No. 23-13892

In the

United States Court of Appeals

for the

Eleventh Circuit

JEFFREY THELEN;

Plaintiff-Appellant,

vs.

SOMATICS, LLC,

Defendant-Respondent.

Appeal from an Order of the United States District Court for the Middle District of Florida, Case No. 8:20-cv-01724-TPB-JSS
Hon. Thomas Barber

APPELLANT'S OPENING BRIEF

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Appellant submits this list, which includes the trial judge, and all attorneys, person, associations or persons, firms, partnerships, or corporations that have an interest in the outcome of this review:

1. Abrams, Richard (Co-Owner of Somatics, LLC)
2. Alarcon, Monique (Attorney)
3. Barber, Thomas P. (District Court Judge)
4. Benkner, Jason (Attorney)
5. Cole, Susan J. (Attorney)
6. Esfandiari, Bijan (Attorney)
7. Freiman, Jonathan (Attorney)
8. Hess, Tana (Court Reporter)
9. Jones, Bill (Court Reporter)
10. Lockwood, Rebekah (Court Reporter)
11. Mirkovich, David (Manager of Somatics, LLC)
12. Nunn, Emma (Attorney)
13. Schlein, Mark (Attorney)
14. Sneed, Julie S. (Magistrate Judge)

15. Somatics, LLC (Defendant/Appellee)

16. Swartz, Conrad (Co-Owner of Somatics, LLC)

17. Thelen, Jeffrey (Plaintiff/Appellant)

STATEMENT REGARDING ORAL ARGUMENT

Appellant, Jeffrey Thelen, submits that oral argument will facilitate the Court's resolution of this appeal. The district court's dismissal of Thelen's products liability claim for design defect under Nebraska law, its exclusion of a non-retained expert's causation testimony, its ruling on jury instructions concerning proximate causation under the learned intermediary doctrine, and the District Court's evidentiary rulings at trial, present both novel issues of law and intensive fact-bound inquiries, such that oral argument would aid the Court's decisional process. Accordingly, pursuant to Federal Rule of Appellate Procedure 34(a) and Eleventh Circuit Rules 28-1(c) and 34-3(c), Thelen respectfully requests oral argument.

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JURISDICTIONAL STATEMENT

This products liability action was initiated on July 24, 2020, in the United States District Court for the Middle District of Florida. The district court possessed subject-matter jurisdiction under 28 U.S.C. § 1332(a) because, at the time of filing, the amount in controversy exceeded the sum or value of $75,000.00. Appellant, Jeffrey Thelen, is a citizen of Nebraska, and Defendant-Appellee, Somatics, LLC, is a limited liability company formed and existing under the laws of the State of Florida with its principal place of business in Florida.[1] ECF 1 at 2-3; ECF 132 at 1-2. Accordingly, at all relevant times, the parties were of diverse citizenship.

On June 8, 2023, following a seven-day jury trial, the jury found Somatics had failed to provide adequate instructions and warnings concerning its ECT device, but that the absence of such instructions or warnings was not the proximate cause of damage to Thelen. ECF 246 at 1.[2] The district court accordingly entered judgment in favor of Somatics on June 9, 2023. ECF 249 at 1.

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[1] Somatics' Co-Manufacturer, Elektrika, Inc., was also a defendant in the district court proceedings. Elektrika, Inc. is a New York corporation with its principal place of business in New York.

[2] Record references are to the ECF filing number in the district court case below (Case No. 8:20-CV-01724-TPB-JSS), unless otherwise indicated.

On July 7, 2023, Thelen timely filed a Rule 59 Motion for a New Trial and Motion to Alter or Amend the Judgment (ECF 269 at 1), thereby tolling the deadline for filing a notice of appeal. *See* Fed. R. App. P. 4(a)(4)(v); *see also Ruiz v. Wing*, 991 F.3d 1130, 1137 (11th Cir. 2021). On November 7, 2023, the district court entered an order denying Thelen's Rule 59 Motion. ECF 287 at 9. Thelen timely filed his notice of appeal of the final judgment on November 27, 2023. ECF 288 at 1-2. Accordingly, this Court has jurisdiction over Thelen's appeal of the final judgment and related prior orders pursuant to 28 U.S.C. § 1291.

ISSUES PRESENTED

1. Whether the district court erred in dismissing plaintiff's design defect claim when the defendant failed to meet its burden of production on summary judgment and the plaintiff nonetheless presented competent evidence creating a triable issue of fact concerning design defect and the expectations of an ordinary consumer under Nebraska law?

2. Whether, in a claim against a medical device manufacturer for a failure to warn of a risk, the court erred in instructing the jury that the learned intermediary doctrine applied to the plaintiff's *causation* burden under Nebraska law?

3. Whether the court erred in *sua sponte* dismissing a plaintiff's meritorious negligence claim to "simplify" the case?

4. Whether the court abused its discretion in excluding medical causation testimony of plaintiff's treating provider who personally examined him and treated him for several years?

5. Whether the court abused its discretion in excluding admissible video evidence of plaintiff's treating physician (which plaintiff had viewed prior to consenting to his ECT procedure) showing physician's knowledge of the risks of a medical treatment?

6. Whether the court erred in refusing to reopen the case to admit video evidence of plaintiff's treating physician discussing his knowledge of the risks of treatment once the jury deliberations had begun and the jury asked questions concerning the physician's knowledge of the risks of treatment?

7. Whether the court erred in refusing to give plaintiff's requested curative instructions after defense counsel on multiple occasions misrepresented the law on causation during her closing?

STATEMENT OF THE CASE

I. Procedural History

In this products liability action, Plaintiff, Jeffrey Thelen ("Thelen"), alleges he suffered brain damage, resulting in permanent memory loss and neurocognitive injury, after receiving 95 sessions of electroshock therapy ("ECT") with a device manufactured by Defendant Somatics, LLC. ECF 1 at 1-2; ECF 261 at 203:2-204:6.

Thelen initiated this action against Somatics and its co-manufacturer Elektrika, Inc., alleging claims of negligence (failure to warn, failure to test, and design defect) and strict liability (failure to warn and design defect), among others. ECF 1 at 20-25.

Following discovery, Somatics and Elektrika moved for summary judgment on various grounds. Defendants also moved to exclude two of Thelen's six retained expert witnesses, as well as the specific causation opinion of Thelen's non-retained treating clinical psychologist, Dr. Mark Hannappel, who performed neuropsychological testing on Thelen in 2017, diagnosed him with a neurocognitive disorder, and continuously treated Thelen for his condition since 2020. ECF 170 at 4-6.

On May 5, 2023, the district court granted Somatics' summary

judgment motion, in part. ECF 169 at 17-18. The district court erroneously dismissed Thelen's claim for design defect (on grounds never argued or factually supported by defendants) and held Thelen had not offered any evidence of the expectations of the ordinary consumer, aside from his own expectation. *Id*. at 14; ECF 154.

The court also granted defendants' motion to exclude the specific causation opinion of Thelen's treater, Dr. Hannappel, erroneously finding that, under *Daubert*, Dr. Hannappel was not qualified to render an opinion on medical causation and his medical causation testimony was unreliable (based on the court's own weighing of the evidence). ECF 155; ECF 170 at 4-6.

Thereafter, during pretrial proceedings, and even during and post-trial, the district court made various rulings, including rulings on jury instructions that contradicted Nebraska substantive law, which governs this diversity action, and federal procedural rules. *First*, the court *sua sponte* dismissed Thelen's negligence claim (which survived summary judgment) by "merging" it with Thelen's strict liability failure to warn claim, to "simplify" the trial. ECF 258 at 13-16; ECF 262 at 235. *Second*, the court issued erroneous and prejudicial jury instructions concerning Thelen's

failure to warn claim and his burden on proximate causation. *See* ECF 244 at 4. Contrary to Nebraska law, the court instructed the jury: "In order to prove that the inadequate instructions or warnings proximately caused Thelen's injury, Thelen *must prove* that his prescribing physician would have altered his conduct…." *Id*. In fact, the learned intermediary doctrine is limited to the issue of duty and the jury should have been instructed accordingly.

During trial, the court made several evidentiary rulings, and failed to give a critical curative instruction Thelen requested, all of which individually and collectively prejudiced Thelen's presentation of his case. On June 8, 2023, following a seven-day trial, the jury returned a verdict finding Somatics had indeed failed to issue adequate warnings concerning its ECT device, but found the failure to warn was not a proximate cause of Thelen's injuries. ECF 246 at 1. This verdict came after Thelen's case in chief was severely truncated as his claims for design defect and negligence were dismissed, the causation opinion of his treating provider was excluded, critical video evidence by his ECT-prescribing provider was excluded, and the jury instructions submitted to the jury were flawed, coupled with improper closing arguments made by defense counsel.

Plaintiff appeals from the judgment entered on June 9, 2023, and all other orders subsumed or incorporated in that judgment, including the district court's summary judgment and *Daubert* orders. ECF 288 at 1.

II. Factual Summary

A. The Jury Found Somatics Failed to Warn Thelen's Prescribing Doctor of the Risk of Brain Damage and Permanent Memory Loss Associated with Somatics' Electroconvulsive Shock (ECT) Device

ECT is the practice of inducing a grand mal seizure through application of electricity to the brain. ECF 258 at 199:13-17. The procedure was discovered over 80 years ago, during the lobotomy era, in hopes of replacing insulin-induced comas to treat mental illness. Several early proponents of ECT argued ECT worked by reducing intellectual functioning and erasing traumatic memories. *Id.* at 199:23-202:12; 224:21-226:11. The effect of ECT on the brain is similar to closed-brain injury or traumatic brain injury. *Id.* at 226:6-228:22; *see also* ECF 262 at 50:14-65:12. Studies have shown that between 12 and 55 percent of patients suffer permanent autobiographical memory loss following ECT. ECF 258 at 229:14-230:7. According to a comprehensive review of previously conducted ECT studies, there have only been 11 poorly designed double blind "sham" studies ever conducted of ECT's efficacy, all pre-dating 1986,

and no study has shown ECT is better than sham ECT beyond the end of treatment, i.e., ECT cannot be said to have any long-term benefits. ECF 258 at 205:19-215:5.

Despite this history, Somatics manufactured and sold its Thymatron ECT device without conducting any studies and never undertook to study the risk of brain injury with its device. ECF 259 at 91-92. Nor did Somatics warn medical providers, including Thelen's medical providers, of the risks associated with its ECT device, even though it knew or should have known such risks. *See* ECF 247-1; ECF 262 at 63:13-24, 66:20-67:5, 69:9-70:13, 71:4-72:22, 87:17-88:19, 98:19-101:14 (Swartz testimony). In fact, in 2006, in response to a fear of potential lawsuits because its product labeling did not contain any warnings concerning the risk of brain damage or permanent memory loss, Somatics's owners contemplated adding stronger warnings, but ultimately decided *not* to add a warning. *Id.;* ECF 247-3.

B. Had Somatics Warned Thelen's Doctor About the Risk of Brain Damage, His Doctor Would Have Relayed Those Warnings to Thelen and Had Thelen Been So Warned, He Would Have Refused ECT

Jeffrey Thelen agreed to undergo ECT treatment based on the repeated assurances of his psychiatrist, including his ECT-prescribing

doctor, Dr. Arun Sharma, that ECT was safe and would be an effective means of treating his depression. ECF 259 at 144:2-148:17; ECF 261 at 68:19-69:12; ECF 261 at 203:2-204:6. From May 2014 to July 2016, Thelen received 95 sessions of ECT with Somatics' machine at CHI Hospital in Omaha, Nebraska. *Id*.

Dr. Sharma testified he did not believe ECT causes brain damage; however, he also testified that, if he had been informed ECT can cause brain damage, that is information he would pass on to his patients. ECF 260 at 217:5-218:23; 223:19-25.

After stopping ECT treatment, Thelen was left with severe and profound memory loss caused by a neurocognitive disorder his own physicians attributed to ECT. ECF 263 at 89:21-93:23; 101:11-106:9. The evidence presented at trial revealed Thelen, formerly an arborist, was unable to recall most of his autobiographical memories predating ECT. ECF 259 140:4-141:20; ECF 261 at 205:16-1. Now, Thelen cannot recall his ex-wife or memories from his childhood. ECF 259 146:4-147:7; ECF 261 at 205:16-206:20. Daily, Thelen struggles with retaining basic information, requiring him to carry a pocketbook to write things down, so he does not forget them. ECF 259 161:1-162:1; ECF 261 at 65:3-68:4. He often gets lost in

his own neighborhood, even on the way to his parents' house. ECF 142-7 at 131:6-21. His profound memory loss and cognitive difficulties have led Thelen to become severely isolated, confounding his depression. ECF 198 at 197:21-198:22; ECF 261 at 206:8-20; ECF 261 at 68:5-18; ECF 260 at 73:20-76:4; ECF 263 at 116:5-117:11.

SUMMARY OF THE ARGUMENT

The district court committed seven categories of error that individually and collectively warrant reversal of the judgment below.

First, the dismissal of Thelen's valid design defect claim on summary judgment was in error and prejudicial. Specifically, Somatics never met its burden of production to warrant summary judgment, and even if it had, Thelen submitted more than adequate evidence to create a triable issue of fact that defendant's device was defectively designed under Nebraska's consumer expectation test. This error was prejudicial because the ordinary consumer in a design defect claim is the patient (as opposed to the physician) and thus the jury instructions on causation would have been different and not included reference to the inapplicable conduct of the physician.

Second, the court erred in *sua sponte* dismissing Thelen's valid and

meritorious negligence cause of action to "simplify" the case pursuant to Rule 16 of the Federal Rules of Civil Procedure. Rule 16 does not give the court discretion to dismiss meritorious causes of action. Contrary to the court's views, Thelen's failure to warn claim was not duplicative of his strict liability warning claims (as it also included a negligent failure to test claim) and, under Nebraska law, a plaintiff may bring both a negligence and a strict liability claim based on the same facts and a negligent testing claim is independent of a labeling claim.

Third, the court's jury instructions on proximate cause were inconsistent with Nebraska Supreme Court precedent since the court introduced the learned intermediary doctrine into both elements of duty and causation, yet Nebraska law (and the Eighth Circuit law which effectuated the learned intermediary doctrine) is clear that the doctrine only applies to the issue of duty (or defect) and does *not* apply to causation.

Fourth, the court committed error in excluding relevant causation testimony from Thelen's treater, Dr. Hannappel, who performed neuropsychological testing on Thelen, treated him for several years, and concluded that Thelen's cognitive issues and memory loss were caused by his exposure to ECT.

Fifth, the court erred in refusing to admit and allow Thelen to play a patient consent video that was relevant to Dr. Sharma's knowledge of ECT's risks and corroborated the testimony of Thelen and his family concerning what the doctor told them about ECT's risks. The district court excluded the video without reviewing the video which on its own is an abuse of discretion, i.e., excluding evidence without even examining it.

Sixth, the court erred in refusing to reopen the case to allow admission of the Sharma video when, from the jury's written questions, it became clear they were interested in Sharma's knowledge of ECT's risks and the video would have addressed the jury's questions.

Seventh, the court erred in refusing to give Thelen's requested curative instructions after Somatics' counsel in her closing argument made multiple misrepresentations concerning the law and Thelen's causation burden.

STANDARDS OF REVIEW

Various standards govern this Court's review. *First*, this Court reviews a district court's grant of summary judgment *de novo*, viewing all evidence and drawing all reasonable inferences in favor of the non-moving party. *State Farm Mut. Auto. Ins. Co. v. Spangler*, 64 F.4th 1173, 1178 (11th

Cir. 2023); Fed. R. Civ. P. 56(a).

Second, a court's decisions about jury instructions are reviewed *de novo* to determine whether the instructions misstate the law or mislead the jury to the prejudice of the objecting party. *Goldsmith v. Bagby Elevator Co.*, 513 F.3d 1261, 1276 (11th Cir. 2008). Failure to give a proposed instruction warrants reversal if this failure prejudiced the requesting party. *Id.*

Third, this Court reviews a court's decision to exclude an expert's testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) under an abuse of discretion standard. *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1334 (11th Cir. 2010). On the other hand, appellate review concerning the applicability of *Daubert* is a question of law that is reviewed *de novo*. *City of Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F.3d 548, 556 (11th Cir. 1998).

Fourth, a district court's evidentiary rulings are reviewed for abuse of discretion. *Aycock v. R.J. Reynolds Tobacco Co.*, 769 F.3d 1063, 1068 (11th Cir. 2014). A district court abuses its discretion "if it applies an incorrect legal standard, applies the law in an unreasonable or incorrect manner, follows improper procedures in making a determination, or makes findings of fact that are clearly erroneous." *Brown v. Ala. Dept. of Transp.*, 597 F.3d 1160,

1173 (11th Cir. 2010). A clear error of judgment is also an abuse of discretion. *United States v. Brown*, 415 F.3d 1257, 1266 (11th Cir. 2005).

Finally, a district court's rulings about improper remarks made during closing argument is reviewed for abuse of discretion, see *Id.* at 1275, as is the court's failure to follow its own rules. *Mann v. Taser Int'l, Inc.*, 588 F.3d 1291, 1303 (11th Cir. 2009).

ARGUMENT

I. The District Court Erred in Dismissing Thelen's Design Defect Claim on Summary Judgment

A. District Court Abused Its Discretion in Allowing Defendants to Proceed with Summary Judgment Motions That Did Not Contain the Mandatory Separate Statement

Both defendants moved for summary judgment on various grounds. ECF 79 & 93. Somatics' motion did not brief the issue of design defect, rather Somatics incorporated by reference the arguments of co-defendant Elektrika. ECF 79 at 3. In violation of the Court's Case Management Order ("CMO"), neither defendant submitted the required "separate statement" of facts. This made it difficult for Thelen to determine what specific facts defendants contended supported their specific arguments. *See e.g.*, ECF 19 at 2-3 (¶¶6(a), (b) &(g)).

In his opposition brief, Thelen argued defendants' motions should be denied outright because they violated the CMO. ECF 99 at 6; *see also* ECF 19 at 3 (¶6(g)) ("A violation of any of these directives will result in the Court *sua sponte* striking a party's motion for summary judgment and incorporated memorandum of law without notice."). Rather than striking the summary judgment motions, the district court issued an *after-the-fact* order "dispens[ing] with the requirements of paragraph 6 of the November 2, 2020 [Case Management] Order." *See* ECF 121 (Minute Order).

Thelen, in compliance with the CMO, filed separate statements in opposition to the facts he was able to identify in defendants' respective briefs (*see* ECF 103 & 104; and 110 & 112) and a separate statement of additional facts, outlining material facts in opposition to the two summary judgment motions (ECF 101).

The district court abused its discretion by disregarding its own rules (after-the-fact) concerning the requirement of a separate statement, which severely prejudiced Thelen's ability to determine the bases of defendants' motions and the specific facts defendants contended were undisputed regarding each cause of action. This prejudice was magnified (as discussed *infra*) when the district court subsequently granted defendants' motion as

to design defect on a basis that was never legally articulated or factually supported by the defendants. *See In re Smith,* 231 B.R. 130, 132 (Bankr. M.D. Ga. 1999) ("the [separate] statement serves to notify the party opposing the motion as to what facts are claimed not subject to a genuine dispute so that the nonmoving party can consider whether a dispute exist[s].")

The requirement for separate statements in support of summary judgment "is not a mere technicality." *Mann,* 588 F.3d at 1303. Rather, the separate statement's purpose is to help the opposing party and the court identify and organize the issues in the case. *Id.*; see also *Garland v. Advanced Med. Fund, L.P. II*, 86 F. Supp. 2d 1195, 1199 (N.D. Ga. 2000) ("Imprecise and unsupported factual statements, which go to the very heart of a summary judgment determination, have a tendency to lead to imprecise and somewhat vague responses as the non-movant attempts to cover all the proverbial bases."). The district court abused its discretion in dispensing with the separate statement requirement to the prejudice of Thelen. The court should have denied the deficient motions outright.

B. Defendant Never Met its Burden of Production on Summary Judgment and, Under Eleventh Circuit Precedent, its Motion Should have been Denied

This Court undertakes *de novo* review of a grant of summary judgment. *Mann*, 588 F.3d at 1303. In moving to dismiss the design defect cause of action, the *sole* "evidence" defendant cited was a single page of the deposition transcript of one of Thelen's doctors (see ECF 93 at 20). Defendant's argument focused on the premise that, under Nebraska's consumer expectation test, the "ordinary users" of a medical device are doctors as opposed to patients, and that Thelen's doctors purportedly were aware of the risk of memory loss. Thelen opposed the motion by among other things, arguing that, for purposes of a design defect claim, the ordinary user under Nebraska law is the patient (not the doctor) and it is uncontroverted that neither Thelen nor his doctors were aware of the risk of brain damage. ECF 100 at 22-26.

The district court correctly rejected defendants' argument and agreed that, under Nebraska law, the ordinary user is the patient (not the doctor) and further held that a triable issue of fact existed as to whether Somatics had adequately warned. ECF 169 at 6-7 & 14. However, the court perplexingly still dismissed the design defect claim, erroneously holding that Thelen had not offered any evidence of the expectations of the

ordinary consumer, aside from his own expectation. *Id.* at 14. The Court's dismissal warrants reversal.

Procedurally, defendant's motion did not focus on the consumer expectation test from the perspective of an ordinary patient and thus defendant never met its burden of production to show the consumer expectation test had not been established. Rather, *the only* evidence defendants cited was the irrelevant deposition testimony of one of his doctors. ECF 93 at 20. Without any evidence in support of its motion, under established Circuit precedent, defendant did not meet its summary judgment burden and thus the burden never shifted to Thelen to create a triable issue of fact on design defect. *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991). In *Clark*, this Court reversed summary judgment because: "[t]he district court never discussed whether [defendant] met its burden as the moving party on summary judgment. The opinion discusses only what burden the plaintiffs had and why they did not meet it...As we have pointed out, that is *not* the law.") *Clark*, 929 F.2d at 608–09. Here as in *Clark*, summary judgement was inappropriate.

Given defendant failed to carry its burden of production, under *Clark*, the district court should have denied the summary judgment motion from

the outset as the burden never shifted to Thelen to establish a material disputed issue of fact. *Clark*, 929 F.2d at 608–09.

C. Even if the Burden had Shifted to Thelen, he Presented More than Sufficient Evidence to Create a Triable Issue of Fact as to His Design Defect Claim Under Nebraska Law

Under Nebraska law, "[a] product is defective in its design if it fails to perform as safely as an ordinary consumer would expect when it is used in a manner either intended by the manufacturer or reasonably foreseeable by the manufacturer." NEB. PRAC., NJI2d CIV. 11.22; *Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 568 (2000). A plaintiff is not required to show the feasibility of a safer alternative design to prevail on a design defect claim. *Kudlacek v. Fiat S.p.A.*, 244 Neb. 822, 832 (1994).

In his opposition brief and the separate statement of material facts, Thelen cited multiple sources of evidence, including documents, deposition testimony, and expert opinions, to support his design defect claim. *See* ECF 100 at 22-26; *see also* ECF 101. For example, Thelen pointed to the expert opinion of his biomedical engineering expert, Kenneth Castleman, Ph.D., whose report outlined design defects in Somatics' ECT machine, including *inter alia*, that the machine provides for an arbitrarily set dosage based on the age of the patient (so, a patient in his 70s would get 70% of the electrical

dose) even though there is no scientific basis for this arbitrary dose setting and can result in patients getting more than the appropriate dose of electricity, resulting in injury. ECF 100 at 24; ECF 107 at 8-9; *see also* ECF 105 at 12 (¶¶71-72).

Thelen also cited evidence that defendants failed to adequately test the Thymatron device for safety and efficacy. *See* ECF 100 at 24; ECF 106 at 29-43; ECF 105 at 12; ECF 111-17 at 4 & 6 (Somatics Owner admitting: "Somatics has never conducted any studies of any kind"). The Thymatron machine's design defects must also be juxtaposed with the fact that the efficacy of ECT has not been established. *See* ECF 100 at 25; ECF 105 at 10 (¶55).

The forgoing evidence was more than sufficient to establish design defect under Nebraska law. *Freeman*, 260 Neb. 552, 568–69; *Jay v. Moog Auto., Inc.*, 264 Neb. 875, 881 (2002). Indeed, another court reviewing the same evidence denied Somatics' motion for summary judgment for design defect, holding that "[plaintiff] has identified multiple alleged defects with the Thymatron that cause it to be unreasonably dangerous." *O'Neil v. Somatics, LLC*, 2022 WL 4611938, at *8 (D.N.H. Sept. 30, 2022) (New Hampshire). As to defendant's alternative argument that the standard is

the "*subjective* expectations of Thelen and his treating physician" (emphasis added) (ECF 93 at 20), Thelen responded by citing to evidence showing that, because his doctors were never warned about brain injury, he was likewise never informed about the risk by his doctors. ECF 100 at 26; see also ECF 101 at 14-16 (PUF No. 54-65). Thus, to the extent Thelen referred to his own subjective expectations, he did so because that is what the defendant's brief had alternatively argued. ECF 93 at 20. Thelen cannot be faulted for directly responding to the arguments made in defendant's brief and then be criticized and have his claim dismissed for not responding to arguments never advanced by defendant. *Goodman v. Fla. Pop, LLC*, 2022 WL 17366599, at *3 (11th Cir. Dec. 2, 2022); *Roe v. City of Atlanta*, 456 F. App'x 820, 821–22 (11th Cir. 2012) (same).

Thelen supported his opposition brief with *specific* citations to other objective evidence including expert reports, the foundational material identified in the expert reports, depositions and citations to the separate statement as outlined *supra.* Assuming the burden of production had shifted to Thelen, the foregoing objective evidence, which was specifically cited and referenced in the summary judgment opposition brief (ECF 100 at 22-27) was more than sufficient to establish all the elements of design

defect, including consumer expectation, under Nebraska law.

Other exhibits accompanying the summary judgment opposition provided further objective evidence of design defect and consumer expectation, including: (a) copies of the ECT consent document (which did not warn of brain damage) (ECF 111-2); (b) a copy of the hospital patient information pamphlet for ECT (did not warn of brain damage) (ECF 111-6); (c) the device manual (did not warn of brain damage) (ECF 111-30) (the manual was also discussed in Dr. Arrowsmith's report, which was cited in the opposition brief (ECF 100 at 24 & ECF 106 at 32-35); (d) Somatics' advertisements that its ECT device had "superior safety" (did not warn of brain damage) (ECF 111-15); (e) testimony from treaters (ECF 111-5 at 14-15); (f) testimony from Thelen's parents (ECF 111-3 at 8-9 & ECF 111-4 at 10-11); and (g) evidence from various experts showing Somatics knew or should have known ECT could cause brain injury (*see* ECF 105-107) (*see also* ECF 100 at 23-25)).[3]

[3] Most of this evidence was specifically cited by Thelen in his opposition brief to the design defect claim. *See* ECF 100 at 22-26. To the extent any evidence was not specifically referenced in the opposition brief, it was the result of defendant's improper framing of its arguments (ECF 93 at 20) and its failure to submit a separate statement of material facts.

The foregoing, and the other objective evidence Thelen submitted, were more than sufficient for the jury to conclude that, under Nebraska law, an ordinary consumer would not have expected the risk of brain damage to be associated with ECT. *Rahmig v. Mosley Mach. Co.*, 226 Neb. 423, 427 (1987) (plaintiff established objective evidence of design defect under consumer expectation test by among other things showing that the *owner's manual* for the product and information given to purchaser's by the manufacturer did not contain warnings or recommendations concerning the risk at issue); *Freeman*, 260 Neb. at 568-69; *see also Hancock v. Paccar, Inc.*, 204 Neb. 468, 484 (1979) (affirming jury's finding that defendant's car bumper was defectively designed and caused plaintiff's death).[4]

The dismissal of the design defect claim was *critical* given that, under Nebraska law, the learned intermediary doctrine would not have applied to the design defect claim since Nebraska views the patient (not the physician) as the consumer. *Freeman*, 260 Neb. at 567-68. Here, Thelen lost

[4] Case law from other jurisdictions that use consumer expectation are in accord. *Romine v. Johnson Controls, Inc.*, 224 Cal. App. 4th 990, 1005 (2014); *McCabe v. Am. Honda Motor Co.*, 100 Cal. App. 4th 1111, 1125 (2002); *Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 554 (2008) ("jury may rely on their own experiences to determine what an ordinary consumer would expect.")

his failure to warn case on proximate causation grounds, and the proximate causation instructions the district court gave were limited to failure to warn, they included the learned intermediary doctrine, and focused exclusively upon Thelen's physician. *See* ECF 244 at 4. Specifically, in defining proximate cause, the jury instructions stated: "In order to prove that the inadequate instructions or warnings proximately caused Thelen's injury, Thelen *must prove* that his prescribing physician would have altered his conduct…." ECF 244 at 4 (emphasis added).

However, for purposes of design defect, the Nebraska Supreme Court has held the ordinary consumer is the *patient* and (not the physician) thus, had design defect been in the case, the causation instructions for the design defect claim would not have (and could not have) included instructions that focused *exclusively* on the physician. *See e.g., Freeman*, 260 Neb. at 567-68; *see also Langner*, 492 F. Supp. 3d at 933. The district court's dismissal of Thelen's design defect cause of action should be reversed.

II. The District Court Erred in Dismissing Thelen's Negligence Claim

At the May 15, 2023, Final Pre-trial Conference, the court informed the parties it was considering *sua sponte* merging Thelen's negligence claim with his strict liability failure to warn claim into a single cause of action.

ECF 208 at 39-45. Thelen objected and, among other things, argued that (a) under Nebraska law, negligent failure to warn and strict liability failure to warn are two independent and separate causes of action and (b) more importantly, the negligence cause of action is not limited to failure to warn but includes other negligent conduct including negligent failure to *test* the ECT device and failure to investigate adverse events. *Id*.

On May 31, 2023, the first day of trial, the district court issued a verbal order stating that, under Rule 16 it was exercising its authority to "simplify" the case by only submitting a single cause of action for strict liability failure to warn to the jury (thus *sua sponte* dismissing Thelen's negligence cause of action), to which Thelen again objected. ECF 258 at 13-16.[5] Thelen further objected to the elimination of his negligence claims at the jury charge conference. ECF 262 at 235.

On June 12, 2023, *after the jury reached its verdict,* the district court issued its written order concerning its prior elimination of the negligence cause of action. ECF 250 at 2-6. Relying on the fact that, in *Freeman*, the

[5] Thelen also objected during the second day of trial when defendant sought to use the dismissal of the negligence cause of action to preclude certain evidence and argument. ECF 259 at 16-21.

Nebraska Supreme Court had merged the doctrine of *implied warranty of merchantability* with *strict liability*, the district court concluded Thelen's negligence claim should also be merged with strict liability. ECF 250 at 2-6 (*citing Freeman*, 260 Neb. at 572). However, *Freeman's* merger of implied warranty with strict liability provides no logical basis for concluding that other theories of liability such as negligence are likewise merged with strict liability. Contrary to the district court's actions, *Freeman* specifically held that a plaintiff can pursue *both* a negligence *and* a strict liability cause of action:

> *Aside from pleading theories of recovery under strict liability for specific product defects, a plaintiff may assert a theory of recovery based on negligence*…Thus, even if a comment k. defense is determined to apply to exempt the defendant from strict liability, the plaintiff can always attempt to show that the defendant acted negligently.

Freeman, 260 Neb. at 577 (internal quotes omitted) (emphasis added). Thus, the district court committed error by relying on *Freeman* to rule that Thelen's strict liability claims are merged with his negligence claims, when *Freeman* held to the contrary. *Freeman*, 260 Neb. at 577. Even after *Freeman*, the Nebraska Supreme Court once again recognized that a plaintiff may

bring both a negligence and strict liability claim utilizing the same operative facts. *Jay v. Moog Auto., Inc.*, 264 Neb. 875, 880 (2002).

Second, and most importantly, Thelen's negligence claim was not limited to failure to warn allegations. Rather, Thelen's negligence claims included allegations concerning defendant's failure to "*test*" its ECT machine and defendant's failure to investigate adverse events. ECF 1 at 21, Complaint ¶68(ii) & ¶68(iii). Nebraska law allows a plaintiff to bring a negligence claim premised upon defendant's failure to adequately test its product. *Hancock v. Paccar, Inc.*, 204 Neb. 468, 486–87 (1979) (jury could find defendant liable for being "negligent in failing to conduct tests, inspections, and calculations necessary to determine the…" safety of the product); *see also Jay*, 264 Neb. at 881 (jury could find defendant negligent based upon the fact that plaintiff's expert "testified that [defendant's] testing of the product was inadequate."); *Freeman*, 260 Neb. at 576 (plaintiff may proceed on a claim that drug company acted negligently in "testing" the drug as long as factually supported).

Here, Thelen presented evidence that Somatics never conducted any studies of any kind and never undertook to study the risk of brain injury with its Thymatron device. Somatics' owner, Dr. Abrams testified:

Q. Has Somatics ever conducted any studies to determine whether any brain injury could be caused by ECT?
A. Somatics has never conducted any studies of any kind.
Q. Has Somatics ever conducted any studies that compared the potential side effects associated with single dose versus double dose?
A. Somatics has never conducted any studies.
Q. Of any kind?
A. We're in the business of selling Thymatrons.

See ECF 259 at 91-92. Such a cavalier attitude toward safety and failure to conduct any studies or testing of any kind prior to releasing its ECT device onto consumers is sufficient to allow the jury to conclude Somatics was negligent (i.e., if it failed to act as a reasonable careful company would do under similar circumstances). NEB. PRAC., NJI2d CIV. 3.02; NEB. PRAC., NJI2d CIV. 11.10; *Hancock*, 204 Neb. at 486–87; *Jay*, 264 Neb. at 881.

Third, Thelen is not aware of any case law, nor did the district court cite any, that permits the court to utilize Rule 16 of the Federal Rules of Civil Procedure to *sua sponte* dismiss meritorious negligence claims (indeed, claims that had survived summary judgment (ECF 169)), merely to "simplify" the trial. *See e.g., Jefferson Fourteenth Assocs. v. Wometco de Puerto Rico, Inc.*, 695 F.2d 524, 526 (11th Cir. 1983) ("The Federal Rules of Civil Procedure do not provide for *sua sponte* dismissal by the court of a case on the merits."); *Wilson v. Univ. of Virginia*, 663 F. Supp. 1089, 1092 (W.D. Va.

1987) ("the right to a trial by jury is too precious to be sacrificed on the altar of judicial economy"); *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 967 (E.D. Wis. 2009) (court should avoid "sacrifice[ing] substantive justice on the altar of administrative convenience").

Finally, *sua sponte* dismissal of Thelen's negligence claim was prejudicial. Had the negligence claim remained, it would have resulted in different testimony and arguments and more importantly different jury instructions (including different instructions on causation) which could have resulted in a different verdict. A general negligence cause of action premised upon negligent testing would not have interjected the learned intermediary into the causation instruction, since a negligent failure to test is distinct from a failure to warn claim. *See Freeman*, 260 Neb. at 577. In its Order (issued three days after the verdict), the district court held it deemed a negligent testing claim to be redundant of a failure to warn claim, *see* ECF 250 at 5, however, the district court's ruling is at odds with Nebraska law which has held a negligent testing claim is *distinct* from an inadequate warning claim. *Freeman*, 260 Neb. at 577; *Hoelck v. ICI Americas, Inc.*, 7 Neb. App. 622, 636 (1998) (negligent testing claim doesn't constitute a failure to warn claim); *see also Hancock*, 204 Neb. at 471–72 & 487.

In *Hancock*, the Nebraska Supreme Court affirmed a verdict in favor of the plaintiff that was premised on a negligent failure to conduct tests and inspections – and importantly, there were *no* warning claims alleged in that case (rather the only two causes of action at issue were negligent design and strict liability design defect). *Hancock*, 204 Neb. at 471–72 & 487. *Freeman*, *Hoelk* and *Hancock* confirm that negligent testing claims are independent of failure to warn claims. Indeed, even by statute, Nebraska recognizes that a negligent testing claim is independent of a labeling claim. NEB. REV. STAT. ANN. § 25-21,182 (West) ("In any product liability action based upon negligent or defective design, testing, or labeling…").

The jury instructions Thelen proposed for his negligence cause of action, which were modeled after the Nebraska pattern instructions, did not have the learned intermediary physician focused proximate cause instructions (as they are inapplicable). *See* ECF 177 at 38 (Joint Proposed Instruction Re Definition of Negligence); ECF 177 at 39 (Joint Proposed Instruction Re Proximate Cause) (given this was a "joint" proposed instruction, even Somatics agreed that the general proximate cause instruction should not include any learned intermediary instruction concerning the physician); ECF 177 at 50 (Plaintiff's Proposed Instruction

Burden of Proof for Negligence). Accordingly, had the common law negligence claim remained (which would have included the negligent failure to test), akin to the design defect claim discussed *supra*, the common law negligence cause of action would not have contained a learned intermediary instruction. *Freeman*, 260 Neb. at 567-68 & 577. In sum, the impermissible *sua sponte* dismissal of Thelen's valid and meritorious negligence claim (to "simplify" the case) was in error, and highly prejudicial to Thelen thus warranting reversal. *See Lind v. Aetna Cas. & Sur. Co.*, 374 F.2d 377 (5th Cir. 1967); *McCullough v. Beech Aircraft Corp.*, 587 F.2d 754, 760–61 (5th Cir. 1979) (finding reversible error when the district court's jury instructions were limited to failure to warn and the court impermissibly removed design defect and other claims from the jury's consideration).

III. The District Court Issued Erroneous and Prejudicial Jury Instructions on Proximate Causation

The district court's jury instructions on proximate causation were erroneous and prejudicial resulting in the jury's adverse ruling on causation. Reversal is warranted. In defining proximate cause, the court's instructions stated: "In order to prove that the inadequate instructions or

warnings proximately caused Thelen's injury, Thelen *must prove* that his prescribing physician would have altered his conduct…." ECF 244 at 4 (emphasis added).

However, the Nebraska Supreme Court has never required that a plaintiff, as part of his causation burden, must establish his prescribing physician would have altered his conduct had adequate instructions been provided. The court's instruction misinterpreted the learned intermediary doctrine (which is limited to the issue of *duty*) and imposed a burden on *causation* that finds no support under Nebraska Supreme Court precedent. Thelen objected to the inclusion of such an instruction, including objecting when proposed by defendant (*see* ECF 177 at 73-74) and reiterating his objections at the jury charge conference (ECF 262 at 229-231 & 233-235). In lieu of the instructions given by the district court, Thelen proposed instructions, including causation instructions, based upon the Nebraska pattern jury instructions and Supreme Court precedent. Unlike the district court's instructions, Thelen's did not include the learned intermediary doctrine in the causation element but rather limited the learned intermediary doctrine to the issue of duty (consistent with *Freeman*). *See* ECF 177 at 39 (Joint Proposed Instruction Re Proximate Cause); and ECF

177 at 48 (Plaintiff's Proposed Learned Intermediary Instructions for Strict Liability Warning Defect); see also NEB. PRAC., NJI2d CIV. 3.41 & 11.23; *Kudlacek v. Fiat S.p.A.*, 244 Neb. 822, 833 (1994); *Freeman*, 260 Neb. 552.

In Nebraska, "[a] manufacturer or other seller is subject to liability for failing either to warn or adequately to warn about a risk or hazard inherent in the way a product is designed that is related to the intended uses as well as the reasonably foreseeable uses that may be made of the products it sells." *Freeman*, 260 Neb. at 570 (*quoting Rahmig v. Mosley Mach. Co.*, 226 Neb. 423, 446 (1987). Ordinarily, a manufacturer's duty to warn runs to consumers, however, in cases involving prescription devices, Nebraska adopted the learned intermediary doctrine whereby the device manufacturer may discharge its *duty* by warning the prescribing medical provider in lieu of the consumer. *Freeman*, 260 Neb. at 570-71; *Vallejo v. Amgen, Inc.*, 2014 WL 4922901, at *3 (D. Neb. Sept. 29, 2014) ("When the learned intermediary doctrine applies, a defendant's duty to warn is *discharged* ***if*** *the defendant provided adequate warnings to a patient's prescribing health-care provider*…") (emphasis added).

Thus, the learned intermediary doctrine is only applicable *if* the manufacturer provided adequate warnings to the prescribing physician.

Freeman, 260 Neb. at 570-71. Here, the district court's instructions on *defect/duty* implemented the learned intermediary doctrine. *See* ECF 244 at 3. The district court, however, erred by modifying Nebraska's *causation* jury instruction to further interject the learned intermediary doctrine into *causation*, and adding an erroneous element (i.e., that the unwarned doctor must hypothetically have altered his conduct) which is contrary to Nebraska law, the Eighth Circuit, and at odds with the doctrine as other courts have recognized.

First, if Nebraska law applied the learned intermediary doctrine to causation, *Freeman* would have mentioned it, but *Freeman* only applied the doctrine (adopted from Section 6(d) of the Third Restatement) *exclusively* to the context of *duty*. *Freeman*, 260 Neb. at 570 ("Pharmaceutical products have historically been treated differently in regard to *a duty to warn*.") (emphasis added). At no point did *Freeman* extend the doctrine to the issue of *causation* and thus it was inappropriate for the district court to instruct the jury on the issue of proximate cause in a manner never recognized nor intended by the Nebraska Supreme Court. *See e.g., Wooden v. Bd. of Regents of Univ. Sys. of Georgia*, 247 F.3d 1262, 1287 (11th Cir. 2001).

Indeed, in adopting the learned intermediary doctrine as articulated

in Section 6(d) of the Third Restatement, the full doctrine states:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Freeman, 260 Neb. at 571. Because the learned intermediary doctrine as adopted by *Freeman* envisions the potential need for the manufacturer to warn *the patient* when it "knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm…," *Freeman*, 260 Neb. at 571, it follows that the district court's inclusion of the learned intermediary doctrine into causation (and requiring Thelen to prove what his *physician* would have done had he been warned) is completely at odds with *Freeman*.[6] Here, the evidence established that Somatics had not issued *any* warnings regarding brain injury in its ECT manual provided to

[6] The learned intermediary doctrine instruction which Thelen proposed included verbatim the above block quote from *Freeman* (*see* ECF 177 at 48), yet the instructions were ignored by the district court and tellingly the district court's final instructions did not even include the second numbered paragraph of the *Freeman* rule (ECF 244 at 3-4).

Thelen's treaters, it knew that the treaters were not adequately warned (as Somatics' owners admitted in internal e-mails), thus, under *Freeman* and paragraph two of the Section 6(d) of the Third Restatement, its duty reverted to directly warning patients. *Freeman*, 260 Neb. at 571; RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d)(2) (1998).

Second, extending the doctrine to causation is at odds with precedent that originated the learned intermediary doctrine. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). In *Sterling*, the manufacturer, which failed to warn the doctor, sought to absolve itself of liability by pointing to the purported conduct of the doctor. In rejecting the manufacturer's arguments, the Court held:

> The sole issue was whether appellant negligently failed to make reasonable efforts to warn appellee's doctors. *If appellant did so fail, it is liable regardless of anything the doctors may or may not have done*. If it did not so fail, then it is not liable for appellee's injury.

Sterling, 370 F.2d at 85 (emphasis added).[7] *Third*, other courts discussing the doctrine have similarly reached this conclusion. The Arizona Supreme Court explained: "the [learned intermediary doctrine] is based on

[7] In objecting to Somatics' instructions and the court's instructions during the jury charge, Thelen cited to *Sterling* a basis as to why the learned intermediary has no application to the element of causation. ECF 177 at 74; ECF 262 at 233-235.

principles of duty, ***not causation***." *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 23(2016) (emphasis added). The Arizona Supreme Court went on to endorse the court of appeals' holding that, "[i]n its application, the [learned intermediary doctrine] appears to be less a rule of causation and more a standard for determining when a drug manufacturer has satisfied its duty to warn." *Watts*, 239 Ariz. at 23 (citations omitted); see also *Glover v. Bausch & Lomb, Inc.*, 343 Conn. 513, 539 (2022); *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972) ("having put a dangerous drug on the market without adequate warning defendant cannot be heard to say that the physician might have disregarded a proper one."); *Hamilton v. Hardy*, 37 Colo. App. 375, 387 (1976) ("What the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case.") (*overruled on other grounds by State Bd. v. McCroskey*, 880 P.2d 1188 (Colo. 1994)).[8]

[8] Common law courts outside of the U.S., such as the Canadian Supreme Court, have likewise held that the learned intermediary doctrine is limited to duty:
I do not think a manufacturer should be able to escape liability for failing to give a warning it was under a duty to give, by simply presenting evidence tending to establish that even if the doctor had been given the warning, he or she would not have passed it on to the patient, let alone putting an onus on the plaintiff to do so. Adopting such a rule would, in some cases, run the risk of leaving the plaintiff with no compensation for her injuries. She would not be able to recover against a doctor who had not been negligent with respect to the information that he or she *did* have; yet she also would not be able to recover against a manufacturer who,

Fourth, the district court's proximate cause instruction forced Thelen to overcome an intervening or superseding cause burden (i.e., prove the conduct of the prescribing treater was not an intervening or superseding cause) that is not applicable under the facts of this case, nor is it proper under Nebraska law. Nebraska is clear, where defendant has been found negligent, it is liable for the plaintiff's injury irrespective of the conduct of a third party. *Kudlacek v. Fiat S.p.A.*, 244 Neb. 822, 833 (1994) ("If the effects of a defendant's negligence actively and continuously operate to bring about harm to another, the fact the active negligence of a third person is also a substantial factor in bringing about the harm does not protect the defendant from liability...").[9]

Simply put, the *foreseeable* effect of Somatics' failure to warn brain damage is that the prescribing doctor would not be informed of this serious risk and, thus, could not pass those warnings to Thelen and his family (which is exactly what occurred in this case). See ECF 247-1 (Thymatron

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despite having failed in its duty to warn, could escape liability on the basis that, had the doctor been appropriately warned, he or she still would not have passed the information on to the plaintiff. Our tort law should not be held to contemplate such an anomalous result.

See Hollis v. Dow, 1995 CarswellBC 967, 4 S.C.R. 634, 685 at ¶60-61 (1995) (Canada). A copy of *Hollis* is attached to Thelen's Request for Judicial Notice.

[9]

manual); ECF 247-3 (2006 Swartz email); ECF 262 at 63:13-24, 66:20-67:5, 69:9-70:13, 71:4-72:22, 87:17-88:19, 98:19-101:14 (Swartz testimony); ECF 260 at 223:19-224:16 (Sharma testimony); ECF 262 at 200:21-201:19 (stipulation); ECF 261 at 68:19-69:12; 69:19-22 (Thelen testimony); ECF 259 at 144:23-25, 145:1-13, 145:19-24 (Patricia Thelen testimony); ECF 261 at 202:2-16, 202:25-204:6, 205:1-5 (Dennis Thelen testimony).

Thelen should be afforded a new trial as the erroneous causation jury instructions were contrary to Nebraska Supreme Court precedent. The erroneous instructions were prejudicial as the jury found against Thelen exclusively on the issue of causation, and the questions the jury asked during deliberation related to Dr. Sharma (see ECF 245 at 2), further confirming the challenged causation instructions were prejudicial and responsible for the jury's adverse finding on causation. *Fillippon v. Albion Vein Slate Co.*, 250 U.S. 76, 82 (1919) ("in jury trials erroneous rulings are presumptively injurious, especially those embodied in instructions to the jury; and they furnish ground for reversal unless it affirmatively appears that they were harmless."); *Ward v. Atl. Coast Line R. Co.*, 362 U.S. 396, 398–400 (1960) (reversing district court due to erroneous jury instructions); see also *Wollenhaupt v. Andersen Fire Equip. Co.*, 232 Neb. 275, 279 (1989)

(granting new trial due to erroneous jury instructions on causation)

IV. The District Court Improperly Limited Dr. Hannappel's Testimony under *Daubert*

Dr. Hannappel is a clinical psychologist who first saw Thelen in August 2017, one year after Thelen's last ECT treatment. ECF 142-6 at 2. Thelen was referred by his treating psychiatrist for a neuropsychological evaluation "to determine cognitive abilities and aid in diagnostic impressions." *Id.;* ECF 142-7 at 11:9-11; 27:12-28:17. Based on his testing and assessment of Thelen, Dr. Hannappel diagnosed Thelen with "Neurocognitive Disorder, primarily related to another medical condition." *Id.* at 2-11; ECF 142-7 at 28:15-33:7. Thereafter, Thelen began treating with Dr. Hannappel in 2020 and continued treating with him on a weekly basis. ECF 142-7 at 68:7-69:14. When Dr. Hannappel was deposed in May 2022, after treating Thelen for two years, he testified he believes Thelen's ECT treatments were more likely than not a contributing factor to his diagnosis of neurocognitive disorder, and the ECT treatments were a substantial factor in Mr. Thelen's diagnosis of neurocognitive disorder. *Id.* 142:4-22.

The court granted Somatics' motion to exclude Dr. Hannappel's independent causation opinion under *Daubert.* The court's error in

excluding Hannappel's causation opinion was two-fold. *First*, the court erred as a matter of law in applying *Daubert* to Hannappel's causation opinions which were formed during the course of his treatment of Thelen. *Second*, in applying *Daubert*, the court abused its discretion in finding Hannappel was not qualified to render a medical causation opinion and that his methodology was unreliable. *See* ECF 170 at 4-6.

A. Dr. Hannappel's Causation Opinion is Not Subject to *Daubert* Because He Formed His Opinion Concerning the Cause of Thelen's Neurocognitive Disorder During His Treatment

As a treating medical provider, Dr. Hannappel's opinions concerning Thelen's injuries, and their cause, are not subject to *Daubert*. *See Wilson v. Taser Int'l, Inc.*, 303 F. App'x 708, 712 (11th Cir. 2008) ("a treating physician may testify as a lay witness regarding his observations and decisions during treatment of a patient"); *United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005); *Davoll v. Webb*, 194 F.3d 1116, 1138 (10th Cir. 1999) ("A treating physician is not considered an expert witness if he or she testifies about observations based on personal knowledge, including the treatment of the party."); *see also Weese v. Schukman*, 98 F.3d 542, 550 (10th Cir. 1996).

This view is consistent with how courts determine whether a treating provider is required to disclose a Fed. R. Civ. Proc. 26(a)(2)(B) expert report or need only be identified in a Rule 26(a)(2)(C) summary. *See Torres v. Wal-Mart Stores E., L.P.*, 555 F. Supp. 3d 1276, 1297 (S.D. Fla. 2021); *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, at 870 (6th Cir. 2007) ("This conclusion is supported by the obvious fact that doctors may need to determine the cause of an injury in order to treat it. Determining causation may therefore be an integral part of 'treating' a patient."); *see also Ngo v. Standard Tools & Equip., Co.*, 197 F.R.D. 263, 267 (D. Md. 2000).

The district court determined *Daubert* applied to Hannappel's causation opinions, erroneously concluding that, "at the time [Hannappel] formed his opinions, Hannappel was consulting with Thelen's treating physicians rather than treating Thelen himself and his recommendations for treatment focused on addressing Thelen's symptoms without regard to the cause." ECF 170 at 5. To the contrary, the record before the court demonstrated Hannappel formed his causation opinion based on his *ongoing treatment* of Thelen, which began in 2020 and continued on a weekly basis through the time Hannappel was deposed and through trial. ECF 142-8 at 192:22-195:7; ECF 261 at 71:10-17. While Hannappel's initial

evaluation of Thelen in 2017 was to aid the diagnostic assessment of his treating physicians, his prescribing providers acted on Hannappel's 2017 diagnosis and impressions of Thelen, and his medical providers went on to diagnose Thelen with "major neurocognitive disorder **secondary to previous ECT**." ECF 263 at 89:21-93:23. Based on this diagnosis, which was aided by Hannappel's 2017 evaluation, Thelen's providers prescribed him medication for dementia. *Id.* at 101:11-106:9.

Moreover, Hannappel's treatment of Thelen from 2020 to 2023 was specifically to provide psychological care for Thelen's neurocognitive issues that were "interfering with all aspects of his functioning and relationships" and contributing to Thelen feeling isolated, increased depression, and frustration with not being able to function like he had historically been able to. *Id.* Hannappel's treatment of Thelen's cognitive impairment also included educating Thelen on compensation devices and strategies to help compensate for his ongoing memory issues. ECF 142-8 at 195:9-196:11; ECF 142-7 at 131:6-135:4. Thus, as a treating witness who was not retained for litigation and formed his opinion that Thelen's neurocognitive disorder was caused by ECT during the course of his

ongoing treatment of Thelen for his neurocognitive issues, the district court erred in applying *Daubert* to exclude his testimony.

B. Dr. Hannappel is Qualified to Administer and Interpret Neuropsychological Testing and Reach Conclusions Concerning the Cause of an Identified Neurocognitive Injury

Even if the Court were to apply *Daubert* to Dr. Hannappel's causation opinions, Dr. Hannappel's qualifications and methodology pass muster. The district court's finding that Hannappel was unqualified to offer medical causation opinion concerning whether ECT was the cause of Thelen's neurocognitive disorder was an abuse of discretion. *See e.g.*, ECF 170 at 4-5.

First, "[a] witness is qualified as an expert if he is the type of person who should be testifying on the matter at hand." *Moore v. Intuitive Surgical, Inc.*, 995 F.3d 839, 852 (11th Cir. 2021). "[I]t is not necessary that the witness be recognized as a leading authority in the field in question .... Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony not its admissibility." *Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 692 (N.D. Ga. 2006). Importantly, "federal law recognizes no *per se* rule of exclusion prohibiting a psychologist from rendering opinion testimony regarding the cause of organic brain

damage." *Ostroski v. United States*, 2007 WL 9701868, at *3 (S.D. Fla. Aug. 23, 2007). Here, the fact Dr. Hannappel is not a *medical* doctor did not render him unqualified to offer specific causation opinion testimony, because he was nonetheless qualified by his knowledge, experience, training, and education in diagnosing and assessing the cause of neurocognitive injuries, which falls within the field of neuropsychology. *See* Fed. R. Evid. 702.

Dr. Hannappel obtained his bachelor's degree in psychology from Creighton University and obtained a Ph.D. in clinical psychology from the University of Missouri, St. Louis. ECF 142-7 at 7:1-10. He has practiced in a clinical setting since obtaining his Ph.D. in 1991. *Id*. at 7:11-20. He has extensive training in neuropsychological testing, which he has performed for several years. *Id*. at 162:9-163:15. He attends conferences and trainings to educate himself about neuropsychological assessments, and he keeps current with the scientific and medical literature on psychotherapy. *Id*. at 11:19-25; 162:9-163:15. He also has experience assessing the possible etiology of neurocognitive disorders. ECF 142-8 at 191:22-192:9.[10]

[10] Tellingly, Somatics' retained neuropsychologist, Dr. Bilder, who is also not a medical

Second, in concluding Dr. Hannappel was unqualified because he had no training or experience with ECT treatments specifically, the district court imposed an evidentiary burden that was too high. This Circuit's authority "does not support a bright line rule that an expert witness is qualified to testify regarding the cause of an injury only if he personally has used the allegedly defective product." *Moore*, 995 F.3d at 854. This Court has expressly rejected such a rule. *Id; see also Mitchell v. United States*, 141 F.3d 8, 15 (1st Cir. 1998); *Santos v. Posadas De Puerto Rico Associates, Inc.*, 452 F.3d 59, 63 (1st Cir. 2006) (finding that, to qualify as an mTBI expert, the neuropsychologist need not have conducted research nor written articles on mTBI).

C. Dr. Hannappel Utilized a Reliable Methodology in Forming His Causation Opinions

In assessing an expert's methodology under *Daubert*, the Court's focus "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. The district court found Dr. Hannappel's methodology did not meet *Daubert*'s reliability

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doctor, was permitted to testify as to medical causation at trial. ECF 260 at 58:2-10. This is unsurprising because psychologists are routinely permitted to offer *medical* causation opinions. *See Bado–Santana v. Ford Motor Co.*, 482 F. Supp. 2d 192, 196 (D.P.R. 2007).

requirement, but in doing so, the court improperly based its evidentiary determinations on the weight and persuasiveness of the evidence. The court opined that Dr. Hannappel only "briefly" considered alternative causes and relied on Thelen's self-reporting of his medical history rather than obtain Plaintiff's medical records. ECF 170 at 6.

It is well-established, however, that as a treating provider, Hannappel can testify "based upon his treatment and care of Plaintiff, as to his opinions on causation which are sufficiently related to the information disclosed during the course of Plaintiff's treatment." *Britt v. Wal-Mart Stores E., LP*, 599 F. Supp. 3d 1259, 1264 (S.D. Fla. 2022). To the extent Hannappel "failed to consider any of prior Plaintiff's medical records" Somatics was free to address that during cross-examination of Hannappel. *Id*. "Medical professionals reasonably may be expected to rely on self-reported patient histories." *Walker v. Soo Line R. Co*., 208 F.3d 581, 586 (7th Cir. 2000); *see also Brown v. NCL (Bahamas) Ltd*., 190 F. Supp. 3d 1136, 1144 (S.D. Fla. 2016) ("[T]he opinions of treating physicians on injury causation—based on medical knowledge, physical examination, and patient histories—are routinely admitted in federal courts.").

Moreover, Hannappel performed a differential diagnosis, and he conducted an in-person neuropsychological evaluation of Thelen, utilizing standardized neuropsychological. Federal courts routinely permit neuropsychologists to testify about brain injuries diagnosed through neuropsychological testing, and their cause. As one court aptly noted "...neuropsychological testing is the only means of diagnosing some forms of brain damage." *Bado-Santana*, 482 F. Supp. 2d at 195. *See also Botelho v. Nordic Fisheries, Inc.*, 2018 WL 2291315, at *7 (D. Mass. May 18, 2018) (denying motion to exclude testimony of a treating neuropsychologist regarding causation); *Penny v. State Farm Mut. Auto. Ins. Co.*, 474 F. Supp. 3d 1176, 1178 (W.D. Wash. 2020) (same).

The court weighed the strength of Dr. Hannappel's differential diagnosis stating he did little to determine the existence of other possible causes. ECF 170 at 6. However, Thelen presented sufficient evidence that Hannappel considered Thelen's family history, medical history, and his history of depression. ECF 142-7 at 28:15-33:7. He considered to what extent Thelen's ongoing depression and anxiety contributed to some of his neurocognitive problems, as well as his history of drug and alcohol use. *Id.* at 39:12-41:10; 42:4-43:7; 123:25-128:21. Based on his training and

experience assessing patients with severe depression and patients with brain injuries, Hannappel determined Thelen's symptoms went beyond what is typically seen in a profile primarily explained by depression (ECF 142-6 at 11) and found Thelen's symptoms were more in line with those seen in patients with brain injuries. *Id.* at 131:6-135:4. He also considered that Thelen's testing results showed his *memory* scores were considerably lower than his scores in other domains which were in the average range. ECF 142-7 at 39:12-41:10. Hannappel ruled out these possible alternative causes and determined ECT was a reasonable and plausible explanation for Thelen's cognitive problems. ECF 142-8 at 167:7-169:14. This differential diagnosis methodology satisfies the reliability requirement of *Daubert*. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1342 (11th Cir. 2010) ("differential diagnosis itself has been recognized as a valid and reliable methodology").

Similarly, the court's finding that Hannappel performed only "cursory research into risks and benefits of ECT" was unsupported by the record. Hannappel read medical literature on ECT and consulted his neuropsychology book concerning ECT. ECF 142-7 at 12:6-22; ECF 142-7 at 141:4-142; *see also* ECF 142-8 at 191:22-192:9. He was also familiar with the medical literature on causes of brain damage in psychiatric patients. ECF

142-4 at 165:16-164:8. Hannappel did not need to perform an extensive review of the literature or recite exact articles at his deposition to support his treatment-derived specific causation opinion that ECT was more likely the cause of Thelen's neurocognitive disorder. This weighing of the evidence was improper under *Daubert*.

The court also focused on language in Hannappel's initial 2017 testing report of Thelen (which was not prepared for litigation and was before Hannappel's ongoing treatment of Thelen) in which Hannappel stated Thelen's cognitive decline was "possibly related to the ECT treatments" and left it to Thelen's treating physicians to rule out other explanations. ECF 170 at 6; ECF 142-6 at 11. Dr. Hannappel's ultimate opinion, however, was formed after treating Thelen continuously for two more years, and he unequivocally testified he believes Thelen's "90 plus" ECT treatments were **more likely than not** a contributing factor to his diagnosis of neurocognitive disorder, and that Thelen's ECT treatments were a **substantial factor** in his diagnosis. ECF 142-7 at 142:4-22.

The district court's abuse of discretion in excluding Dr. Hannappel's causation opinion was significantly prejudicial as it further limited the presentation of evidence concerning Thelen's ongoing treatment with

Hannappel. For instance, in ruling on deposition designations, the court excluded Hannappel's testimony that the neuropsychological literature he read on the side effects of ECT stated ECT can damage certain parts of the brain, like the hippocampus. ECF 211-5 at 108-109; ECF 211-6 at 36-37; ECF 226. On the other hand, the court allowed Somatics' retained neuropsychologist (also not a medical doctor) to testify concerning studies he read in the field of neuropsychology concerning the side effects of ECT and an ECT research study he worked. ECF 260 at 12:3-10; 15:21-20:19. The court also admitted testimony in which defense counsel questioned Dr. Hannappel about whether he had seen some medical records indicating Thelen's brain imagining was normal, yet the Court *excluded* Dr. Hannappel's answer explaining he was not aware of those records, but there are certain conditions, like Alzheimer's where brain scans will appear normal. ECF 211-5 at 70; ECF 226.

The court also reasoned that Hannappel's medical causation testimony would also be cumulative of Thelen's retained expert, Bennet Omalu, M.D., who conducted a differential diagnosis. ECF 170 at 6. In the eyes of a jury, however, the testimony of a non-retained, unbiased, treating expert's causation opinion carries significant weight.

As demonstrated herein, Dr. Hannappel applied valid and reliable neuropsychological principles and methods in assessing Thelen and determining the cause of his injuries, following years of weekly treatment. Whether Thelen suffered a brain injury as a result of ECT was a paramount issue in his case. The court's exclusion of Thelen's treating provider's causation testimony should be reversed, and this matter remanded for a new trial.

V. Evidentiary Rulings Made During Trial

A. The District Court Abused Its Discretion in Excluding Dr. Sharma's Patient Consent Video on ECT Which was Highly Probative of Dr. Sharma's Knowledge Concerning the Long-Term Risks of ECT

"To gain a reversal based on a district court's evidentiary ruling, a party must establish that (1) its claim was adequately preserved; (2) the district court abused its discretion in interpreting or applying an evidentiary rule; and (3) this error affected 'a substantial right.'" *Proctor v. Fluor Enterprises, Inc.*, 494 F.3d 1337, 1349 (11th Cir. 2007) (quoting *United States v. Stephens*, 365 F.3d 967, 974 (11th Cir. 2004); Fed. R. Evid. 103(a)). Thelen has satisfied all requirements, demonstrating the district court abused its discretion in erroneously excluding critical evidence concerning

his treating physician's knowledge of the risks of ECT, pursuant to Fed. R. Evid. 403.

On several occasions throughout the trial, and even on a motion to reopen evidence, *see infra*, Thelen attempted to introduce Plaintiff's Trial Exhibit 32, a patient consent video featuring Thelen's treating physician, Dr. Sharma, titled "Dispelling the Myths of ECT" ("Sharma video"). ECF 111-11; ECF 216. The video is a 16-minute patient consent video produced by CHI Hospital (where Thelen received his ECT treatments), the introduction of which depicts Dr. Sharma explaining his understanding of the risks and benefits of ECT. The evidence at trial demonstrated the Thelen family watched the patient consent video while they were at CHI Hospital. ECF 259 at 144:12-18; *see also* ECF 259 at 181:21-182:4.

Dr. Sharma testified the video was created by the hospital, he was featured in the introduction, and it was available and used with patients during the consent process. ECF 260 at 170:1-171:20; 242:7-15; 212:3-7.

When Thelen's counsel first attempted to introduce the Sharma video into evidence, following examination of Thelen's mother, Somatics objected to the video, arguing it was unclear whether it was the video the Thelen family watched, and falsely represented to the court that Thelen *did not*

recall watching any video when his deposition was taken. ECF 259 at 258:24-260:6. To the contrary, Thelen testified at his deposition he *did* watch a video on ECT in the CHI waiting room. ECF 111-1 at 28:21-29:3. The district court reserved ruling on the admissibility of the video at that time. ECF 259 at 258:24-261:6.

On the third day of trial, after the video deposition of Dr. Sharma was played for the jury, Thelen moved again to admit the Sharma video into evidence, to which Somatics objected and Thelen responded. ECF 260 at 236:15-239:1; see also ECF 260 at 170:15-171:20 (Dr. Sharma testimony he only made one ECT video). Following argument concerning its admissibility, the court admitted the video, stating:

> It's admitted, totally admitted, the whole thing, but I'm not going to let you publish it to the jury…. and then you can tell the jury in closing "Members of the jury, here's what's there," **and if they think they care about it, it's something that's going to their decision, then they can watch it**.

ECF 260 at 234:19-236:14 (emphasis added).

On the fourth day of trial, Thelen's counsel attempted to show the Sharma video, during Thelen's direct examination, but Somatics objected, and the district court ordered counsel to move that exhibit to the end of his examination. ECF 261 at 70:4-16; 82:3-83:2. After further consideration,

and Thelen's numerous attempts to introduce the Sharma video as part of his direct examination of Thelen, the Court correctly determined the Sharma video did not have sufficient authenticity issues to deny admission on that basis and it was a medical business record. *See* ECF 261 at 82:24-94:2; *see also* FRE 803(4); FRE 803(6); see also ECF 261 at 92:17-93:2.

However, despite overruling Somatics' objections, the court *sua sponte* raised Fed. R. Evid. 403 concerns and excluded the video on the basis that the video might confuse the issues, because the jury's focus would be on "disclosures that were given to the patient from the doctor as opposed to disclosures given from the manufacturer to the patient." ECF 261 at 92:17-94:2; see also ECF 261 at 87:10-89:10.

As explained, *supra*, however, Somatics' duty to warn in this case ran to the doctor, and Somatics' defense was that Dr. Sharma already knew the full extent of the risks of ECT, thus, it had no duty to warn. The court's jury instructions expressly included the learned intermediary doctrine as to both duty and (erroneously) causation. ECF 244 at 3-4. Therefore, given the district court's jury instructions and Somatics' primary defense, Dr. Sharma's knowledge of the full nature and extent of ECT's risks, and what he communicated to patients about such risks, was *essential* to the issue of

whether Somatics' failure to warn was the proximate cause of Thelen's injuries. Indeed, the court recognized the relevance of such critical evidence concerning what Dr. Sharma knew at the time, yet inexplicably excluded the evidence under Fed. R. Evid. 403. See ECF 261 at 92:17-94:2.

As this Court recognized, however, "[a]s evidence becomes more essential, its probative value becomes greater." *Aycock*, 769 F.3d at 1069. "Because it allows a trial court to exclude evidence that is probative, Rule 403 is 'an extraordinary remedy which should be used sparingly.'" *Id.* .

The district court's *sua sponte* exclusion of Thelen's Exhibit 32 based on FRE 403 was an abuse of discretion. As evidenced by the jury's questions during deliberations, Dr. Sharma's knowledge of the risks of ECT was *critical* to their verdict on proximate cause. *See* ECF 245 at 2 & 4.

Unfortunately, the jury was deprived of the opportunity to examine all relevant and admissible evidence, including the short video of Sharma demonstrating he was unaware of the full nature and extent of ECT's risks. In the video, Dr. Sharma states, in pertinent part:

> [S]ide effects include a recent memory loss in which a person is not able to remember what really had happened just prior to ECT. It's a recent memory impairment. **There are no studies showing really any long-term memory problems or long-term**

memory effect with ECT or as a side effect of ECT.

ECF 111-11 at 9:43 to 11:45; *see also* ECF 261 at 88:5-89:10.

As the Supreme Court and Eleventh Circuit have held, "if one cannot say, with fair assurance, ... that the judgment was not substantially swayed by the error, it is impossible to conclude that substantial rights were not affected." *Ad-Vantage Tel. Directory Consultants, Inc. v. GTE Directories Corp.*, 37 F.3d 1460, 1465 (11th Cir. 1994) (quoting *Kotteakos v. United States*, 328 U.S. 750, 765 (1946)). Thelen was deprived of the opportunity to show the jury evidence central to a pivotal issue in his case, thereby substantially affecting his right to a fair trial. Where an erroneous evidentiary ruling addresses a material issue in the case, a new trial is the only relief available to remedy the unfair prejudice to a party. *Burchfield v. CSX Transp., Inc.*, 636 F.3d 1330, 1338 (11th Cir. 2011); *see also Ewing v. Carnival Corp.*, 2022 WL 1719315, at *1 (S.D. Fla. May 27, 2022). The district court's exclusion of Dr. Sharma's video should be reversed, and this matter should be remanded for a new trial.

VI. The District Court Abused its Discretion in Refusing to Re-Open the Trial Record to Admit the Sharma Video Which Would Have Directly Responded to the Jury's Questions Concerning Dr. Sharma's Knowledge of ECT's Risks

The relevance of the Sharma video was magnified when the jury

began its deliberations and submitted written questions to the court concerning Sharma's knowledge and beliefs concerning permanent memory loss with ECT. See ECF 245. After receiving the jury's questions, Thelen's counsel requested, once again, that the court admit the Sharma video into evidence. ECF 264 at 73:18-75:3; 84:20-86:11. Although the district court suggested the possibility of reopening the case to put the video into evidence, and Thelen's counsel so moved, the court, without explanation, declined to reopen the record. ECF 264 at 87:2-16; ECF 241 at 1; ECF 242; ECF 252 .

In its verdict, the jury ultimately found Somatics failed to provide adequate warnings concerning ECT's risks, however, as the verdict indicates, it believed Somatics' failure to warn was not a proximate cause of Thelen's injuries almost certainly based on the court's erroneous jury instructions (as discussed *supra*) and their confusion (based on their questions) concerning Dr. Sharma's knowledge of ECT's risks and whether he was fully aware ECT could cause permanent memory loss. The short video in which Sharma explains to patients (including Thelen and his parents) his understanding of the safety and risks of ECT and Sharma's statement that "there are no studies showing really any long-term memory

problems or long-term memory effect with ECT or as a side effect of ECT" would have directly addressed the jury's written questions. ECF 111-11 at 9:43 to 11:45; see also ECF 261 at 88:5-89:10; see also ECF 245 at 4. The court erred in preventing Thelen from introducing the video during his case in chief (as discussed *supra*), and further erred when it denied Thelen's motion to reopen the case to admit the video, which would have addressed the jury's questions.

Trial court rulings on motions to reopen civil cases to permit additional evidence are reviewed for an abuse of discretion. *See Lundgren v. McDaniel*, 814 F. 2d 600, 607 (11th Cir. 1987); *U.S. v. Cohen*, 888 F.2d 770, 775 (11th Cir. 1989). It is generally understood that a trial court abuses its discretion if its refusal to reopen works an "injustice" under the circumstances. *See Rivera-Flores v. Puerto Rico Telephone Co.* 64 F.3d 742, 746, 749 (1st Cir. 1995); *Levy v. Lexington County, S.C.*, 589 F. 3d 708, 714 (4th Cir. 2009). In *Rivera* the First Circuit held the district court abused its discretion in refusing to reopen the case because the evidence was critical concerning an essential element of plaintiff's claim and reopening the case would not have resulted in substantial delay. *Rivera-Flores,* 64 F.3d at 748. Here, Thelen sought to introduce one short video, the relevant portions of

which were only two to three minutes long. Thelen had multiple times attempted to introduce the video into evidence without success. The district court's refusal to reopen the trial record under the circumstances worked an injustice and, thus, was an abuse of discretion.

VII. Somatics' Counsel's Closing Argument Misstated the Law Concerning the Learned Intermediary Doctrine and a Curative Instruction Should Have Been Given

In deciding closing argument issues on appeal, this Court considers "the entire argument, the context of the remarks, the objection raised, and [any] curative instruction." *Sowers v. R.J. Reynolds Tobacco Co.*, 975 F.3d 1112, 1124 (11th Cir. 2020) (citations omitted). To constitute reversable error, statements made in oral argument must be "plainly unwarranted and clearly injurious." *Id.*

Prior to jury deliberations, the parties heavily debated the appropriate language to include in the jury instruction on proximate causation. Somatics urged the court to include an improper proximate cause standard which would have required Thelen to prove that, had Somatics issued adequate warnings, Thelen's treating physician would not have *prescribed* ECT to Thelen. ECF 177 at 73-74; ECF 261 at 215:24-216:19. The court rejected Somatics' argument and issued a proximate cause

instruction (although also erroneous as discussed *supra*) that focused more broadly on the physician's *conduct*, rather than his prescribing practices. ECF 244 at 4.

Notwithstanding the court's ruling on jury instructions, Somatics' counsel deliberately argued the wrong legal standard to the jury during closing arguments, *several* times, including stating:

> Plaintiff has failed to prove, as they must, to win this case, 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.

ECF 264 at 54:22-25 (emphasis added); *see also* ECF 264 at 46:23-47:2 & 264 at 67:11-15. So as not to interfere with the limited time the district court allotted for closing arguments (*see* ECF 264 at 14:8-15:9) and not draw further attention to the improper standard articulated by counsel, Thelen's counsel did not object in the moment. However, after the jury asked their first set of questions during deliberations, including whether they could review Dr. Sharma's testimony, Thelen alerted the court that Somatics' counsel had argued the wrong standard during closing argument, focusing on the *prescribing* conduct of the doctor, the very standard the Court rejected. ECF 264 at 73:19-76:5. Thelen asked the court to re-read the jury instruction

concerning causation, and to give a curative instruction explaining the physician's *prescribing* decision is not the standard. *Id.* The court declined to give a curative instruction, and the jury returned a verdict finding for defendant on the issue of proximate cause. *Id.*; ECF 246 at 1.

Failure to *contemporaneously* object to improper statements made during closing argument did not prevent the district court from giving a curative instruction once deliberations began, nor does it prevent this Court from considering this error on appeal. *See McWhorter v. City of Birmingham*, 906 F.2d 674, 677 (11th Cir. 1990) ("improper argument may be the basis for a new trial even if no objection has been raised"); see also *Christopher v. Florida*, 449 F.3d 1360, 1367, n.8 (11th Cir. 2006); *Hall v. Freese*, 735 F.2d 956, 961 (5th Cir. 1984). Defense counsel's remarks concerning the burden of proof on causation were a deliberate misstatement of law (and had specifically been rejected by the court) and were highly prejudicial, particularly given the juror's written questions and ultimate verdict. Consistent with *McWhorter,* the trial court should have issued the requested curative instructions and its failure to do so constitutes reversible error.

CONCLUSION

For the foregoing reasons, Thelen respectfully requests that the district court's judgment be reversed and the case remanded for a new trial.

Dated: April 17, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this motion for request of judicial notice contains 12992 words, excluding the items exempted by Fed R. App. P. 32(F). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Book Antiqua.

Dated: April 17, 2024

/s/ Monique Alarcon
Monique Alarcon

CERTIFICATE OF FILING AND SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on April 17, 2024, I electronically filed the foregoing Appellants' Initial Brief via ECF, and service was accomplished on counsel of record by that means.

/s/ Monique Alarcon
Monique Alarcon