FOR PUBLICATION

In the

United States Court of Appeals

For the Eleventh Circuit

No. 23-13892

JEFFREY THELEN,

Plaintiff-Appellant,

versus

SOMATICS, LLC,

Defendant-Appellee,

ELEKTRIKA, INC.,

Defendant.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 8:20-cv-01724-TPB-JSS

Before ROSENBAUM, NEWSOM, and MARCUS, Circuit Judges.

MARCUS, Circuit Judge:

Jeffrey Thelen received 95 electroconvulsive therapy ("ECT") treatments between 2014 and 2016 at a CHI Health hospital in Omaha, Nebraska in order to treat his severe depression. Thereafter, Thelen suffered severe memory loss, and in 2017, was diagnosed with neurocognitive disorder.

In 2020, Thelen sued Somatics, the manufacturer of the Thymatron IV device used to administer the ECT treatments, in the United States District Court for the Middle District of Florida. He alleged negligence, strict product liability, breach of express and implied warranties, violation of Nebraska's Consumer Protection Act, and fraudulent misrepresentation. At its core, Thelen claimed that the company failed to adequately warn him of the risks associated with electroconvulsive therapy. The district court disposed of most of his claims before trial, dismissing Thelen's claims for violation of Nebraska's Consumer Protection Act and fraudulent misrepresentation, merging the strict liability and breach of implied warranty claims, and entering summary judgment for Somatics on the plaintiff's design defect and manufacturing defect theories and on his claim for breach of express warranty.

Thereafter, the case was tried by a jury on the negligence and strict liability claims, which the district court merged in order to simplify the case for the jury, since both claims were rooted in

the same alleged warning defect. Ultimately, the jury found that while there was a failure to adequately warn, this failure was not the proximate cause of any injuries sustained by the plaintiff.

On appeal, Thelen alleges that the district court erroneously granted summary judgment for Somatics on the design defect claim. He also says that the district court erroneously merged his negligence and strict liability claims, that the district court's jury instructions on proximate cause were erroneous, and that the district court abused its discretion in excluding some pieces of evidence he had offered.

After thorough review, and with the benefit of oral argument, we find none of these claims persuasive and, accordingly, affirm the judgment of the district court.

I.

A.

Jeffrey Thelen suffered from severe depression and other mental health issues for many years, which resulted in his hospitalization on several occasions. Thelen attempted suicide a number of times and had a long history of inflicting self-harm, including incidents in which he slit his wrists, jumped into traffic, and stabbed, starved, and shot himself. He also had a record of serious substance abuse, including drinking excessively and abusing opioids and cocaine.

In 2013, Thelen's physician recommended that he try electroconvulsive therapy ("ECT") to treat his severe depression.

Between May 2014 and July 2016, Thelen received 95 ECT treatments at a CHI Health hospital in Omaha, Nebraska. This therapy was administered by a number of physicians including his psychiatrist, Dr. Arun Sharma, utilizing a Thymatron IV ECT device that is manufactured and sold by Somatics. Before each treatment, Thelen signed a consent form which expressly warned him that ECT could cause, among other things, "short term memory loss," "permanent memory loss," "prolonged seizures," "temporary or permanent heart abnormalities," or "mortality"; the form did not use the term "brain damage."

After completing his ECT treatments over two years, Thelen was diagnosed in 2017 by a neuropsychologist, Mark Hannappel, with a neurocognitive disorder that caused severe memory loss. According to Thelen's mother, he suffered from both short-term and long-term memory loss after receiving ECT. She testified that Thelen could not remember many of his family members or his high school years. Thelen's mother also said that her son forgot how to perform such basic tasks as doing laundry or unloading the dishwasher. For this reason, she added, Thelen now writes everything down in a "little black book" to avoid forgetting things. According to Dr. Hannappel's 2021 progress report, Thelen said he even forgot where his parents' home was located, the very home he had grown up in since he was six years old.

B.

On July 24, 2020, Thelen commenced this product liability lawsuit against Somatics, alleging that the company had failed to

warn him of the many substantial risks associated with ECT.[1] The complaint asserted that the electroconvulsive therapy treatment had caused him to suffer neurocognitive injuries, including permanent memory loss and brain damage. It also claimed that Somatics had failed to comply with the FDA's pharmacovigilance requirements by not adequately testing and investigating its device or reporting safety risks and adverse events caused by its device. *See* 21 C.F.R. §§ 803 *et seq*. Thelen asserted claims for: (1) negligence; (2) strict liability; (3) breach of implied warranty of merchantability; (4) breach of implied warranty of fitness for a particular purpose; (5) breach of express warranty; (6) violation of Nebraska's Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 *et seq*.; and (7) fraudulent misrepresentation.

The district court disposed of most of these claims, dismissing some of them, merging some, and granting summary judgment on some others. First, in February 2021, the district court granted Somatics's motion to dismiss Thelen's claims for violation of Nebraska's Consumer Protection Act and fraudulent misrepresentation, determining that the Nebraska statute did not provide for a private right of action, and that the fraudulent misrepresentation claim had not been pleaded with the particularity required

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[1] The complaint was initially filed against both Somatics and Elektrika, which, Thelen alleged, assembled and repaired the Thymatron IV ECT devices for Somatics. But after Elektrika moved for summary judgment in December 2022, Thelen and Elektrika reached a settlement agreement. Accordingly, Elektrika was dismissed from the complaint in May 2023, leaving Somatics as the only defendant.

by Federal Rule of Civil Procedure 9(b). The court also merged Thelen's two claims for breach of implied warranty with his strict liability claim, explaining that Nebraska law "unequivocally" required this result. *See Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842–44 (Neb. 2000) (finding "persuasive" the "reasoning" of "many courts [that] have merged theories of recovery for breach of implied warranty and strict liability on the basis that each theory states the same strict liability claim").

Then, after the completion of discovery, Somatics moved for summary judgment on the plaintiff's remaining claims for negligence, strict liability, and breach of express warranty. The district court granted the motion in part. To the extent Thelen's negligence claim was grounded in Somatics's failure to report adverse events to the FDA, the court concluded that this theory was impliedly preempted by federal law. *See* 21 U.S.C. § 337(a) (providing that actions to enforce FDA requirements "shall be by and in the name of the United States"); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) ("[P]laintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law."); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017) ("[I]mplied preemption prohibits state-law claims that seek to privately enforce duties owed to the FDA.").

As for Thelen's claim for breach of express warranty, the district court determined that Thelen failed to prove reliance on an express warranty, as required by Nebraska law. *See Hillcrest Country Club v. N.D. Judds Co.*, 461 N.W.2d 55, 61 (Neb. 1990) ("[S]ince an

express warranty must have been 'made part of the basis of the bargain,' it is essential that the plaintiffs prove reliance upon the warranty.") (quoting *Wendt v. Beardmore Suburban Chevrolet, Inc.*, 366 N.W.2d 424, 428 (Neb. 1985)). The court reasoned that Thelen had not established that he relied on alleged representations found on Somatics's website.

Finally, the district court granted partial summary judgment for Somatics on Thelen's strict liability claim, finding no evidence of a manufacturing or design defect. Under Nebraska law, a "manufacturing defect exists when the product differs from the plan and specifications of the manufacturer." *Freeman*, 618 N.W.2d at 841. The district court explained that Thelen had failed to show that the ECT device used to treat him contained a manufacturing flaw that deviated from its intended specifications. As for the strict liability claim rooted in a design defect, the Nebraska Supreme Court has instructed that this claim should be measured against the consumer's expectations, which asks whether a product is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* at 840. The district court agreed with Thelen that for these purposes, the relevant "consumers" are patients, not physicians, but determined that Thelen offered no evidence to establish the expectations of an ordinary patient about ECT devices, and instead only described his own subjective expectations. However, the district court did not grant summary judgment for Somatics on Thelen's strict liability claim under a failure to warn theory.

Somatics argued separately on summary judgment that Thelen had offered no competent evidence that ECT causes permanent memory loss and brain damage. The district court rejected this argument too. In Nebraska, in order to establish causation in a product liability claim, a plaintiff must show both general and specific causation. *See King v. Burlington N. Santa Fe Ry. Co.*, 762 N.W.2d 24, 34 (Neb. 2009). General causation refers to whether the product can cause the injury in question, and is shown by expert testimony establishing the association between the product and the injury through epidemiological studies and the biological plausibility of a causal relationship. *Id.* at 34–42. In concluding that Thelen made a sufficient showing to allow the issue to go to the jury, the district court credited Thelen's expert Dr. John Read, a clinical psychologist, who offered the opinion that "to a reasonable degree of scientific certainty . . . ECT causes persistent/permanent memory loss and brain damage in a substantial proportion of recipients, somewhere in the range of 12% to 55%."

Specific causation refers to whether a product in fact caused the plaintiff's injury and is established by expert testimony employing a technique known as differential diagnosis, which involves ruling in and out possible causes of the patient's condition. *Id.* at 34, 50–51. While the district court excluded testimony on this matter from Thelen's expert psychologist, Dr. Mark Hannappel, who is not a medical doctor, it sufficiently credited Thelen's expert Dr. Bennet Omalu, a medical doctor and forensic pathologist, who opined that ECT treatment caused brain injury in Thelen's case. In the course of the trial, however, the district court barred Dr.

Omalu's testimony on general causation, but not his opinion on specific causation.

After granting partial summary judgment on some claims and dismissing most of the others, what remained to be tried were: (1) plaintiff's strict liability claim on a failure to warn theory (but not on a manufacturing or design defect theory); and (2) plaintiff's negligence claim arising from a failure to test or investigate and a failure to warn. The district court excluded any theory about a failure to report to the FDA.

On the first day of trial, the district court merged the strict liability and negligence claims because it determined that, pursuant to Rule 16 of the Federal Rules of Civil Procedure and Nebraska law, "sending the case to the jury under two different warning theories would lead to confusion and inconsistent results." The trial court also concluded that the failure to test or investigate component of the plaintiff's negligence claim "would be redundant," explaining that unless Somatics's "negligent failure to test resulted in a warning defect," it couldn't have caused cognizable injury and thus was not independently actionable. The court added that there is "no separate cause of action for failure to test," because this theory is "subsumed within a claim for failure to properly design or properly warn."

During the course of the trial, Thelen unsuccessfully offered a portion of a sixteen-minute patient consent video featuring Thelen's treating physician, Dr. Sharma, that had been produced by the CHI Health hospital. The district court excluded the video under

Federal Rule of Evidence 403 since it determined that the video would "end up confusing the issues because then we're going to be focusing on disclosures that were given to the patient from the doctor as opposed to disclosures given from the manufacturer to the patient."

The district court instructed the jury on proximate cause this way: "In order to prove that inadequate instructions or warnings proximately caused Thelen's injury, Thelen must prove that his prescribing physician would have altered his conduct had adequate warnings and instructions been provided." During closing argument, counsel for Somatics told the jury that for Thelen to succeed, the plaintiff must show that "Dr. Sharma would not have prescribed ECT to Mr. Thelen if the words brain damage were in the manual instead of permanent memory loss." Thelen's counsel did not object to these statements when they were made during closing. Counsel interposed an objection only later, after the jury had commenced its deliberative process, and only after the jury passed a note to the court asking a series of questions. Thelen sought a curative instruction; the district court rejected it as untimely.

At the conclusion of a seven-day trial, the jury determined that Somatics placed its ECT device on the market without adequate instructions or warnings to the physician who prescribed the treatments to Thelen, but it found that the absence of adequate warnings was not the proximate cause of injury to Thelen. The jury awarded Thelen no damages, and the district court affirmed the jury verdict in its final judgment.

Thereafter, Thelen moved for a new trial under Federal Rule of Civil Procedure 59. Thelen claimed that: Dr. Sharma's patient consent video was highly probative yet erroneously excluded; the district court issued an erroneous jury instruction on proximate cause under Nebraska law; a curative instruction should have been given after Somatics's closing argument on proximate cause; the district court improperly excluded Dr. Hannappel's testimony; and the district court erroneously dismissed Thelen's design defect claim at summary judgment. The district court denied Thelen's Rule 59 motion.

This timely appeal ensued.

II.

We review a district court's grant of summary judgment de novo, taking "the evidence and all reasonable inferences drawn from it in the light most favorable to the nonmoving party." *Tesoriero v. Carnival Corp.*, 965 F.3d 1170, 1177 (11th Cir. 2020) (quoting *Hornsby-Culpepper v. Ware*, 906 F.3d 1302, 1311 (11th Cir. 2018)). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Tesoriero*, 965 F.3d at 1177 (citation omitted).

We review a district court's denial of a motion for a new trial for abuse of discretion. *Lamonica v. Safe Hurricane Shutters, Inc.*, 711 F.3d 1299, 1312 (11th Cir. 2013). "The only grounds for granting [a

Rule 59] motion are newly-discovered evidence or manifest errors of law or fact." *Arthur v. King*, 500 F.3d 1335, 1343 (11th Cir. 2007) (quoting *In re Kellogg*, 197 F.3d 1116, 1119 (11th Cir. 1999)). A district court's refusal to give a requested jury instruction, including a curative instruction, is only reviewed for abuse of discretion. *Lamonica*, 711 F.3d at 1309 (citing *Pensacola Motor Sales Inc. v. E. Shore Toyota, LLC*, 684 F.3d 1211, 1224 (11th Cir. 2012)).

"We review jury instructions de novo to determine whether they misstate the law or mislead the jury to the prejudice of the objecting party, but the district court is given wide discretion as to the style and wording employed in the instructions." *Goldsmith v. Bagby Elevator Co.*, 513 F.3d 1261, 1276 (11th Cir. 2008) (citations omitted). "Reversal is warranted for the failure to give a proposed instruction only if this failure prejudiced the requesting party." *Id.* That is, "[s]o long as his jury instructions reflect the pertinent substantive law, the trial judge is given wide discretion as to the style and wording that he may employ." *Andres v. Roswell-Windsor Vill. Apartments*, 777 F.2d 670, 673 (11th Cir. 1985).

Finally, we review for abuse of discretion a district court's decision to admit or exclude certain evidence or expert testimony. *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc). We will not reverse a district court's evidentiary ruling on expert testimony "unless the ruling is manifestly erroneous." *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997)). Thus, a reviewing court "will reverse only if the error may have had a substantial influence on the outcome of the proceeding." *Knight ex rel.*

Kerr v. Miami-Dade County, 856 F.3d 795, 813 (11th Cir. 2017) (quoting *United States v. Augustin*, 661 F.3d 1105, 1127 (11th Cir. 2011)).

III.

A.

First, Thelen argues that the district court erred in granting summary judgment for Somatics on his design defect claim. Reviewing the evidence de novo and taking it in the light most favorable to Thelen, we are satisfied that the district court properly disposed of this claim.

All parties agree that we look to the substantive law of Nebraska to inform the meaning of a design defect. To establish a design defect under Nebraska law, a plaintiff must show that a defect renders a product "unreasonably dangerous," meaning that it "has a propensity for causing physical harm beyond that which could be contemplated by the ordinary user or consumer." *Pitts v. Genie Indus.*, 921 N.W.2d 597, 608 (Neb. 2019). The plaintiff must also prove by a preponderance of the evidence that the defect was the "proximate" cause of his injury. *Id.* at 609. The relevant consumer for design defect claims is the patient, not the physician. *See Langner v. Bos. Sci. Corp*, 492 F. Supp. 3d 925, 933 (D. Neb. 2020) ("Although not stated explicitly in Nebraska case law, it is implicit that the consumer or user of a medical device or prescription drug is the patient -- not the physician.").

Thelen failed to present sufficient evidence to create a genuine issue for trial on his design defect claim -- he has not shown that

the product was unreasonably dangerous or that any claimed defect was the proximate cause of injury.

First, Thelen offers as relevant evidence of a design defect the ECT consent form, a CHI Health hospital information pamphlet, Somatics's website advertisement, and a Thymatron IV device manual. He claims that none of them warns a patient of the risk of "brain damage." But the various documents in fact alert the patient to the serious, indeed potentially grievous, risks associated with ECT, including risks to the brain. The documents confirm that ECT can cause death as well as the permanent loss of memory. The consent form specifically warns that ECT could cause "short term memory loss" as well as "mortality, temporary or permanent heart abnormalities, . . . prolonged seizures and permanent memory loss." The CHI Health pamphlet states that potential risks include "mortality, temporary or permanent heart abnormalities, oral injuries, reactions to medications, injuries to muscles, bones or other parts of body, prolonged seizures, and permanent memory loss." The device manual also observes: "Please note that nothing in this manual constitutes, or should be construed as, a claim by Somatics LLC that confusion, cognitive impairment, or memory loss (short-term, long-term, recent, remote, transient, or persistent) can not occur as the result of ECT. Many patients experience temporary loss of recent or remote memories with ECT . . . . A few patients have reported experiencing persisting loss of memories or memory functions after ECT."

While these documents do not use the term "brain damage," they unambiguously warn the patient of the potential serious, even fatal, risks associated with ECT -- including short- and long-term memory loss, bodily injury, and even death. A reasonable consumer -- the focal point of our analysis -- would readily contemplate that the risk of "brain damage" is encompassed in the risk of permanent memory loss. It is hard to imagine an ordinary consumer not understanding that "permanent memory loss" is associated with some kind of injury to the brain. Indeed, Dr. Omalu, one of Thelen's experts, observed at trial: "It is a fact" that "brain damage is equivalent . . . in Mr. Thelen's case to loss of memory." He also testified that: "[W]henever any human being suffers a seizure, it is a manifestation of brain injury and brain damage." Another one of Thelen's experts, Dr. Read, said this at trial: "[P]ersistent/permanent memory loss and brain damage" are used "interchangeably to the extent that brain damage is a term which there is no consensus or agreement on."

Thelen also relies on expert testimony from Dr. Kenneth Castleman (a biomedical engineer), who is not a medical doctor. Dr. Castleman submitted a declaration stating that: "Despite its widespread use, ECT exposes patients to risks of brain damage that have not been thoroughly evaluated." After reviewing the scientific literature, Dr. Read separately concluded in his expert report that "ECT causes persistent/permanent memory loss and brain damage in a substantial proportion of recipients, somewhere in the range of 12% to 55%." Thelen argues that this testimony suggests a design defect in Somatics's Thymatron IV device. But, as we've

observed, to establish a design defect, Thelen must show that the product is dangerous "beyond that which could be contemplated by the ordinary user or consumer." *Pitts*, 921 N.W.2d at 608. Thelen has not presented evidence that the specific Thymatron IV device used was unreasonably dangerous relative to ordinary expectations, but rather that ECT generally presents certain detailed risks (including the most grievous ones), which were made known to Thelen before his treatments.

Finally, Thelen offered testimony from his treating physician and parents as evidence of a design defect. Dr. Sharma testified, when asked about whether he had seen ECT cause brain damage in any of his patients: "No. I have not." Thelen's mother likewise testified that the various physicians she spoke with, including Dr. Sharma, said that "ECT doesn't cause brain damage." And Thelen's father testified that Dr. Sharma did not "say anything about the potential to suffer any sort of brain injury" from ECT. But as the district court found, the fact that Thelen's physician and parents were seemingly unaware about the risks of ECT does not mean that the *ordinary patient* would not have been aware of these risks. Again, Thelen must present objective evidence of "ordinary knowledge common to the community" concerning ECT, not subjective evidence about "his own expectations."

Moreover, to prove that a design defect rendered the product unreasonably dangerous, the plaintiff must show that the defect was the proximate cause of the injury. *See id.* at 609. Thelen's only claim here is that the product was marketed without adequate

warnings, which in turn caused Dr. Sharma to inadequately warn Thelen. The problem with the argument is that the jury directly found that while the warnings made by Somatics were inadequate, the inadequate warnings did not cause any injury to the plaintiff. On this record, Thelen is hard-pressed to establish that he was prejudiced because the design defect claim was not sent to the jury.

B.

Thelen also argues that the district court erred in merging his negligence and strict liability claims. The court sua sponte merged the claims on the first day of trial to "simplify issues" under Federal Rule of Civil Procedure 16, concluding that both claims were grounded in Somatics's failure to warn. *See* Fed. R. Civ. P. 16(c)(2)(A) ("[T]he court may consider and take appropriate action on the following matters: formulating and simplifying the issues, and eliminating frivolous claims or defenses."). The trial court underscored the risk that "under a two-theory approach, the jury might conclude under the negligence theory that the manufacturer was negligent (that is, failed to act with reasonable care) with respect to the warnings it provided with its product, while at the same time concluding under the strict liability theory that the warnings were adequate." Thelen says, however, that the district court erred because the negligence claim was predicated on more than a failure to warn -- it also encompassed a failure to test and a failure to investigate. We remain unpersuaded.

Under Nebraska law, negligence and strict liability *can* be independent causes of action in failure to warn cases. *See Freeman*,

618 N.W.2d at 845 ("Aside from pleading theories of recovery under strict liability for specific product defects, a plaintiff may assert a theory of recovery based on negligence."). But the Nebraska Supreme Court has also recognized the "merger of doctrines" that allows the court to "adopt[] a single theory approach":

> Instead of focusing on doctrinal tort categories such as negligence or strict liability, the Third Restatement functionally defines each of the three basic types of product defect claims: design, manufacturing, and warning defect claims. The Third Restatement adopts the position that the definition of 'defect' is the important issue and should remain the same regardless of the doctrinal tort category under which it is brought. . . . [T]wo or more factually identical defective-design claims or two or more factually identical failure-to-warn claims should not be submitted to the trier of fact in the same case under different doctrinal labels. . . . To allow two or more factually identical [] claims to go to a jury under different labels, whether 'strict liability,' 'negligence,' or 'implied warranty of merchantability,' would generate confusion and may well result in inconsistent verdicts.

Id. at 843 (citing Restatement (Third) of Torts: Prod. Liab. § 2 (1997)). Since Somatics's purported failure to warn underlay both the plaintiff's negligence and strict liability claims, the district court acted well within its discretion in merging the two claims. The claims were "factually identical" -- they arose out of the same alleged warning defect. *Id.*

Indeed, Thelen's counsel, Mr. Bijan Esfandiari, acknowledged as much in an exchange with the district court:

> **MR. ESFANDIARI:** The negligence claim, Your Honor, is failing to act as a reasonable manufacturer would have done under the circumstances. . . .
>
> **THE COURT:** By doing what, not having air-conditioning in its factory?
>
> **MR. ESFANDIARI:** No, *by failing to warn*, failing to provide warnings.
>
> **THE COURT:** Failure to warn, that's our strict liability claim. Go ahead.
>
> **MR. ESFANDIARI:** Both of them, you can have one under negligence. You can have one under strict liability. . . .
>
> **THE COURT:** Wouldn't that only cause injury if it was -- you know, resulted from a failure to warn? Isn't a failure to investigate or test really an independent cause of action? . . .
>
> **MR. ESFANDIARI:** It's part of a negligence claim that also is -- you know, informs on the conduct of the company and informs on whether the company was *negligent in failing to warn*, because they failed to investigate properly in order to inform themselves of the risk. And, therefore, because they failed to inform themselves of the risk, *they did not provide adequate warnings*. . . .

Pretrial Conference Proceedings Transcript at 42–43, Dkt. No. 208 (emphases added).

Although Thelen now attempts to cast his failure to test and failure to investigate claims as independent theories of negligent liability, as Thelen's counsel acknowledged, both theories require proving a failure to warn in order to succeed. Under Nebraska's merger doctrine, as explicated by its high court, the district court did not err in exercising its broad discretion under Rule 16 to merge the two claims. *See Pac. Indem. Co. v. Broward County*, 465 F.2d 99, 103 (5th Cir. 1972) (holding that Rule 16 "gives the trial court broad discretion in conducting pre-trial procedures in order to narrow the issues, reduce the field of fact controversy for resolution, and to simplify the mechanics of the offer and receipt of evidence").[2]

C.

Thelen further claims that the district court fatally erred in its jury instruction on proximate cause. For starters, while Thelen asked for a very broad jury instruction on proximate cause, the instruction the court actually gave was quite broad, especially when compared to Somatics's narrower request. The court told the jury: "In order to prove that inadequate instructions or warnings proximately caused Thelen's injury, Thelen must prove that his prescribing physician would have altered his conduct had adequate warnings and instructions been provided." Thelen argues that this instruction was erroneous because Nebraska law has never required

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[2] In *Bonner v. City of Prichard*, 661 F.2d 1206 (11th Cir. 1981) (en banc), we adopted as binding precedent all Fifth Circuit decisions issued before October 1, 1981. *Id.* at 1209.

a plaintiff to establish that his physician would have altered his conduct had adequate instructions been provided. Thelen maintains that the instruction erroneously applied the learned intermediary doctrine -- which applies to the element of duty -- to the element of causation. Thelen's proposed jury instruction read more generally: "A proximate cause is a cause that produces a result in a natural and continuous sequence, and without which the result would not have occurred."

However, as the district court noted in its Rule 59 order, "Thelen cites no contrary Nebraska authority" to support his view that the learned intermediary doctrine does not apply to causation. While there is "no controlling Nebraska authority on this principle of causation," several federal district courts interpreting Nebraska law have applied the learned intermediary doctrine to the causation inquiry too. *See, e.g.*, *Langner*, 492 F. Supp. 3d at 933 ("Under the learned intermediary doctrine, the failure of a manufacturer to provide the physician with adequate warnings must be the cause in fact and proximate cause of the plaintiff's injuries. . . . In other words, the plaintiff must demonstrate that the treating physician would not have prescribed the medical device if the manufacturer had given a different warning.") (citing *Ideus v. Teva Pharms. USA, Inc.*, 361 F. Supp. 3d 938, 946 (D. Neb. 2019) ("[T]o avoid summary judgment, Ideus must demonstrate that had the package insert contained a different warning, the treating physician would not have used or prescribed [the product].")).

Inasmuch as Thelen has not shown that the district court "misstate[d] the law or misle[]d the jury to the prejudice of the objecting party," his argument on appeal fails. *Goldsmith*, 513 F.3d at 1276. Additionally, Thelen's counsel conceded at several points during the charge conference that the proximate cause instruction as given was correct. When asked if Thelen had to "prove that his treating physicians would have altered their conduct had adequate warnings been given," his counsel said, "Yes. Your Honor has it correct." Thelen's counsel also said that "whoever wrote these jury instructions knew the law, and it's the conduct of the physician that matters," and "I think the instructions on this point are accurate as written." At another point in the proceedings, counsel argued "for the appellate record" that "when Somatics or any manufacturer fails to warn the physician, then it no longer can seek shelter behind the learned intermediary defense." While Thelen may have preserved his argument for appeal, his counsel's concessions also suggest that the district court was not mistaken in giving this jury instruction, and regardless, that he would not be prejudiced by it.

Moreover, even if the instruction were erroneous -- and we do not believe that it was -- Thelen does not explain how he suffered "prejudicial harm" warranting reversal. *McElroy ex rel. McElroy v. Firestone Tire & Rubber Co.*, 894 F.2d 1504, 1509 (11th Cir. 1990). He has not shown (as he must) that he would have succeeded on proximate cause if the court had provided a slightly broader jury instruction.

Ultimately, "the trial judge is entitled to wide discretion over the style and wording employed as long as the instructions accurately reflect the law." *Schafer v. Time, Inc.*, 142 F.3d 1361, 1368 (11th Cir. 1998). Thelen cannot fairly claim that the trial court abused this wide discretion in its jury instruction on proximate cause.

D.

Thelen also raises a related claim that Somatics's counsel offered the wrong legal standard for proximate cause during his closing argument and that the district court abused its discretion in failing to give a curative instruction. This error, he asserts, required the district court to set aside the verdict. Again, we are unpersuaded.

During closing, Somatics's counsel said that in order for Thelen to succeed on his claim, "Dr. Sharma *would not have prescribed ECT* to Mr. Thelen if the words brain damage were in the manual instead of permanent memory loss." Jury Trial Proceedings Transcript at 54, Dkt. No. 264 (emphasis added). Defense counsel's emphasis on prescription was more specific than the court's jury instruction, which, again, required that the "prescribing physician would have altered his conduct." Thelen protested that Somatics "used the word prescribed when the instructions are the conduct of the physician," and asked the court for a curative instruction. The court denied the request, finding that the objection had been lodged too late.

The district court did not abuse its discretion in failing to give a curative instruction or in failing to reread its jury instruction

on proximate cause. For one thing, Thelen failed to make a contemporaneous objection and did not object until after the jury had already begun deliberations, waiving his objection in the process. *See Oxford Furniture Cos. v. Drexel Heritage Furnishings, Inc.*, 984 F.2d 1118, 1129 (11th Cir. 1993) (rejecting defendants' claims about plaintiff's closing argument because defendants, "while now claiming severe prejudice because of the argument, made no attempt to object to the [closing] arguments when they were made"). The whole point of interposing a timely objection, after all, is to provide the district court with the opportunity to timely correct the error.

Moreover, and even more basic, Thelen has not established that he was prejudiced by the district court's decision not to provide a curative instruction. *Cf. McWhorter v. City of Birmingham*, 906 F.2d 674, 677 (11th Cir. 1990) ("Where the interest of substantial justice is at stake, improper argument may be the basis for a new trial even if no objection has been raised.") (citation modified). Simply put, Thelen has not shown that Somatics's closing argument negatively affected the jury's verdict in any way. Defense counsel's language largely mirrors the more general jury instruction that Dr. Sharma would have needed to alter his conduct. It reasonably follows from the jury instruction that altering the physician's conduct in this case would mean not prescribing the ECT treatment to his patient. Thelen has not offered any other plausible reading.

In any event, even if there was some error in Somatics's argument about the controlling law, the judge made it crystal clear

that the jury was required to follow the law as he explained it and that anything the lawyers say is not evidence and is not binding on the jury. "We generally presume that jurors follow their instructions." *United States v. Hill*, 643 F.3d 807, 829 (11th Cir. 2011). In short, Thelen has not established that he was prejudiced by the court's refusal to provide a curative instruction because it is exceedingly remote that Somatics's slightly narrower instruction on proximate cause affected the verdict.

E.

Next, Thelen argues that the district court abused its discretion in excluding a 2009 patient consent video featuring Dr. Sharma because he claims that it was relevant to Dr. Sharma's knowledge about the risks associated with ECT treatment. While the judge first said that the video would be admissible, although he would not allow it to be published to the jury, he later changed his mind, and excluded the video entirely, citing to Rule 403 of the Federal Rules of Evidence. *See* Fed. R. Evid. 403 ("The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."). The court's expressed concern was that the video would confuse the jury because it focused on "disclosures that were given to the patient from the doctor as opposed to disclosures given from the manufacturer to the patient," and the heart of Thelen's claim turned on the disclosure made by the manufacturer to the physician.

The district court did not abuse its discretion under Rule 403. For one thing, as the district court observed, the jury was already aware from Dr. Sharma's own testimony that he did not believe ECT posed a risk of brain damage. ("That's what the doctor knew at the time, because that's what he was conveying in his video, which, of course, that's already in evidence through his testimony."). So the admission of the video would have been wholly cumulative about Dr. Sharma's understanding of the risks associated with ECT treatment. Because Dr. Sharma's views were fully disclosed to the jury, the probative value of admitting the video evidence was marginal, and the district court could readily determine, as it did, that the video's slender evidential value was substantially outweighed by the risk of creating jury confusion about the legal standard surrounding a failure to warn case involving a learned intermediary. The district court's Rule 403 determination did not amount to an abuse of discretion.

What's more, any evidentiary error by the district court may compel a reversal of a jury verdict only if the "error affected 'a substantial right.'" *Proctor v. Fluor Enters., Inc.*, 494 F.3d 1337, 1349 (11th Cir. 2007) (quoting *United States v. Stephens*, 365 F.3d 967, 974 (11th Cir. 2004)). In this case, the exclusion of Dr. Sharma's patient consent video did not (and could not) affect the plaintiff's substantial rights, because the jury ultimately determined that "Somatics placed the ECT device on the market without adequate instructions or warnings to the physician who prescribed ECT treatment to Thelen." Since the jury found for Thelen on the failure to warn

issue, it's hard to imagine how the exclusion of the video could have undermined Thelen's position.

F.

Finally, Thelen argues that the district court abused its discretion in excluding Dr. Hannappel's expert testimony on medical causation. Dr. Hannappel is a neuropsychologist who first saw Thelen in August 2017, approximately one year after his final ECT treatment. His evaluation offered that "[f]rom a neuropsychological perspective, testing results and [Thelen's] history suggest moderate circumscribed declines in his cerebral functioning, possibly related to the ECT treatments as there do not appear to be other explanations for the pattern of his neuropsychological deficits." Dr. Hannappel also later testified that he believed Thelen's 90 plus ECT treatments were a "substantial factor in his diagnosis of neurocognitive disorder." Accordingly, Thelen sought to present testimony from Dr. Hannappel in order to establish that the resultant cognitive defects were caused by the ECT treatments.

The district court did not abuse its considerable discretion in barring the admission of Dr. Hannappel's opinion testimony, because he was not competent by background, training, or experience to render a causation opinion, and any opinion he might have offered was not methodologically sound or reliable.

We begin with Rule 702 of the Federal Rules of Evidence, which governs the admissibility of expert testimony. *See* Fed. R. Evid. 702 ("A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of

an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case."). As we have long held, in determining the admissibility of expert testimony under Rule 702, a court must consider whether: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *Frazier*, 387 F.3d at 1260 (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). Ultimately, a trial court has "considerable leeway" in exercising its discretion to admit or exclude expert testimony. *Frazier*, 387 F.3d at 1258 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

The district court's *Daubert* determination was well founded. For one thing, Dr. Hannappel was a neuropsychologist, not a physician. For another, as even he conceded at his deposition, he was not "qualified to offer medical causation opinions." Moreover, he explained that "treatment with ECT is outside of my scope of expertise."

What's more, as the district court concluded, Dr. Hannappel's methodology for opining about causation was unreliable because he failed to evaluate alternative explanations for Thelen's cognitive decline in 2017. Thelen argues that Dr. Hannappel performed a differential diagnosis to arrive at his causation opinion, but by Dr. Hannappel's own account, he did not do so. "A reliable differential analysis requires an expert to 'compile a comprehensive list of hypotheses that might explain' a plaintiff's condition." *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1310 (11th Cir. 2014) (quoting *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1195 (11th Cir. 2010)). But Dr. Hannappel did not consider whether the plaintiff's serious substance abuse of alcohol, opioids, and cocaine or prior suicide attempts might have contributed to Thelen's mental state. *See e.g.*, *Chapman*, 766 F.3d at 1309 (holding that a "reliable differential analysis . . . 'must at least consider other factors that could have been the sole cause of the plaintiff's injury'") (quoting *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010)). And in Dr. Hannappel's own words from his 2017 evaluation: "Obviously, all potential reversible conditions that might be causing his cognitive decline should be ruled out," something Dr. Hannappel never did. In short, the district court did not abuse its considerable discretion in determining that Dr. Hannappel was unqualified to opine on medical causation.

Thelen argues in the alternative that even if Dr. Hannappel's expert opinions were properly excluded, as Thelen's treating physician, he should have been able to offer them as a lay witness under Rule 701 of the Federal Rules of Evidence. *See* Fed. R. Evid. 701

("If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is: (a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702."); *see, e.g.*, *United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005).

The first problem with this argument is that the opinion Dr. Hannappel was offering on medical causation required a diagnostic explanation far more complex than simply observing a broken jaw or a broken arm. *See, e.g.*, *Travelers Prop. Cas. Co. of Am. v. Ocean Reef Charters LLC*, 71 F.4th 894, 907 n.9 (11th Cir. 2023) ("[W]e have not held that any treating physician can testify as a lay witness about any diagnosis she made while treating the patient."). Rule 701 expressly prohibits lay opinions based on scientific, technical, and specialized knowledge. *See* Fed. R. Evid. 701(c). The explanation of the cause of Thelen's cognitive decline required a complex diagnostic process, plainly calling for scientific and technical reasoning. Any opinion Dr. Hannappel might have offered on causation, even as a treating physician, would properly be considered under Rule 702 and be subject to *Daubert* standards. *See Chapman*, 766 F.3d at 1316 n.23 ("[A] treating doctor . . . is providing expert testimony if the testimony consists of opinions based on 'scientific, technical, or other specialized knowledge' *regardless of whether those opinions were formed during the scope of interaction with a party prior to litigation*.") (emphasis added) (citation omitted).

Thelen's additional argument that Dr. Hannappel should have been allowed to testify as a lay witness because he was no more than a treating physician fails because the fact is that Dr. Hannappel did not begin treating Thelen until June 2020, nearly three years after he opined that "[t]esting results indicate that [Thelen's] cognitive declines could be related to his ECT treatments." The district court determined when it excluded this testimony that "at the time he formed his opinions, Hannappel was consulting with Plaintiff's treating physicians rather than treating Plaintiff himself."

The long and short of it is that the district court did not abuse its discretion in barring Dr. Hannappel's testimony.

We **AFFIRM** the judgment of the district court.

AFFIRMED.