (internal quotation marks and citations omitted). The district court’s decision to resolve the Rule 26 disclosure issue by giving Mentor additional time to prepare for Dr. Porter’s cross-examination reflects the court’s intention to protect precisely those interests that Rules 26 and 37 were designed to protect.

⁷ Greater concern perhaps would have been warranted if Dr. Porter’s trial testimony had involved a new and more elaborate, fleshed-out explanation of reasons why one reasonably could conclude that ObTape caused Taylor’s bladder injuries. Had it done so, defense counsel would have been at a much greater disadvantage in cross-examining him.

Nor is the Court persuaded by Mentor’s reliance on *Tenbarge v. Ames Taping Tool Systems, Inc.*, 190 F.3d 862 (8th Cir. 1999), an Eighth Circuit product liability case in which the Circuit held that a new trial was warranted after an expert witness for the defense testified to previously undisclosed opinions on the cause of the plaintiff’s injuries. *Id.* at 864-65. Even if *Tenbarge* were binding on

26 report that Taylor's medical history showed that her urethra was very thin where the ObTape had been removed that he had found during his own examination that Taylor had "an irregular trapezoid shape mesh along the urethra. It feels that the edges have rolled." This description was suggestive of an injury to the urethral tissues posited by Dr. Porter to have been caused by ObTape.

We conclude that the trial court acted well within the bounds of its discretion in allowing the jury to consider Dr. Porter's testimony relating to specific causation. Mentor was not entitled to judgment as a matter of law.⁸

this Court, the district court there denied the plaintiff's request for additional time to further depose the expert witness. Here, Mentor did not ask for additional time to depose Dr. Porter. Rather, it asked for an overnight continuance to prepare for cross-examination, and that request was granted.

⁸ Mentor argues also that it was entitled to judgment as a matter of law because Taylor failed to present enough evidence for the jury to conclude that she suffered injuries as a result of Mentor's failure to warn either before or after implantation of the increased risks of erosion and infection associated with ObTape. There is some disagreement between the parties as to whether the verdict form provided to the jury was a general verdict or a special verdict under Rule 49 of the Federal Rules of Civil Procedure. Were it necessary to resolve this question, it might warrant close consideration. *See Mason v. Ford Motor Co., Inc.*, 307 F.3d 1271, 1274-75 (11th Cir. 2002). But the point is immaterial. The verdict form asked the jury to determine whether each of a design defect, negligence, or pre- or post-failure to warn was a legal cause of Taylor's injuries. The form then asked the jury, in the event that it found that *any* of the four was a legal cause of Taylor's injuries, to determine the appropriate amount of compensatory damages. It follows from our conclusion that Dr. Porter's testimony was properly considered by the jury that Mentor is not entitled to judgment as a matter of law with respect to Taylor's design defect and negligence theories of recovery. Accordingly, we need not reach Mentor's arguments related to recovery under a failure-to-warn theory. *See Stewart & Stevenson Servs., Inc. v. Pickard*, 749 F.2d 635, 644-45 (11th Cir. 1984); *King v. Ford Motor Co.*, 597 F.2d 436, 439 (11th Cir. 1979).

B. Motion for a New Trial

“We review the denial of a motion for a new trial only for an abuse of discretion.” *Walter Int’l Prods., Inc. v. Salinas*, 650 F.3d 1402, 1407 (11th Cir. 2011) (citing *St. Luke’s Cataract & Laser Inst., P.A. v. Sanderson*, 573 F.3d 1186, 1201 n.16 (11th Cir. 2009)). “Deference “is particularly appropriate where a new trial is denied and the jury’s verdict is left undisturbed.”” *Id.* (quoting *St. Luke’s*, 573 F.3d at 1201 n.16 (quoting *Rosenfield v. Wellington Leisure Prods., Inc.*, 827 F.2d 1493, 1498 (11th Cir. 1987))). A trial court’s decisions regarding the admissibility and reliability of expert testimony also are reviewed for abuse of discretion, *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S.136, 141-43 (1997)), and will only be reversed if they are “manifestly erroneous.” *Id.* (quoting *Joiner*, 522 U.S. at 142) (internal quotation marks omitted); see also *United States v. Brown*, 415 F.3d 1257, 1264-66 (11th Cir. 2005).

Mentor argues, pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), that it is entitled to a new trial because the district court abused its discretion in admitting the general causation testimony given by Dr. El-Ghannam.⁹ It asserts that Dr. El-Ghannam’s testimony on the degradation and shedding of the ObTape mirrors testimony on substance toxicity and that it therefore

⁹ Mentor properly preserved this objection at trial.

was necessary for Dr. El-Ghannam to address the “dose-response relationship” – that is, how much of the substance was necessary to create a risk of harm to Taylor.

Mentor relies entirely on a group of toxic tort cases involving allegedly toxic drugs and chemicals. In particular, Mentor concentrates its attention on an analogy to *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005), a toxic tort case involving a weight loss supplement called Metabolife 356. In *McClain*, we reversed a jury verdict and remanded against Metabolife after concluding that the district court erroneously had admitted the plaintiffs’ expert testimony on causation. The plaintiffs there alleged that the supplement, which contained ephedrine and caffeine, caused them to suffer from heart attacks and strokes. In such cases, given the “importance of individual responses to toxins,” a plaintiff must demonstrate both the level of exposure to the allegedly harmful chemical that is hazardous to a human being and the amount of the chemical to which the plaintiff was exposed. *Id.* at 1241-42 (citations omitted).¹⁰ The evidence at trial was sufficient to find that ephedrine – and specifically the amount of ephedrine in Metabolife 356 – was found in hundreds of over-the-counter products then available to the public. In addition,

¹⁰ The rationale behind this methodology is that in the case of a toxic chemical, “[o]ften ‘low dose exposures – even for many years – will have no consequence at all, since the body is often able to completely detoxify low doses before they do any damage.’” *McClain*, 401 F.3d at 1242 (quoting David L. Eaton, *Scientific Judgment & Toxic Torts – A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & POL’Y 1, 13 (2003)). Moreover, “‘for most types of dose-response relationships following chronic (repeated) exposure, thresholds exist, such that there is some dose below which even repeated, long-term exposure would not cause an effect in any individual.’” *Id.* (quoting Eaton, *supra*, at 16).

one of the expert witnesses at trial testified that the effects of the supplement would “vary from patient to patient” and in fact might not be harmful at all. This evidence signaled that the dose-response relationship was particularly relevant in the case of Metabolife 356. *Id.* at 1241. We therefore concluded that the expert witnesses’ failure to opine on the dose of Metabolife 356 required to injure someone was fatal in the face of a *Daubert* challenge. *Id.* at 1241, 1252.

The case before us is markedly different. The dose-response relationship is not implicated here. The logic of *McClain* therefore is not transferrable to this case. In *McClain*, the missing piece – among others – was how much ephedrine and caffeine were required to start a chain reaction leading to a stroke or heart attack. That piece was important because there evidently was a level of ephedrine and caffeine that a person could consume safely. But in this case, Dr. El-Ghannam 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.

We are not persuaded that Dr. El-Ghannam’s testimony about “an incubation period” warrants a different result. His testimony was not that the ObTape would not cause inflammation or other harm to the patient during such incubation period. Rather, he testified that the injuries would take a longer period of time to manifest.

But it was only a matter of time – a question of *when*, not *whether*, the patient would suffer harm from the ObTape. As he opined, in any patient, “degradation at one point would cause the infection, the degradation at one point would cause the erosion, the degradation at one point would cause the failure of the implant.” In this case, which is focused on the physiological response to a design defect in a medical device, the dose-response relation is not implicated¹¹ and there was no abuse of discretion in admitting the testimony.

We have considered Mentor’s remaining evidentiary challenges and conclude that the district court at no point exceeded the bounds of its discretion. Mentor therefore was not entitled to a new trial.

¹¹ The only case involving a medical device to which Mentor points is *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329 (11th Cir. 2010). There, we affirmed the district court’s dismissal of negligence and product liability claims related to the use of a pain pump that had been inserted into the patient’s shoulder and administered bupivacaine, an anesthetic, intra-articularly. The plaintiff had offered expert testimony that the use of pain pumps to administer bupivacaine intra-articularly could cause glenohumeral chondrolysis (a complete breakdown of cartilage in the shoulder joint), *id.* at 1336, but the expert based his conclusion on literature that was insufficient to satisfy the reliability threshold of *Daubert*. *Id.* at 1337-41. There we highlighted one study upon which the expert purportedly had relied, which had examined the connection between the use of intra-articular pain pumps, bupivacaine, and chondrolysis in rabbit cartilage, and concluded that the study could not support the expert’s opinion as to causation. We so concluded because the study acknowledged that no data existed as to the impact of intra-articular administration of bupivacaine on human cartilage and that the study could not explain the possible differences in dose-response relationship between rabbits and humans. *Id.* at 1338-39. Although the pain pump indeed was a medical device, the need for testimony on the dose-response relationship followed from the plaintiff’s causation theory that his injuries were caused by a certain method of administering a certain chemical – not by the physical design of the pain pump itself.

C. Punitive Damages

Finally, the parties dispute the propriety of the punitive damages awarded in this case. The jury found that Taylor proved by clear and convincing evidence that punitive damages should be awarded against Mentor; that at the time of Taylor's injuries, Mentor had a specific intent to harm her and did in fact harm her; and that Mentor was motivated solely by unreasonable financial gain and actually knew about both the unreasonable danger of the conduct and the high likelihood of injury resulting from the conduct. It then awarded her \$4 million in punitive damages. On Mentor's motion, the district court reduced the punitive damages award to \$2 million, concluding that the evidence presented at trial was insufficient for the jury to conclude that Mentor acted with specific intent to harm.

Mentor argues that the evidence at trial was insufficient to warrant any punitive damage award and Taylor challenges the district court's reduction. We review the propriety of punitive damages *de novo*. *Myers v. Cent. Fla. Invs., Inc.*, 592 F.3d 1201, 1212 (11th Cir. 2010).

Under Florida law, “[a] defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence.” Fla. Stat. § 768.72(2). The statute defines the terms as follows:

“‘Intentional misconduct’ means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability

that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage. . . .

“‘Gross negligence’ means that the defendant’s conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.”

Id. § 768.72(2)(a)-(b).

Florida imposes also various statutory caps on punitive damages. Punitive damages may not exceed the greater of three times the amount of compensatory damages or \$500,000, except that (1) punitive damages may not exceed the greater of four times the amount of compensatory damages or \$2 million if “the fact finder determines that the wrongful conduct proven under this section was motivated solely by unreasonable financial gain and determines that the unreasonably dangerous nature of the conduct, together with the high likelihood of injury resulting from the conduct, was actually known by the managing agent, director, officer, or other person responsible for making policy decisions on behalf of the defendant” and (2) there is no cap on punitive damages if “the fact finder determines that at the time of injury the defendant had a specific intent to harm the claimant and determines that the defendant’s conduct did in fact harm the claimant.” *Id.* § 768.73(1).

1. Availability of Punitive Damages

The district court concluded that Taylor “presented sufficient evidence for a jury to find, based on clear and convincing evidence, that Mentor was grossly

negligent with regard to the risks of ObTape – both its porosity and its propensity to degrade.” *In re Mentor Corp.*, 2016 WL 6138253, at *11. We agree.

We are not persuaded by Mentor’s argument that the jury improperly considered “[e]vidence of erosions and infections purportedly experienced by others through different causal mechanisms” in awarding punitive damages.¹² Mentor contends that because Taylor suffered from a thinning of her urethral wall, the evidence at trial pertaining to women who had suffered from vaginal erosion purportedly because of ObTape’s small pore size could not serve as a proper basis for punitive damages.

We conclude that this distinction is immaterial. The evidence at trial was sufficient for the jury to find that the pores in ObTape were too small to allow adequate tissue ingrowth, which in turn permitted the implant to move around and rub against the nearby tissue until that tissue eroded. From Dr. Hyman’s testimony, it would have been reasonable to conclude that the movement of the ObTape could have eroded any nearby tissue – whether vaginal or urethral. We agree with the

¹² It is true that the “Constitution’s Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties or those whom they directly represent.” *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007). Nor may a jury “base its award upon ‘dissimilar’ acts of a defendant.” *Id.* at 356 (citation omitted); *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003). But “[e]vidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public and so was particularly reprehensible.” *Philip Morris USA*, 549 U.S. at 355; *see also id.* at 357. It is the burden of the district court to prevent “unreasonable and unnecessary risk” of jury confusion in this regard. *Id.* at 357.

district court that the evidence presented at trial permitted a reasonable juror to conclude that Taylor, who suffered from a thinning of her urethral wall, had “an erosion-type movement of the ObTape through her bodily tissue, even though it did not become completely exposed.” *In re Mentor Corp.*, 2016 WL 6138253, at *6. Accordingly, the evidence permitted the inference that poor tissue ingrowth in fact caused the thinning of Taylor’s urethral wall and therefore that vaginal erosion and the thinning of her urethral wall resulted from the same design defect in the porosity of the ObTape. Accordingly, the district court did not err in admitting evidence of vaginal erosion experienced by other women who had been implanted with ObTape.

Having dispensed with Mentor’s evidentiary argument, we see no reason to disturb the jury’s finding that Mentor’s conduct warranted punitive damages. Indeed, Mentor does not present any arguments to the contrary. The district court set forth an extensive overview of evidence in the record that permitted a reasonable juror to conclude that Mentor (1) did not conduct sufficient product testing, including tests as to degradation despite it being well known that heat and pressure cause polypropylene to degrade, (2) knew of the relatively high rate of complications associated with ObTape but nonetheless concealed or materially understated those risks, and (3) ignored warnings from both Mentor employees and physicians outside of the company. *Id.* at *11-12. We conclude that the record was sufficient to authorize punitive damages under Florida law.

2. Unreasonable Financial Gain & Actual Knowledge

Mentor next argues that punitive damages should have been remitted to \$1.2 million (three times the compensatory damage award) because the evidence was insufficient to show that Mentor’s wrongful conduct was “motivated solely by unreasonable financial gain” or “that the unreasonably dangerous nature of the conduct, together with the high likelihood of injury resulting from the conduct, was actually known” by the relevant decisionmakers at Mentor.

On appeal, Mentor states that “the district court did not, and cannot, identify any evidence that the alleged flaws in Mentor’s manufacturing process that purportedly caused ObTape to degrade were motivated purely by unreasonable financial gain.” But the district court had no opportunity to do so because Mentor raises the question for the first time on appeal. Before the district court, Mentor argued only that Taylor had “introduced no evidence at trial that, at the time of her implant, anyone at Mentor – let alone anyone with policy-making authority – was aware of any injuries experienced due to alleged flaws in ObTape’s manufacturing process that cause degradation and polypropylene particle-shedding.”

“As a general matter, ‘issue[s] not raised in the district court and raised for the first time in an appeal will not be considered by this [C]ourt.’” *Cita Trust Co. AG v. Fifth Third Bank*, 879 F.3d 1151, 1156 (11th Cir. 2018) (quoting *Access Now, Inc.*

v. Sw. Airlines Co., 385 F.3d 1324, 1331 (11th Cir. 2004)) (alteration in *Cita Trust*).¹³

Accordingly, the point is deemed to have been abandoned. In any event, we note that after Taylor made this argument in her response brief on appeal, Mentor did not revisit the question in its reply brief. We take this to be a concession that Mentor indeed waived the issue of whether Mentor's conduct was "motivated solely by unreasonable financial gain."

On the question of actual knowledge, the district court held that "a jury could conclude that ObTape had a higher risk of erosion and infection than similar mesh products due to its physical characteristics, including its porosity" and that "Mentor executives knew about the risks but decided not to disclose them to anyone so that Mentor could continue selling ObTape." *In re Mentor Corp.*, 2016 WL 6138253, at *13.

¹³ We have permitted issues to be raised for the first time on appeal in five circumstances, namely:

"First, an appellate court will consider an issue not raised in the district court if it involves a pure question of law, and if refusal to consider it would result in a miscarriage of justice. Second, the rule may be relaxed where the appellant raises an objection to an order which he had no opportunity to raise at the district court level. Third, the rule does not bar consideration by the appellate court in the first instance where the interest of substantial justice is at stake. Fourth, a federal appellate court is justified in resolving an issue not passed on below ... where the proper resolution is beyond any doubt. Finally, it may be appropriate to consider an issue first raised on appeal if that issue presents significant questions of general impact or of great public concern."

Cita Trust Co. AG, 879 F.3d at 1156 (quoting *Access Now, Inc.*, 385 F.3d at 1332). However, none of these circumstances apply to this case.

To the extent that Mentor again argues that the district court erred by focusing on irrelevant evidence of vaginal erosion injuries, that point is rejected for the reasons stated above. Furthermore, the district court's opinion is supported by the extensive evidence at trial that Mentor employees and executives knew that ObTape was associated with serious risks of complications and actively attempted to conceal or understate those risks. For example, after one of Taylor's witnesses, Dr. Michel Cosson, wrote an editorial on the risks associated with ObTape, Mentor decided not to respond to the article because it assessed that doing so "might trigger . . . another article from Cosson, with more solid facts, and details of the . . . ObTape's serious cases." Moreover, in August 2005, two Mentor employees wrote a report on "ObTape Erosion and Infections" in which they detailed the various problems with ObTape – including its propensity to lead to chronic inflammation, its small pore size and the consequent risk of increased rates of erosion and infection, and the fact that it was made out of heat-welded polypropylene – and recommended that Mentor take ObTape off the market. The chief executive officer of Mentor's French division knew about the report, but nonetheless ordered the authors to maintain "full radio silence."

This evidence was sufficient to permit a reasonable juror to conclude that Mentor executives actually knew that ObTape posed serious risks of injury and actively decided to withhold that information from the public.

3. Specific Intent

The final issue on appeal is whether Mentor had “a specific intent to harm the claimant,” in which case Florida law would permit uncapped punitive damages. This is the sole issue on which the district court did not affirm the jury’s findings. Instead, it concluded that the record was insufficient to support a finding of specific intent and reduced the punitive award to \$2 million pursuant to Fla. Stat. § 768.73(1)(b).

The district court concluded that there was no evidence at trial that Mentor had a “specific intent” to harm the women who were implanted with ObTape. With neither party able to find Florida law interpreting “specific intent to harm the claimant,” the court looked to a Georgia case, *Viau v. Fred Dean, Inc.*, 418 S.E.2d 604 (Ga. Ct. App. 1992), in which the Georgia Court of Appeals interpreted a similar, though not identical, “specific intent” provision in Georgia’s punitive damages statute in the context of a drunk driver who had caused a wreck. The statute then read, “if it is found that the defendant acted, or failed to act, with the specific intent to cause harm, there shall be no limitation regarding the amount which may be awarded as punitive damages.” 1987 Ga. Laws 919 (codified at O.C.G.A. § 51-12-5.1(f)). The court in *Viau* relied on the Second Restatement of Torts, which stated that the word “intent” was used “to denote that the actor desires to cause [the] consequences of his act, or that he believes that the consequences are substantially certain to result from it.” *Viau*, 418 S.E.2d at 608 (quoting Restatement (Second) of

Torts § 8A (1965)). It concluded that while the drunk driver’s intent to drink and drive amounted to a “conscious indifference to the consequences of driving while intoxicated,” it did not establish “a specific intent that his driving while intoxicated would cause harm.” *Id.*

Relying on *Viau*, the district court here concluded that the evidence was sufficient for a jury to conclude that Mentor acted with conscious disregard or indifference to the safety of women receiving ObTape implants, but there was no evidence to support a finding that Mentor acted with a specific intent that ObTape would cause harm to the women who were implanted with it. *In re Mentor Corp.*, 2016 WL 6138253, at *14. Taylor challenges that decision on appeal.

We assume without deciding that the district court articulated the proper standard – that is, that a defendant acts with “specific intent to harm” if the defendant acts “with the purpose of producing that consequence” or “knowing that the consequence is substantially certain to result.” *See* Restatement (Third) of Torts: Phys. & Emot. Harm § 1 (2010) (articulating materially identical definition of “intent”). We assume also, again without deciding, that the statutory language “specific intent to harm the claimant” does not limit uncapped awards of punitive damages to cases in which a defendant knew the identity of the claimant and intended specifically to harm that claimant. Rather, we assume that the district court properly evaluated whether the evidence was sufficient to find that Mentor acted

with specific intent to harm “the women who were implanted with ObTape.” *In re Mentor Corp.*, 2016 WL 6138253, at *14.¹⁴

Even under this broad interpretation of the statute, however, we conclude that the evidence at trial was insufficient to support the jury’s finding of specific intent.

Taylor relies on three pieces of evidence. First, she points to evidence that “Mentor executives knew the French Ministry of Health conducted a survey of products and determined ObTape had complication rates five times higher than similar products.” Second, she highlights evidence that “Mentor ‘certainly knew’ that ObTape was causing an abnormally high number of complications.” Third, she points to evidence that “Mentor received a report stating: ‘based on the information explained in detail below, we recommend today that sales of OBTAPE™ be stopped’ and recommending discontinuance due to an increase in the frequency and severity of complications.”

¹⁴ Although we do not reach the question here, we note that the district court’s interpretation is appealing. One could imagine absurd results from a requirement that a defendant know the precise identity of the claimant in advance of causing injury. Indeed Section 1 of the Restatement (Third) of Torts limits tort liability to “situations in which the defendant has knowledge to a substantial certainty that the conduct will bring about harm to a particular victim, or to someone within a small class of potential victims within a localized area.” Restatement (Third) of Torts: Phys. & Emot. Harm § 1 cmt. e (2010); *cf. Lawnwood Med. Ctr. Inc. v. Sadow*, 43 So.3d 710, 725-26 (Fla. Dist. Ct. App. 2010) (describing “specific intent” provision of Florida punitive damages statute as “eliminat[ing] mathematical proportionality with compensatory damages . . . in cases of intentionally malicious harmful misconduct” without emphasizing familiarity with specific claimant). We nevertheless neither endorse the view expressed in the Restatement nor express an opinion on whether a group of end users of the same defective device would constitute a “small class of potential victims within a localized area.”

We conclude that this evidence was not a sufficient basis for a finding of “specific intent to harm.” Florida’s punitive damages statute distinguishes between situations in which “the unreasonably dangerous nature of the conduct, together with the *high likelihood of injury* resulting from the conduct, was *actually known* by the managing agent, director, officer, or other person responsible for making policy decisions on behalf of the defendant” and those in which “at the time of injury the defendant had a *specific intent to harm* the claimant and determines that the defendant’s conduct did in fact harm the claimant.” If this distinction is to have any meaning, the evidence to which Taylor points evinces only a finding that Mentor knew that there was a high likelihood of injury. To be substantially certain that someone will be harmed as a result of wrongful conduct requires a belief much closer to total certainty, in this case, that anyone who used an ObTape would be harmed. Evidence that Mentor knew of a high incidence of injury does not reach this threshold. We therefore affirm the district court’s reduction of the punitive damages award to \$2 million.

III. CONCLUSION

The judgment appealed from is AFFIRMED.

JULIE CARNES, Circuit Judge, concurring specially:

I concur in the decision to uphold the district court’s judgment awarding plaintiff Teresa Taylor compensatory and punitive damages pursuant to the jury’s verdict finding Mentor liable to Taylor for injuries she suffered after she was implanted with ObTape. As to the question that has prompted a dissent—whether the district court should have struck the testimony of one of plaintiff’s experts, Dr. Porter—I write separately to discuss the points raised by Judge Tjoflat.

I share Judge Tjoflat’s chagrin that plaintiff’s counsel failed to alert Mentor prior to trial that Dr. Porter’s opinion as to the cause of Taylor’s injuries had, since his deposition, “evolved” in a way that bolstered the doctor’s conclusion that Mentor’s product had caused Taylor injuries.¹ My dissenting colleague understandably worries that an affirmance here will send a bad signal that counsel can get away with failing to alert the opposing side when an expert witness changes his mind concerning a material matter on which he has been deposed.

If that were what we were holding, it would also give me pause, but my reasons for concurring are much narrower and rest on the particular objection made by defense counsel when it moved to strike. At bottom, I agree with the author of the majority opinion, Judge Kaplan, that the district court did not abuse its

¹ Albeit part of the evolution was a devolution, as Dr. Porter defaulted back to an opinion expressed in his expert report.

discretion when it refused to strike the testimony, but instead granted the alternative remedy specifically requested by Mentor: an overnight continuance to prepare its cross-examination of Dr. Porter. Indeed, so close do I find the legal question to be that the deferential abuse of discretion standard, as applied to the district court's granting of a request by defense counsel for alternative relief, constitutes the tie-breaker for me.

I. Abuse of Discretion Standard

As noted in both the majority and dissenting opinions, our review of the district court's ruling on Mentor's motion to strike Dr. Porter's testimony is governed by the abuse of discretion standard. *See Knight through Kerr v. Miami-Dade Cty.*, 856 F.3d 795, 808 (11th Cir. 2017). Deference to the district court is the hallmark of that standard, which requires us to affirm the denial of Mentor's motion to strike unless the ruling is "based on an error of law" or "reflects a clear error of judgment." *In re Hubbard*, 803 F.3d 1298, 1307 (11th Cir. 2015). Indeed, "our review of evidentiary rulings by trial courts on the admission of expert testimony is very limited," *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002) (internal quotation marks omitted) and we must "defer to the district court's evidentiary ruling unless that ruling is manifestly erroneous." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1340 (11th Cir. 2003) (internal quotation marks omitted). *See also Michigan Millers Mut. Ins. Corp. v.*

Benfield, 140 F.3d 915, 921 (11th Cir. 1998) (“It is very much a matter of discretion with the trial court whether to permit the introduction of [expert] evidence, and we will not reverse the decision of the trial court regarding the exclusion or admission of such evidence unless the trial court’s decision is manifestly erroneous.” (internal quotation marks omitted)).

In short, the abuse of discretion standard recognizes that there is a range of permissible conclusions a district court may reach on an evidentiary issue, and consequently that “there will be occasions in which we affirm the district court even though we would have gone the other way had it been our call.” *United States v. Frazier*, 387 F.3d 1244, 1259 (11th Cir. 2004).

II. Rule 37(c)(1)’s Sanctions When A Party Fails to Provide Information That Is Required To Be Disclosed in Discovery Pursuant to Rule 26

Rule 37(c)(1) states 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 . . . at a trial, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the court, on motion and after giving an opportunity to be heard:

- (A) may order payment of the reasonable expenses, including attorney’s fees, caused by the failure;
- (B) may inform the jury of the party’s failure; and
- (C) may impose other appropriate sanctions, including any of the orders listed in Rule 37(b)(2)(A)(i)-(vi).

Fed. R. Civ. P. 37(c)(1). Rule 26(a)(2) requires the disclosure of the identity of any expert witness a party may use at trial, accompanied by a written report that contains “a complete statement of all opinions the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2). Pursuant to Rule 26(e), and importantly for this case, the expert’s report and deposition must be supplemented “in a timely manner” if a party learns the report or deposition “is incomplete or incorrect.” Fed. R. Civ. P. 26(e).

The district court concluded that Dr. Porter’s testimony should not be excluded because the failure to supplement Dr. Porter’s proffered opinions could be remedied by acceding to Mentor’s request for an overnight continuance to prepare for Mentor’s cross-examination.² That Mentor requested—and received—this alternative remedy is key to my assessment of its current argument that the district court erred by not striking the testimony altogether. But I address first the question whether, absent Taylor’s showing of harmlessness as a result of her failure to alert Mentor to one of her expert’s “evolution,” the district court was required to automatically, and without the exercise of any further discretion, strike the testimony in question.³

² Notably, Mentor did not request an opportunity to re-depose Dr. Porter prior to questioning him before the jury. Mentor likewise did not request a mistrial.

³ Not all of Dr. Porter’s testimony would necessarily have been subject to exclusion, as much of it was consistent with his deposition testimony.

The dissent reads Rule 37(c)(1) to mandate, as an automatic sanction, the exclusion of trial evidence that was not earlier disclosed in violation of Rule 26, absent a showing of harmlessness by, and substantial justification for, the non-disclosure. The dissent posits that a harmless non-disclosure under Rule 37(c)(1) must: (1) be a mistake rather than a deliberate or fraudulent attempt to gain a litigation advantage and (2) involve information that is already known to the opposing party. Concluding that the non-disclosure here was neither a mistake nor was it harmless, the dissent would find reversible error in the district court's failure to strike the expert's testimony.

Rule 37(c)(1) does not define the term harmless, but the Advisory Committee notes to Rule 37 provide support for the dissent's extrapolation of these two elements. The examples of harmless non-disclosures set out in the Advisory Committee notes all involve an "inadvertent" omission of information that was available to the opposing party. *See* Rule 37 advisory committee notes. More generally, the Advisory Committee notes suggest that the harmlessness exception is intended to "avoid unduly harsh penalties in a variety of situations." *Id.*

At the same time, though, the text of the rule also offers support for a conclusion that exclusion is not automatically required, even if the omission is not harmless. That is, although Rule 37(c)(1) states, in its first sentence, that a party who fails to provide information as required by 26(e) "is not allowed to use that

information . . . at a trial, unless the failure was substantially justified or is harmless,” the next sentence provides: “In addition to or instead of this sanction, the court” may impose “other appropriate sanctions.” Fed. R. Civ. P. 37(c)(1); Fed. R. Civ. P. 37(c)(1)(C) (emphasis added). In other words, given that text, one can also argue that exclusion is not automatically required by the rule.

In fact, there is a split between the circuit courts on this question. According to a recent and very thorough district court opinion, three circuits—the Second, Sixth, and Seventh—have concluded that the absence of substantial justification or harmlessness does not automatically result in exclusion, whereas four circuits—the First, Fourth, Eighth, and Ninth— provide for automatic, or near-automatic, exclusion under the same circumstances. *See Pitts v. HP Pelzer Auto. Sys., Inc.*, 2019 WL 2448821, at *5 n.7, __ F.R.D. __ (S.D. Ga. June 20, 2019) (Hall, C.J.).⁴

Although it picks up on some language from our caselaw that arguably suggests that exclusion is not automatic even without a showing of harmlessness, *Pitts* acknowledges that the Eleventh Circuit has not squarely decided this issue. *Id.* at *5. Nor do we do so today. This is so because, although I am concurring in the affirmance of the district court’s decision not to exclude the expert’s testimony, I am doing so based on the specific request for relief made by defense counsel for

⁴ The *Pitts* decision also collects district court cases from within this circuit, noting a split not just between districts, but also within districts. *Pitts*, 2019 WL 2448821, at *5 n.8.

Mentor and on what I consider to be a ruling on this request that constituted a proper exercise of the district court's discretion.

III. The District Court Properly Exercised Its Discretion When It Granted One of Defendant Mentor's Two Alternative Requests for Relief

Whenever one is considering whether a trial court has properly exercised its discretion, one must look at the circumstances that the court was facing when called on to make a decision. Here, immediately at the conclusion of Dr. Porter's direct examination, defense counsel asked the court to strike the expert's testimony, given that some of his testimony consisted of new opinions. Plaintiff's counsel responded that Plaintiff had always taken the position that the ObTape caused inflammation and that Dr. Porter's testimony was merely an evolution of that theory based upon the hypothetical given to him at trial based on another expert's testimony. Following that response, and without waiting for any interjection by the court as to its leaning, defense counsel offered:

If the Court is not going to grant our motion, we would ask for the alternative form of relief that we at least be given the night to prepare a cross. Getting these new opinions literally on the day of and then expecting to cross him on the fly is completely improper. So that's the alternative

Both counsel then disputed whether Dr. Porter's trial testimony had contradicted his deposition testimony, with Plaintiff's counsel arguing that the expert had merely responded to a hypothetical question with regard to the degradation issue, and, as to urethral thinning, the expert's trial testimony was consistent with his

overall deposition testimony that, because the expert could provide no other likely reason for any of Plaintiff's symptoms, the thinning was also likely caused by the ObTape.

At the end of this brief exchange, the district court indicated that it would not strike the expert's testimony, but that it would grant defense counsel's alternative request for an overnight recess to allow it further preparation before cross-examining the doctor. So, the question is whether the district court abused its discretion when it granted Mentor one of the two alternative requests for relief it made. I say no. The district court was in the middle of a lengthy and complex trial and not made privy to the legal briefing we have now received about Rule 37, advisory committee notes, the distinction between the concepts of prejudice and harmlessness, a sharp circuit split, or the like. Instead, the court was responding to a litigant who had a beef and who had asked for one of two remedies. The court awarded that litigant one of its requested remedies.

Notably, in its contemporaneous objection requesting relief, defense counsel never argued to the district court that Rule 37 required, as a mandatory sanction, that the court strike the testimony unless there was a finding of harmlessness. That defense counsel paired its request to strike with an alternative request for a recess surely suggested to the district court that striking the testimony was not mandatory. For defendant Mentor to now suggest that the court erred by not intuiting a

mandatory obligation to strike—when none was articulated by defense counsel—asks us to examine the court’s exercise of discretion on facts that were not before it. Just as it is not sporting to ambush opposing counsel with undisclosed expert testimony, it is likewise unfair to seed the record with an appellate issue not aired before the district court at the time that it has been asked to rule.⁵

Further, nothing that occurred after the district court granted the recess and after defense counsel cross-examined Dr. Porter reasonably suggested that the court should retroactively strike the doctor’s testimony. Mentor had an opportunity on cross to point out Dr. Porter’s changing opinions. And, as the district court noted, its cross-examination of the expert was quite effective.

The dissent notes that granting only an overnight continuance deprived Mentor of the opportunity to: (1) obtain an amended expert report containing Dr. Porter’s revised opinions, (2) depose Dr. Porter a second time concerning his revised opinions, and (3) present rebuttal testimony. But Mentor presented rebuttal testimony. And, for understandable strategic reasons, it never requested an amended expert report or a chance to re-depose Dr. Porter. As to a new expert report, an updated expert report from Dr. Porter would have been identical to his

⁵ And counsel for Mentor could have purposely decided not to go for the gusto by pushing hard on a motion to strike Dr. Porter’s testimony, given that counsel was aware that it would be calling, as its own expert rebuttal witness, Dr. Klutke, who testified for the first time at trial that he had experienced bowel perforations with the procedure that was used to implant mesh slings before ObTape was introduced.

original report—which is to say, Dr. Porter would have concluded in the updated report that ObTape likely caused Taylor’s chronic inflammation and other complications because her symptoms began only after she was implanted with ObTape and there did not seem to be any other explanation for them.

And evidently Mentor did not need an updated report to effectively respond to Dr. Porter’s “evolved” opinions, each of which was rebutted by extensive testimony from multiple experts. For example, defense expert Dr. Klutke testified that there was no evidence Taylor had a urethral erosion and that Taylor’s inflammation, urethral thinning, and other maladies were most likely caused by Durasphere or the hormonal changes and vaginal atrophy associated with Taylor’s hysterectomy, not by the ObTape. Defense expert Dr. Juma likewise testified that Taylor did not have a urethral erosion and that her other symptoms could be attributed to Durasphere and atrophic vaginitis.

As for an opportunity to re-depose Mentor, presumably Mentor did not ask for another deposition because it did not want a second deposition of Dr. Porter. That decision makes sense from Mentor’s perspective because the original deposition provided Mentor with the most helpful deposition testimony it could hope to get from Dr. Porter in terms of disproving causation. A second deposition would have given Dr. Porter an additional opportunity to clarify and rehabilitate his testimony. Thus, it is understandable that Mentor chose to rest its defense on

the existing record, which gave it an opportunity to focus on undermining Dr. Porter's credibility by pointing out the inconsistencies between the testimony Dr. Porter had just given the jury and the testimony Dr. Porter provided in his prior deposition, as well a chance to confront the doctor with other possible causes of Taylor's injuries. As Mentor apparently recognized, its strategy likely would have been thwarted by conducting a second deposition of Dr. Porter.

IV. Conclusion

Like the dissent, I agree that we should not encourage the kind of conduct exhibited by Taylor's counsel. And given the particular facts of this case and the narrow ground on which I concur, I do not believe we have done so. Certainly, the discussion in the majority, concurring, and dissenting opinions should put all parties on notice that they act at their own peril when they ignore their duties under Rule 26 and Rule 37. We leave for another day a more dispositive ruling as to the circumstances under which a litigant's violation of Rule 37(c)(1) should result in automatic exclusion of undisclosed evidence.

For the above reasons, I concur in the decision to affirm the district court.

TJOFLAT, Circuit Judge, dissenting:

Today's majority opinion contains two serious legal errors. First, it applies the wrong legal standard to determine whether Dr. Porter's trial testimony should have been excluded under Federal Rule of Civil Procedure 37(c)(1). Second, even assuming the majority's preferred legal standard, the opinion botches the analysis in concluding that Taylor's Rule 26 violation was not prejudicial.

But the opinion does more than that. By neutering Rule 37(c)(1) and the "self-executing,"¹ "automatic sanction"² of exclusion, the majority gives the green light to Taylor's "ambush tactics." *See Licciardi v. TIG Ins. Grp.*, 140 F.3d 357, 359 (1st Cir. 1998). Taylor's Rule 26 violation wasn't an honest or harmless mistake—by convincing Dr. Porter to "evolve" his position on Taylor's inflammation and urethral erosion without filing an amended report, Taylor's counsel denied Mentor a meaningful opportunity to respond. Whereas Rule 37(c)(1) clearly calls for the exclusion of an expert witness's testimony in these circumstances, the majority reads the rule to allow a district court to excuse a party's Rule 26 violation so long as *the opposing party* erases the prejudice through cross-examination. Because the majority misapplies the applicable law

¹ Fed. R. Civ. P. 37(c)(1) advisory committee's note to 1993 amendment [hereinafter "Rule 37 committee note"].

² *Id.*

and, in so doing, stamps its imprimatur on Taylor's unscrupulous trial tactics, I respectfully dissent.

I.

A.

Under Rule 26, a party seeking to call an expert “must disclose” the identity of the expert and provide a written report that “must contain” not only “a *complete* statement of *all* opinions the witness will express and the basis and reasons for them,” but also “the facts or data considered by the witness in forming them.” Fed. R. Civ. P. 26(a)(2)(B)(i)–(ii) (emphases added). If a party does not comply with this disclosure obligation, Rule 37 says that the witness's testimony must be excluded “unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1); *see also* *Finley v. Marathon Oil Co.*, 75 F.3d 1225, 1230 (7th Cir. 1996) (“The sanction of exclusion is thus *automatic* and *mandatory* unless the party to be sanctioned can show that its violation of Rule 26(a) was either justified or harmless.” (emphases added)). The burden is on the rule-breaking party to show harmlessness.³ *See Knight through Kerr v. Miami-Dade County*, 856 F.3d 795, 812 (11th Cir. 2017) (noting that plaintiffs had “not carried their burden” under Rule 37(c)(1) of showing substantial justification); *Yeti by Molly, Ltd. v. Deckers*

³ The Court's opinion in this case does not alter this burden because Judge Carnes's special concurrence resolves this case on the narrow ground that the objecting party was granted the alternative relief it requested.

Outdoor Corp., 259 F.3d 1101, 1107 (9th Cir. 2001) (“Implicit in Rule 37(c)(1) is that the burden is on the party facing sanctions to prove harmlessness.”).

In finding that the “overnight continuance” was sufficient to remedy Taylor’s Rule 26 violation, the District Court concluded that the violation was “harmless.” *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, Nos. 4:08-MD-2004 (CDL), 4:12-cv-176 (Taylor), 2016 WL 6138253, at *6 n.3 (M.D. Ga. Oct. 20, 2016) (citation omitted). Despite reciting the correct standard, the District Court analyzed the violation as if it were determining prejudice rather than harm. This was reversible error because “[h]armlessness . . . is the key under Rule 37, not prejudice.” *Sommer v. Davis*, 317 F.3d 686, 692 (6th Cir. 2003).

The District Court failed to appreciate the distinction between these two standards, and on appeal Taylor pooh-poohs it as nothing but word games. Appellee’s Br. at 29 (“Reversing the District Court because at trial it found ‘no prejudice’ instead of ‘harmlessness’ would exalt form over substance and require the use of magic words.”). But the question is not whether the “harm” and “prejudice” standards are different in a purely semantic sense. The question instead is whether Rule 37(c)(1)’s specific harm standard differs from ordinary prejudice analysis. As the advisory committee notes explain, the meaning of harm in the Rule 37(c)(1) context is different from the meaning of prejudice:

Limiting the automatic sanction [of exclusion] to violations “without substantial justification,” coupled with the exception for

violations that are “harmless,” is needed to avoid unduly harsh penalties in a variety of situations: *e.g.*, the *inadvertent* omission from a Rule 26(a)(1)(A) disclosure of the name of a potential witness *known to all parties*; the failure to list as a trial witness a person *so listed by another party*; or the lack of knowledge of a *pro se* litigant of the requirement to make disclosures. In the latter situation, however, exclusion would be proper if the requirement for disclosure had been called to the litigant’s attention by either the court or another party.

Rule 37 committee note (emphases added). The advisory committee’s note “strongly suggests that ‘harmlessness’ involves an honest mistake on the part of a party coupled with sufficient knowledge on the part of the other party.” *Sommer*, 317 F.3d at 692 (citation omitted); *see also Gagnon v. Teledyne Princeton, Inc.*, 437 F.3d 188, 197 (1st Cir. 2006) (noting that the examples in the advisory committee note “suggest a fairly limited concept of ‘harmless’”). Put differently, in order for the automatic sanction of exclusion not to apply to a Rule 26 violation, two conditions must obtain: (1) the nondisclosure must be a mistake, and (2) the undisclosed information must already be known to the opposing party or parties.⁴

⁴ The advisory committee’s examples illustrate these requirements. Consider the first two examples: “the inadvertent omission from a Rule 26(a)(1)(A) disclosure of the name of a potential witness known to all parties; [and] the failure to list as a trial witness a person so listed by another party.” Rule 37 committee note. In each of these examples, the Rule 26 violation was an accident, and the opposing party was not harmed because it already knew the omitted information—the witness was “known to all parties” in the first example and “so listed by another party” in the second.

The third example suggests a more lenient standard for *pro se* litigants insofar as it does not require that the second condition be satisfied. *See* Rule 37 committee note (listing “the lack of knowledge of a *pro se* litigant of the requirement to make disclosures” as the third example of harmlessness). But the violation in the third example is still a mistake, and the advisory committee explains that exclusion *should still apply* if “the requirement for disclosure had been called to the [*pro se*] litigant’s attention.” *Id.*

Taylor’s conduct satisfies neither condition. Dr. Porter’s “evolved” opinion at trial was not a mistake: it resulted from his “having gone over Taylor’s medical records ‘with a fine-tooth comb’ and answering some of the questions Taylor’s attorneys had posed to him after his deposition.” Maj. Op. at 9. Nor could it possibly have been a surprise to Taylor’s counsel given the considerable price tag for Dr. Porter’s testimony. And, as I detail at greater length below, the new information in Porter’s trial testimony was not already known to Mentor. Indeed, it directly contradicted Dr. Porter’s previous statements—statements on which Mentor based its defense strategy. The Dr. Porter who appeared at trial was, in effect, not the Dr. Porter whom Mentor had deposed. He was a brand new expert witness whose identity Taylor had not disclosed.

B.

The majority writes that “Rule 37 gives a trial court discretion to decide how best to respond to a litigant’s failure to make a required disclosure under Rule 26.” Maj. Op. at 18. And so it does. Rule 37 says that “[i]n addition to or instead of [the sanction of exclusion], the court” “may order payment of the reasonable expenses, including attorney’s fees, caused by the failure,” “may inform the jury of

Taylor was represented by counsel. By not automatically excluding Dr. Porter’s testimony, the District Court treated Taylor *more leniently* than it should treat a *pro se* litigant under the rule.

the party’s failure,” and “may impose other appropriate sanctions.” Fed. R. Civ. P. 37(c)(1). By highlighting this language, the majority implies that even though Taylor’s Rule 26 violation might not be substantially justified or harmless, the District Court did not abuse its discretion by ordering a sanction other than exclusion.

The advisory committee notes illustrate, however, that the discretion to order an alternative sanction is reserved for a specific subset of Rule 26 violations. As the committee explains:

Preclusion of evidence is not an effective incentive to compel disclosure of information that, being supportive of the position of the opposing party, might advantageously be concealed by the disclosing party. However, the rule provides the court with a wide range of other sanctions—such as declaring specified facts to be established, preventing contradictory evidence, or, like spoliation of evidence, allowing the jury to be informed of the fact of nondisclosure—that, though not self-executing, can be imposed when found to be warranted after a hearing.

Rule 37 committee note. These alternative sanctions are meant to address Rule 26 violations that the threat of automatic exclusion cannot effectively deter, *e.g.*, nondisclosure of unfavorable information. But they are wholly inappropriate in the mine-run of Rule 26 violations where the threat of exclusion is a sufficient deterrent. Taylor’s failure to supplement Dr. Porter’s opinion is one such case: the threat of exclusion, if credible, is enough to incentivize a party to update its expert’s Rule 26 report. Thus, the District Court should have granted Mentor’s

motion to strike because it did not have discretion under Rule 37(c)(1) to order an alternative sanction.

At bottom, the District Court abused its discretion by misconstruing the relevant standard under Rule 37(c)(1). *See, e.g., Glock v. Glock, Inc.*, 797 F.3d 1002, 1006 (11th Cir. 2015) (“A district court abuses its discretion if it applies an incorrect legal standard” (quoting *FTC v. AbbVie Prods. LLC*, 713 F.3d 54, 61 (11th Cir. 2013))). Under a proper interpretation of Rule 37(c)(1), Dr. Porter’s testimony—a deliberate deviation from his expert report that caught Mentor completely by surprise—was not harmless. Accordingly, Dr. Porter’s testimony should have been excluded, and Mentor should be entitled to judgment as a matter of law.

II.

But let’s assume that the District Court’s harmless-ness-means-prejudice standard was correct. Even in this scenario, the District Court erred in finding that Taylor’s Rule 26 violation was harmless (read: not prejudicial) and thus abused its discretion. *See id.* (“A district court abuses its discretion if it . . . applies the law in an unreasonable or incorrect manner” (quoting *AbbVie Prods. LLC*, 713 F.3d at 61)). The District Court’s prejudice analysis also disregarded the second harm Mentor suffered: the denial of an opportunity to obtain discovery on the motivations underlying Dr. Porter’s reversal. *See infra* Parts II.B & II.C.

A.

Two aspects of Dr. Porter's trial testimony flatly contradicted his report and deposition:⁵ his opinion that ObTape caused Taylor's bladder inflammation, and his opinion that ObTape caused Taylor's urethral erosion.

As to the former, Dr. Porter said in his deposition that ObTape "may contribute" to Taylor's inflammation, but then admitted that he "can't say it's caused [by ObTape]." Later in the deposition, he further admitted that "[t]he only thing that currently we could somewhat relate to her ObTape would be *maybe* some of the tenderness on examination along the mesh." (emphasis added).

Perhaps most damning, when asked whether he could say to a reasonable degree of medical probability that Taylor's bladder inflammation was caused by ObTape, Dr. Porter admitted, "I can't." With respect to alternative explanations for Taylor's inflammation, Dr. Porter admitted that he couldn't "tell you if it's the Aris [a later-implanted urethral sling] or the ObTape."

Fast forward to the trial. Prompted by counsel, Dr. Porter adopted Dr. El-Ghannam's degradation theory, which he had previously rejected. He then

⁵ The majority assumes that the inconsistency between Dr. Porter's trial testimony and his expert report was the only basis for Mentor's motion to strike. Maj. Op. at 17. But Mentor's motion to strike refers to the contradiction between Porter's trial testimony and both his report and his deposition. And, as Rule 26(e)(2) states, "For an expert whose report must be disclosed under Rule 26(a)(2)(B), the party's duty to supplement extends *both* to information included in the report *and* to information given during the expert's deposition." Fed. R. Civ. P. 26(e)(2) (emphases added). Inconsistencies between Dr. Porter's trial testimony and deposition were thus fair game for Mentor's motion to strike.

stated—not in conditional language indicating a hypothetical response, but in straightforward unconditional language⁶—“I believe that the ObTape has probably caused that inflammation. . . . More likely than not.” Dr. Porter also denied, again in unconditional language, that there was “anything in [Taylor’s] medical history that . . . could explain the inflammation,” once again flatly contradicting his prior, unsupplemented testimony.

But it gets worse. On the topic of urethral erosion—one of the two injuries from ObTape Taylor asserted—Dr. Porter’s report noted that Taylor’s medical records “reveal[ed] no erosion of [the] urethra.” Dr. Porter’s story stayed consistent during his deposition, when he acknowledged that Taylor’s medical records disclosed no evidence of erosion. Mid-trial, however, Dr. Porter opined that “to a degree of medical certainty, I feel that ObTape . . . was the cause of the thinning of the tissue damaging the urethra itself.” Asked whether this phenomenon could be termed “erosion,” Dr. Porter responded, “This would be erosion thinning the wall. It would be thinning erosion, exposure of the mesh.”

⁶ The way Dr. Porter responded to the hypothetical almost certainly affected the way the jury received his testimony. Typically, in response to a question describing an “unreal” “hypothetical condition,” an answer contains the word “would” to denote the shift in tense. *Conditional*, Educ. First, <https://www.ef.edu/english-resources/english-grammar/conditional/> (last visited Mar. 20, 2019) [<https://perma.cc/GUW9-U2QR>]. So when Taylor’s counsel asked Dr. Porter to opine whether Taylor’s inflammation was caused by the ObTape based on the hypothetical assumption that ObTape degrades, Dr. Porter should have said that the ObTape “would” cause the inflammation if the degradation theory were true. Instead, however, Dr. Porter simply said, “I believe that the ObTape has probably caused [Taylor’s] inflammation,” omitting any indication that he was responding to a hypothetical.

And when Taylor’s counsel stated the question in stronger, more graphic terms—asking whether ObTape “had eaten away at the urethral wall and made it very thin”—Dr. Porter responded that it had.

This was no mere “evolution” in Dr. Porter’s opinion. This was a complete about-face. Dr. Porter was not the expert Mentor encountered at the pretrial deposition. He was a new expert, one whose identity Taylor deliberately withheld.

B.

Now for the harm. Rule 26(e)(2) required Taylor’s counsel to supplement their discovery “both to information included in [Dr. Porter’s] report and to information given during [his] deposition,” and that supplementation was required “by the time [Taylor’s] disclosures under Rule 26(a)(3) [were] due.” Fed. R. Civ. P. 26(e)(2). Taylor’s nondisclosure deprived Mentor of its right to an amended report containing Dr. Porter’s “opinions . . . and the basis and reasons for them,” “the facts or data considered . . . in forming them,” and “any exhibits . . . used to summarize or support them.” *See* Fed. R. Civ. P. 26(a)(2)(B)(i)–(iii). Further, under Rule 26(b)(4), Mentor could depose Dr. Porter “only after” his report was provided. Thus, not only was Mentor entitled to a new report, but Mentor was also entitled to an opportunity to redepose Dr. Porter and to obtain evidence to rebut Dr. Porter’s new opinions, such as the testimony of an expert witness.

But that's only what Mentor was entitled to concerning the subjects of urethral erosion and inflammation. In these circumstances, Mentor was also entitled to probe the reasons for Porter's last-minute reversal. Rule 26(b)(4)(C) allows a party to depose the opposing party's expert regarding communications between the expert and the opposing party to the extent the communications

(i) relate to compensation for the expert's study or testimony;

(ii) identify facts or data that the party's attorney provided and that the expert considered in forming the opinions to be expressed; or

(iii) identify assumptions that the party's attorney provided and that the expert relied on in forming the opinions to be expressed.

Fed. R. Civ. P. 26(b)(4)(C)(i)–(iii). Here, however, Mentor was entitled to even more. Because Porter's reversal was almost certainly fraudulent⁷—and because Taylor's counsel induced it, a fact that they weren't particularly shy about⁸—Mentor was entitled to communications that Rule 26(b)(4) would normally protect.⁹ That means that Mentor was entitled to the communications between

⁷ Taylor's presentation of Dr. Porter's reversal was fraudulent for the following reason: Taylor knew that Mentor was expecting to counter the opinions Dr. Porter disclosed in his report and deposition. In not disclosing Porter's new opinions, Taylor induced Mentor into relying to its detriment on the fact that Porter would adhere to the opinions he gave in his report and on deposition. The non-disclosure was fraudulent because it constituted a false statement that Dr. Porter's opinions had not changed and was made with the intent that Mentor rely on the false representation.

⁸ On direct examination of Dr. Porter, Taylor's counsel explained that, once the case was scheduled for trial, counsel requested that Dr. Porter thoroughly review the records and answer some of counsel's questions.

⁹ Communications between expert witnesses and counsel are typically protected from discovery. *See* Fed. R. Civ. P. 26(b)(4)(C) advisory committee's note to 2010 amendment

Taylor’s counsel and Dr. Porter regarding the nature of counsel’s request that Dr. Porter go over Taylor’s records with “a fine-tooth comb,” as well as the “questions [counsel] had” about those records.

Of course, Mentor was never given this discovery. Instead, the District Court granted an “overnight continuance”—after a full day of proceedings—so that Mentor could prepare its cross-examination of Dr. Porter. The majority argues that this continuance was enough to ameliorate Mentor’s harm. Maj. Op. at 18–20. But even assuming that’s true with respect to the harm caused by Dr. Porter’s new testimony, the continuance certainly wasn’t enough to address the harm Mentor suffered by being denied the communications between Taylor’s counsel and Dr. Porter. Instead, Mentor was left to cross-examine Dr. Porter about his reversal at its own peril. And Mentor did so completely blind: because it was not afforded time to seek new discovery or even to depose Dr. Porter on his change of heart,

(“Rule 26(b)(4) is amended to provide work-product protection against discovery regarding draft expert disclosures or reports and—with three specific exceptions—communications between expert witnesses and counsel.”). But these protections are relaxed when the communications pertain to fraud. *See Drummond Co. v. Conrad & Scherer, LLP*, 885 F.3d 1324, 1335 (11th Cir. 2018) (“The crime-fraud exception allows a party . . . to obtain discovery that otherwise would be protected by the attorney-client privilege or the attorney work product doctrine.”).

I am convinced that Mentor could make out a showing of fraud on the Court, that is, a showing of “an unconscionable plan or scheme which is designed to improperly influence the court in its decision.” *See Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1338 (5th Cir. 1978) (citation omitted); *see also Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc) (adopting as precedent all decisions of the former Fifth Circuit prior to October 1, 1981).

whatever Dr. Porter said in response to Mentor's cross-examination was the final word.

C.

The District Court held that Dr. Porter's completely new trial testimony did not prejudice Mentor because Mentor's counsel "did a fine job" cross-examining Dr. Porter.¹⁰ And on appeal, the majority concludes that Mentor was not prejudiced by Taylor's Rule 26 violation because the subject of Dr. Porter's testimony—urethral erosion—"generally was a topic of extensive pretrial discovery" that Dr. Porter had addressed in his Rule 26 report. Maj. Op. at 19. I explained above how that's simply not the case: Dr. Porter's testimony at trial was a 180-degree reversal from his Rule 26 report and deposition. Let's not pretend that Dr. Porter's U-turn was anything less.

Moreover, as I explained above, Mentor was harmed not only by denial of discovery concerning Dr. Porter's new opinions, but also by the denial of discovery concerning *how* those new opinions were formed and an opportunity to prepare a rebuttal. Mentor was thus left to cross-examine Dr. Porter completely in the dark. The District Court did not factor this into its harm analysis, and the

¹⁰ In so holding, the District Court impermissibly shifted the burden of showing harmlessness from Taylor, the rule-breaking party, to Mentor, the victim. *See Knight through Kerr*, 856 F.3d at 812; *Yeti by Molly*, 259 F.3d at 1107.

majority similarly excludes it from consideration. But in holding that Taylor’s Rule 26 violation was harmless, the District Court necessarily had to conclude that the outcome would not have been different if Mentor had been given the discovery it was entitled to.

This, I submit, is an impossible conclusion to reach because we simply cannot assess in the abstract whether the error—*i.e.*, Taylor’s Rule 26 violation—was prejudicial. To be sure, we can and do assess most trial errors for harm in this way. But where an error “affects the framework within which the trial proceeds,” the error is structural and “defies analysis by harmless error standards.” *Weaver v. Massachusetts*, 582 U.S. ___, ___, 137 S. Ct. 1899, 1907–08 (2017) (alterations omitted) (citation omitted). Taylor’s Rule 26 violation, which denied Mentor discovery it was entitled to under the Federal Rules of Civil Procedure, fundamentally altered “the framework within which the trial proceed[ed].” *See id.* (citation omitted).

As the Supreme Court recently explained in *Weaver v. Massachusetts*, an error is structural if the “effects of the error are simply too hard to measure.” *See id.* A classic example of this kind of structural error is denial of the Sixth Amendment right to counsel of one’s choice. Because the “effect of the violation cannot be ascertained”¹¹ given the manifold ways one lawyer’s performance might

¹¹ *Id.* at 1908 (citation omitted).

differ from another's, the error is deemed structural and removed from harmless-error analysis. This is true regardless of whether the alternative counsel retained was effective, or whether the denial caused prejudice to the defendant. *United States v. Gonzalez-Lopez*, 548 U.S. 140, 148, 126 S. Ct. 2557, 2563 (2006).

Although Mentor's rights to a new report and to depose Dr. Porter are not as weighty as those protected by the Sixth Amendment, the conclusion is the same. Because it is simply impossible to measure prejudice, the error must be removed from traditional harmless-error analysis.¹²

To illustrate the point, consider the series of mental hoops a court would need to jump through to determine prejudice in this case. First, the court would have to determine how Mentor would have responded to a timely filed, updated report. Would Mentor have redeposed Dr. Porter? Lined up a rebuttal witness? Filed a new *Daubert* motion? All three? Second, the court would have to consider how Mentor's hypothetical response would affect Taylor's burden to prove specific causation. This would be a truly herculean feat of mental gymnastics. The court would have to consider not only the merits of Mentor's hypothetical responses, but also how those responses would affect the jury's receptiveness to Dr. Porter's testimony.

¹² It is perhaps for this reason that the advisory committee sought to apply a more categorical, Rule 37(c)(1)-specific harm standard. *See supra* Part I.A.

And then, of course, the court would have to repeat this analysis with respect to the communications between Taylor's counsel and Dr. Porter that Mentor was entitled to. How would Mentor have responded? What would Mentor have uncovered? How would Mentor's response have affected the jury's perception of Dr. Porter's credibility?

Suffice it to say, a court could not perform this analysis with any reasonable degree of certainty. And no court should have to, because this error was structural.¹³

III.

The consequences of the majority's opinion stretch far beyond the immediate and substantial harm to Mentor. By endorsing the District Court's decision, the majority effectively rewrites Rule 37(c)(1) and invites the procedural abuse that the rule is meant to discourage. If Taylor's egregious Rule 26 violation doesn't deserve the automatic sanction of exclusion, what does?

¹³ Admittedly, structural error typically arises in appellate review of criminal convictions. But the Supreme Court has not limited structural error to the criminal context. And other courts, including two of our sister circuits, have found structural error in civil suits. *See M.L. v. Fed. Way Sch. Dist.*, 394 F.3d 634, 648 (9th Cir. 2005); *Dilley v. Alexander*, 603 F.2d 914, 923–24 (D.C. Cir. 1979); *Doyle v. United States*, 599 F.2d 984, 995–96 (Ct. Cl. 1979), *amended on other grounds sub nom. In re Doyle*, 609 F.2d 990 (Ct. Cl. 1979).

Notably, in each of these cases the error was the denial of a statutory, rather than constitutional, right. Here, we have a right created by the Federal Rules of Civil Procedure, which is equivalent to a statutory right given that the Federal Rules are approved by Congress under the Rules Enabling Act. *See* 28 U.S.C. § 2072.

From now on, a party dissatisfied with its expert's deposition or report will be incentivized to engage in the following tactic. Counsel will first have a conversation with the expert encouraging him to reexamine the basis for his opinion; this, counsel hopes, will lead to the expert's "evolved" understanding of the point at issue. But counsel won't then supplement the expert's report, as mandated by Rule 26(e)(2). Why would he? If exclusion under Rule 37(c)(1) no longer serves as a credible threat, counsel would be much better off ambushing opposing counsel at trial. Why? Because few judges—especially in cases as difficult and protracted as this—will order a true continuance to allow the expert to be redeposed. And now that automatic exclusion is off the table for even the most egregious Rule 26 violations, the victimized party's only recourse will be cross-examination in which the *victimized* party will be saddled with the burden of proving harmlessness.

Does this sound familiar? It should. And now that this behavior has received the majority's seal of approval, I fear that this is not the last we'll see of this trick.

And it's not just procedural abuse that the majority's opinion encourages. By condoning the admission of expert testimony at trial even when it deviates dramatically from the expert's pretrial report and deposition, the majority inadvertently welcomes junk science into the courthouse.

Here's why. In cases involving highly technical subject matter, counsel invariably retain expert witnesses. And in those cases, opposing counsel invariably move for a *Daubert* hearing—or at least they should. See *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 564 n.21 (11th Cir. 1998) (recognizing that *Daubert* hearings, while not “required by law or by rules of procedure, . . . are almost always fruitful uses of the court’s time and resources in complicated cases”). Even if neither party moves for a *Daubert* hearing, the district court still has the duty to act as a gatekeeper to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589, 113 S. Ct. 2786, 2795 (1993). But when an expert witness changes his theory from one in his report to another at trial, he is effectively able to bypass this gatekeeping function. For the same reasons that a district court in these circumstances would likely not order a true continuance, the district court would be even less inclined to pause the trial to hold a *Daubert* hearing. As a result, counsel can introduce *new* theories at trial—even when that move is deliberate and intended to mislead the opposing party, because apparently intent no longer matters¹⁴—that would not have passed evidentiary muster at an earlier stage.

IV.

¹⁴ See *supra* Part I.A; Maj. Op. at 17–18.

As the world becomes increasingly complex, so too do the disputes that find their way into the federal courts. Amid this complexity, the role of expert witnesses—people we rely on to explain complicated and technical subjects—becomes more critical. In this case, for example, the only evidence of specific causation was an expert’s testimony. Without it, Taylor stood no chance of prevailing. And without experts, it would simply be impossible for lay juries to understand the nature of an increasingly large fraction of the disputes the bar litigates today.

It is precisely because expert witnesses are so critical that we must insist on full, timely disclosure of their opinions. The drafters of Rule 26 understood this. In adding an expert-witness disclosure requirement to Rule 26, the drafters hoped to give parties a “reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from [their own] witnesses” by requiring disclosure of testimony “sufficiently in advance of trial.” Fed. R. Civ. P. 26(a)(2) advisory committee’s note to 1993 amendment. And—lest unwitting parties be ambushed by an expert’s later “evolved” opinion—the drafters included a continuing obligation to supplement an expert’s testimony along with the party’s pretrial disclosures. Perhaps most important, the drafters gave this obligation teeth by providing for exclusion of expert testimony when an expert’s untimely change of opinion is not harmless or substantially justified. This regime—the pretrial

disclosure requirements, duty to supplement, and serious penalties for failure to follow the rules—“is consonant with the federal courts’ desire to ‘make a trial less a game of blindman’s buff and more a fair contest with the basic issues and facts disclosed to the fullest practical extent.’” *Thibeault v. Square D Co.*, 960 F.2d 239, 244 (1st Cir. 1992) (quoting *United States v. Proctor & Gamble Co.*, 356 U.S. 677, 682, 78 S. Ct. 983, 986–87 (1958)).

Today’s majority opinion seriously weakens this regime.

Today’s majority opinion also flies in the face of over 80 years of federal discovery practice. “The purpose of our modern discovery procedure is to narrow the issues, to *eliminate surprise*, and to achieve substantial justice.” *Greyhound Lines, Inc. v. Miller*, 402 F.2d 134, 143 (8th Cir. 1968) (emphasis added). As the Second Circuit put it, “The basic purpose of the federal rules, particularly those concerning discovery and disclosure, is to eliminate *trial by ambush*” *Ginns v. Towle*, 361 F.2d 798, 801 (2d Cir. 1966) (emphasis added). In contrast with the pre-Federal Rules practice of discovery—where “fact-revelation w[as] performed primarily and inadequately by the pleadings” and “[i]nquiry into the issues and the facts before trial was narrowly confined and . . . often cumbersome in method”¹⁵—the new Federal Rules were designed to hone the legal and factual issues and to

¹⁵ *Hickman v. Taylor*, 329 U.S. 495, 500–01, 67 S. Ct. 385, 388 (1947).

prevent surprise. As the Supreme Court explained just nine years after the Rules’ adoption:

The new rules, [in contrast to the prior federal practice], restrict the pleadings to the task of general notice-giving and invest the deposition-discovery process with a vital role in the preparation for trial. The various instruments of discovery now serve (1) as a device . . . to narrow and clarify the basic issues between the parties, and (2) as a device for ascertaining the facts, or information as to the existence or whereabouts of facts, relative to those issues. Thus[,] civil trials in the federal courts no longer need be carried on in the dark. The way is now clear . . . for the parties to obtain the fullest possible knowledge of the issues and facts before trial.

Hickman v. Taylor, 329 U.S. 495, 501, 67 S. Ct. 386, 388–89 (1947).

Mentor did all that it could to “ascertain[] the facts” of this case. It did all that it could to “obtain the fullest possible knowledge of the issues and facts before trial.” It did everything it could to play by the discovery rules. And yet, Mentor was ultimately left “in the dark” by Taylor’s counsel, by the District Court, and now—regrettably—by this Court.

* * *

In closing, to understand just how significantly Mentor has been wronged today, consider what we would do if this case were criminal rather than civil. Under Federal Rule of Criminal Procedure 16(a)(1)(G), the government has a duty to “give to the defendant a written summary of any [expert] testimony that the government intends to use.” Fed. R. Crim. P. 16(a)(1)(G). The government’s summary must include the expert witness’s “opinions, the bases and reasons for

those opinions, and the witness's qualifications." *Id.* As with the Civil Rules, the government has the continuing duty to inform the defendant of changes to the expert's opinion. *Id.* 16(c). And, like Civil Rule 37(c), Criminal Rule 16 empowers the district court to "prohibit [a non-compliant] party from introducing the undisclosed evidence." *Id.* 16(d)(2)(C).

Now imagine this were a criminal trial. The government identifies Dr. Porter as an expert witness. Mentor obtains Dr. Porter's summary, deposes Dr. Porter and—based on the information obtained—builds its defense. All seems to go as planned until, mid-trial, Dr. Porter changes his tune in a way that prejudices Mentor. Moreover, the circumstances of the reversal indicate that the government induced Dr. Porter to change his opinion. Mentor moves for a mistrial citing the prejudicial and deliberate Rule 16 violation. The district judge denies Mentor's motion, and Mentor appeals. Now the case is before our Court. What result?

Reversal. *See United States v. Chastain*, 198 F.3d 1338, 1348 (11th Cir. 1999) ("[W]here it is apparent . . . that the defense strategy may have been determined by the failure to disclose, there should be a new trial." (citation omitted) (second and third alterations omitted)). Reversal, and perhaps—because of the violation's deliberateness—a citation of criminal contempt for the prosecution. But over on the civil side—with the *same* degree of prejudice and the *same* degree of deliberateness—we inadvertently reward this behavior.

Why is that? Why do we tolerate in a civil case the same kind of behavior that would require reversal in a criminal case? It seems that we have two standards of ethics and professionalism—one for criminal cases, and another, significantly more lenient standard for civil cases. Lawyers do without a hint of shame in a civil case what they would never think to do in a criminal one. This bifurcated sense of what ethics and professionalism require of the bar is sadly nothing new. But what is new—and what is made worse by today’s majority opinion—is the extent to which we will let civil lawyers get away with behavior that would be unthinkable in a criminal trial.

Respectfully, I dissent.