UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JEFFREY THELEN,

Plaintiff,

v.

SOMATICS, LLC; and ELEKTRIKA, INC.,

Defendants.

Case No.: 8:20-cv-01724-TPB-JSS

Judge: Honorable Thomas P. Barber
Magistrate Judge: Honorable Julie S. Sneed

PLAINTIFF'S MOTION FOR A NEW TRIAL AND MOTION TO ALTER OR AMEND THE JUDGMENT

Plaintiff Jeffrey Thelen ("Plaintiff" or "Thelen"), by and through undersigned counsel, respectfully submits a Motion for New Trial and Motion to Alter or Amend the Judgment, pursuant to Federal Rule of Civil Procedure 59(a) and (e). Plaintiff's motion is based on the attached Memorandum of Points of Authorities and on the grounds that a new trial is necessary due to erroneous jury instruction, improperly excluded evidence, prejudicial statements by Defendant's counsel, and because Plaintiff's design defect claim was improperly dismissed before trial.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

Other Authorities

INTRODUCTION

Plaintiff, Jeffrey Thelen, asserted claims against defendant Somatics, LLC ("Somatics") arising out of brain damage caused by Somatics' electroshock therapy ("ECT") device and negligence. Following trial, the jury returned a verdict finding Somatics failed to adequately warn but that failure was not a proximate cause of Thelen's injuries. Judgment was entered on June 9, 2023. This judgment came after Thelen's case in chief was hampered – his claim for design defect was dismissed, key evidence was excluded, erroneous instructions were given to the jury, and defense counsel made improper statements in closing.

LEGAL STANDARD

Rule 59 provides in relevant part: "The Court may, on motion, grant a new trial on all or some of the issues—and to any party … after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." FED. R. CIV. P. 59(a). "[A] motion for new trial may rest on the fact that 'the verdict is against the weight of the evidence … or that, for other reasons, the trial was not fair to the party moving; and may raise questions of law arising out of alleged substantial errors in admission or rejection of evidence or instructions to the jury.'" *Johnson v. Clark*, 484 F. Supp. 2d 1242, 1246 (M.D. Fla. 2007) (quoting *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940)).

Rule 59 further allows the Court to "alter or amend the judgment after the entry of the judgment." FED. R. CIV. P. 59(e). Rule 59(e) allows a party to direct

the district court's attention to a manifest error of law or fact and enables the court to correct its own errors and thus avoid unnecessary appellate procedures. *Russell v. Delco Remy Div. of Gen. Motors Corp.*, 51 F.3d 746, 749 (7th Cir. 1995).

ARGUMENT

I. The Court Issued Erroneous Jury Instructions on Proximate Cause

A court's grant of a new trial motion under Rule 59(a) may be predicated upon erroneous jury instructions. *Tierney v. Black Bros. Co.*, 852 F. Supp. 994, 1003 (M.D. Fla. 1994); *Pate v. Seaboard R.R.*, 819 F.2d 1074, 1080 (11th Cir. 1987). The Court's instructions on proximate causation stated: "*In order to prove that the inadequate 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*." Dkt. 244 at 4. This is an erroneous statement of Nebraska law and warrants a new trial.[1]

Neither the Nebraska Supreme Court, nor any Nebraska appellate court, has ever held 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 misinterprets the learned intermediary doctrine (which is limited to the issue of *duty*) and imposed a burden on *causation*

[1] Plaintiff timely and on multiple occasions objected to the inclusion of such an instruction, including: (a) objecting in the Joint Proposed Jury Instruction when the instruction was first articulated by Somatics, *see* Dkt. 177 at 73-74 (Plaintiff objecting to this specific instruction); and (b) reiterating the objection at the Jury Charge Conference, Ex. 15 at 233-34.

that finds no support under Nebraska Supreme Court precedent.

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 v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 570 (2000) (*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 has 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 570-7. 1. Here, the Court's instructions on duty/defect implemented the learned intermediary doctrine (i.e., "a product is not accompanied by adequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to prescribing

physicians…"). Dkt. 244 at 3. The Court, however, erred by modifying Nebraska's *causation* jury instruction by introducing the learned intermediary doctrine into causation, and adding an 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 recognized by other courts.

First, if Nebraska law applied the learned intermediary doctrine to causation, *Freeman* would have mentioned it – however, *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* (i.e., what the treating physician would have done had he received a warning he never received) and thus it was inappropriate for this Court to instruct the jury on the issue of proximate cause in a manner that was 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) ("If the Supreme Court intended so significant and potentially far-reaching a change in the law of standing, surely it would have said so directly.").

Second, extending the doctrine to causation is at odds with the precedent that birthed the learned intermediary doctrine. *Sterling Drug, Inc. v. Cornish*, 370

F.2d 82, 85 (8th Cir. 1966). In *Sterling*, the manufacturer, which had 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). *Third*, other courts discussing the doctrine have similarly reached this conclusion. The Arizona Supreme Court explained: "the [learned intermediary doctrine] is based on principles of duty, ***not causation***." *Watts v. Medicis Pharm. Corp*., 239 Ariz. 19, 23(2016) (emphasis added). The 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). This principle was also recently echoed by the Supreme Court of Connecticut:

> Although manufacturers may invoke the learned intermediary doctrine as a shield against claims that they failed to provide adequate warnings to users *as long as they provided such warnings to healthcare providers*…we see nothing in…our case law that would indicate that the doctrine was intended to provide a shield against liability for foreseeable injuries caused by the *withholding* of information about inherently dangerous medical devices.

Glover v. Bausch & Lomb, Inc., 343 Conn. 513, 539 (2022) (emphasis added); *see also 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) ("we hold that where an ethical (i.e., prescription) drug manufacturer puts a drug on the market without adequate warning, the prescribing doctor's conduct may not insulate the manufacturer from liability where the inadequacy of the warning may have contributed to plaintiff's injury. 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)). Common law courts outside the U.S. have likewise concluded the learned intermediary doctrine is limited to the issue of duty and not causation. *See* Ex. 1, *Hollis v. Dow*, 1995 CarswellBC 967, 4 SCR 634, 685 at ¶60-61 (1995) (Canada).[2]

Fourth, the Court's proximate cause instruction appears to force 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. As

[2] The *Canadian Supreme Court* held:

> 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, 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.

Ex. 1, *Hollis*, 4 S.C.R. 634, 685 at ¶60.

the case law outlined *supra* makes clear, when a device manufacturer fails to provide adequate warnings to the prescribing doctor, the hypothetical conduct of the doctor is not an element plaintiff must establish. *Sterling*, 370 F.2d at 85. Moreover, Nebraska law is clear that, 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 that the active negligence of a third person is also a substantial factor in bringing about the harm does not protect the defendant from liability; furthermore, if the separate and independent acts of negligence by different persons combine to produce a single injury, each participant is liable for the damage, although one of them alone could not have caused the result.").[3] Simply put, the *foreseeable* effect of Somatics' failure to warn of 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, as Dr. Sharma testified, *see* Ex. 13 at 217-219. *See also* 1 NEB. PRAC., NJI2D CIV. 3.43 (comments) ("For an act to be a superseding cause, it must have been unforeseeable. An intervening act is not a superseding cause where

[3] *Fuhrman v. State*, 265 Neb. 176, 188 (2003) ("Given appellants' failure to disclose Jeffrey's history to his caregivers, Immanuel's alleged failure to warn and train Fuhrman cannot be said to be an independent act that would break the causal connection between appellants' negligence and Fuhrman's injuries.") (*disapproved on other grounds by Jill B. v. State*, 297 Neb. 57 (2017)).

the likelihood of the act is itself one of the hazards that made defendant's conduct negligent."). Because Somatics' negligent failure to warn was the act that set in motion Dr. Sharma's lack of knowledge, and thus not warning Thelen so as to allow Thelen to receive the warning and guard against the risk, under Nebraska law, the intervening (or hypothetical) conduct of Dr. Sharma did not constitute an intervening cause absolving Somatics' liability.[4] *Kudlacek,* 244 Neb. at 833; *Wollenhaupt v. Andersen Fire Equip. Co.*, 232 Neb. 275, 279 (1989) (granting plaintiff new trial due to erroneous jury instructions on causation).

Thelen should be afforded a new trial as the defective causation jury instruction was contrary to Nebraska Supreme Court precedent. The erroneous jury 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, indicating the challenged instructions were responsible.

II. Dr. Sharma's Patient Consent Video on ECT Produced by CHI Hospital Was Highly Probative and Erroneously Excluded

To obtain a new trial based on an error in an evidentiary ruling, the moving party must establish the error affected a party's substantial rights. *OneSource Facility Servs., Inc. v. Mosbach*, 2008 WL 11430040, at *9 (M.D. Fla. Nov. 18, 2008) (citing FRCP 61 and *Proctor v. Fluor Enterprises, Inc.*, 494 F.3d 1337, 1349

[4] Somatics made no claims that any of Thelen's treaters were negligent and Somatics' main ECT practicing expert confirmed Thelen's treaters were not negligent. *See* Tr. Vol. VI at 81-82.

(11th Cir. 2007)). An error affects a substantial right when it probably had a substantial influence on the jury's verdict. *Id*. Where an erroneous evidentiary ruling addresses a "pivotal issue in the case" a new trial is the only relief available to remedy the unfair prejudice to a party. *Ewing v. Carnival Corp*., 2022 WL 1719315, at *15 (S.D. Fla. May 27, 2022) (citing *Burchfield v. CSX Transp., Inc*., 636 F.3d 1330, 1338 (11th Cir. 2011).

Throughout the trial, and even in a Motion to Reopen the trial, Thelen attempted to introduce Exhibit 32, a patient consent video featuring Dr. Sharma, titled "Dispelling the Myths of ECT." The video is a 16-minute patient consent video produced by CHI Hospital, portions of which depict Dr. Sharma explaining his understanding of the risks and benefits of ECT. *See* Ex. 2

The evidence at trial demonstrated the Thelen family watched the patient consent video at CHI. Ex. 10 at 144:12-18; 182:12-25; 259:24-25. When Thelen's counsel first attempted to introduce the video into evidence, following examination of Thelen's mother, Somatics objected to the video, arguing it was unclear whether the video was the one the Thelens watched, and falsely represented to the Court that Thelen *did not* recall watching any video when his deposition was taken. Ex. 10 at 258:24-259:23. In fact, Thelen testified at deposition that he *did* watch a video on ECT in the CHI waiting room. *See* Ex. 3,

at 41:21-42.[5] Following the direct examination of Plaintiff's mother, the Court reserved ruling on the admissibility of the Sharma video. Ex. 10 at 260:7-261:6. The next day, after the video deposition of Dr. Sharma, Plaintiff moved to admit the video into evidence, and 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.

Ex. 11 at 234:19-236:14. Somatics' counsel further objected, arguing it was not properly identified as the video in existence at the time the Thelen family was at CHI, and it was not a medical record. Ex. 11 at 236:15-237:17. But as Plaintiff's counsel explained during trial, this was the only video produced by the hospital, in response to a third-party subpoena and Dr. Sharma only testified to making one video. Ex. 11 at 164:8-21; 229:25-230:8.

After several days into the trial, the Court determined the Sharma video was authentic and not hearsay, *see* Ex. 12 at 82:24-94:2, yet the Court still excluded this critical video under FRE 403, stating the video might confuse the issues, because the jury's focus would be on disclosures given to the patient from the doctor, as opposed to disclosures given from the manufacturer. *Id.* As explained, *supra*, however, the Court's erroneous proximate cause jury instructions focused on the conduct of Dr. Sharma and thus the video should

[5] Moreover, counsel intended to show the Sharma video to Plaintiff during his direct examination. *See* Tr. Vol. IV at 70:9-12 & 92:17-25.

have been admitted. Moreover, the video is independently relevant to combat Somatics' argument that Dr. Sharma already knew of the risks of ECT.

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:

> Question 1 – Are we able to review Dr. Sharma's testimony, either by video or transcript?
>
> Question 4 – May we rewatch Dr. Sharma's testimony regarding his knowledge:
> (a) Whether ECT causes permanent and/or temporary loss of memories;
> (b) The Task Force's blue book; and
> (c) Whether memories return after ECT treatment and/or Dr. Sharma's beliefs about whether or not memories return after ECT treatment?

Dkt. 245 at 1, 3. Unfortunately, the jury was not given the opportunity to see a short clip of Dr. Sharma that demonstrated he was unaware of the full nature and extent of the risks of ECT and thus could not provide adequate warnings to patients. In the video, Dr. Sharma stated, 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.**

Ex. 2 at 9:43 to 11:45. After receiving the jury's questions during deliberations concerning Dr. Sharma's testimony, Plaintiff's counsel unsuccessfully urged the Court to reopen the case to admit the Sharma video. Ex. 15 at 74:18-75:3; 84:20-23; 87:2-16; *see also* Dkt. 242, 252 (Motion to Reopen the Case Denied).

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. v. GTE Directories Corp.*, 37 F.3d 1460, 1465 (11th Cir. 1994) (quoting *Kotteakos v. US*, 328 U.S. 750, 765 (1946)). Thelen was deprived of the opportunity to show the jury this evidence, which was central to a pivotal issue in the case, thereby substantially affecting his right to a fair trial. On this basis alone, a new trial should be granted. *See e.g., Ewing*, 2022 WL 1719315, at *1 (erroneous admission of evidence was independently sufficient to warrant new trial).

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

Improper argument made by counsel during closing arguments can be grounds for a new trial. *See McWhorter v. City of Birmingham*, 906 F.2d 674, 677 (11th Cir. 1990); *Edwards v. Sears, Roebuck and Co.*, 512 F.2d 276, 286 (5th Cir. 1975). Prior to jury deliberations, the parties heavily debated the appropriate language that should be included in the jury instruction on proximate causation. *See Supra* Part I. Somatics urged the court to include an improper proximate cause standard which would have required Plaintiff to prove that, had Somatics issued adequate warnings, Plaintiff's treating physician would not have *prescribed* ECT to Mr. Thelen. The Court appropriately 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 decision. *See* Dkt. 244 at 4.

Notwithstanding the Court's ruling on the jury instructions, Somatics' counsel deliberately argued the wrong legal standard during closing arguments:

> "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." Ex. 15 at 54:22-25.
>
> "The plaintiff here claims that … if Somatics had used the words, quote, brain damage, instead of the words permanent memory loss, that suddenly Dr. Sharma would have changed his conduct and not prescribed ECT to Mr. Thelen. That's not proven." Ex. 15 at 46:23-25.
>
> "Dr. Sharma knew of the risks of permanent memory loss, and there is no evidence that's been presented to you that Dr. Sharma would have changed his conduct in prescribing ECT if the words brain damage were there instead of the words permanent memory loss." Ex. 15 at 67:11-15.

So as not to interfere with the limited time allotted for closing arguments and to draw further attention to the misstatement, Plaintiff's counsel did not contemporaneously object. However, after the jury asked their first question (whether they could review Dr. Sharma's testimony), Plaintiff's counsel pointed out that Somatics' counsel had argued the wrong standard during closing argument – focusing on the prescribing decision of the doctor – the very standard the Court rejected. Ex. 15 at 73:19-74:17. Plaintiff's counsel asked the court to give a curative instruction explaining that the physician's *prescribing* decision is not the standard. *Id.* The Court declined and the jury returned a verdict finding for Defendant on the issue of proximate cause.

Failure to *contemporaneously* object to improper statements made during closing does not prevent the Court from considering such arguments in a motion for new trial. *See Peeler v. KVH Indus., Inc.*, 13 F. Supp. 3d 1241, 1254, n.6 (M.D.

Fla. 2014). The Eleventh Circuit's decision in *McWhorter*, 906 F.2d 674 at 677, is instructive. In *McWhorter*, plaintiff's counsel improperly argued a theory of liability during closing argument that the district court previously eliminated and, in closing, urged the jury to review evidence contained in an exhibit that should have been excluded from evidence. *Id.* at 676-77. The defendant's counsel did not *contemporaneously* object to the closing argument, but midway through the jury's deliberations, defense counsel notified the court of the disputed exhibit in evidence. *Id*. The court removed the exhibit from the jury room, and during deliberations, the jury asked the court about the disputed exhibit. *Id.* at 677. The court instructed the jury that the exhibit was not in evidence and the jury subsequently returned a verdict for the plaintiff. *Id.* The court granted the defendant's request for a new trial, finding the plaintiff's counsel's improper argument influenced the jury's verdict. *Id.* The Eleventh Circuit affirmed the district court's grant of a new trial, finding the jury's question about the disputed exhibit *during their deliberations* showed their verdict was influenced by counsel's improper closing argument and that defense counsel's failure to object contemporaneously with the objection was not fatal. *Id.* The Court reasoned that "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. *Id.; see also Christopher v. Florida,* 449 F.3d 1360, 1367, n.8 (11th Cir. 2006).

Somatics' counsel's improper and erroneous arguments rendered the trial unfair to Plaintiff and the interest of substantial justice warrants a new trial.

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

On May 26, 2023, five days before trial, the Court issued a minute order that Bennet Omalu, M.D. would not be permitted to testify about general causation. Dkt. 209. After the conclusion of the trial, on June 12, 2023, the Court issued a written order excluding Dr. Omalu's general causation opinion. Dkt. 251. The Court's order limiting Dr. Omalu's testimony, however, was manifestly erroneous under *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 589-95 (1993).

In its exclusion order, the Court held "[a]lthough Dr. Omalu is board certified in epidemiology, he did not rely on epidemiological studies or principles to support his opinions." Dkt. 251 at 6[6]. However, the Eleventh Circuit has held that epidemiological evidence is not required to prove causation. *Rider v. Sandoz Pharmaceutical*, 295 F. 3d 1194, 1199 (11th Cir. 2002); *Wells v. Ortho Pharm. Corp.* 788 F. 2d 741, 745 (11th Cir. 1986); *Waite v. All Acquisition Corp.*, 194 F. Supp. 3d 1298, 1313 (S.D. Fla. 2016). This is particularly true here since no epidemiological studies exist. As the Supreme Court explained in *Daubert*, to be admissible, expert testimony must take what is known, however large or small that body of knowledge may be, and draw conclusions from that knowledge

[6] Dr. Omalu's board certifications include (a) Anatomic Pathology; (b) Clinical Pathology; (c) Forensic Pathology; and (d) Neuropathology. He has a Masters Degree in Epidemiology.

using the scientific method. *Daubert* 509 U.S. at 590. Dr. Omalu did that.

The Court determined Dr. Omalu did not discuss the concept of dose-response relationship…" Dkt. 251 at 6. However, Dr. Omalu did discuss dose response and cited supporting literature. Ex. 5 at 105:9-13; *see also* Ex. 7 at 9. While there is no literature that identifies a particular threshold for injury, Dr. Omalu did cite literature that shows a dose response. *See* Dkt. 198-7, 8, 16 (Dubey, Fink, and Jasper's). The Court further states that "Dr. Omalu asserts that most of his opinions in this case are based on his education, training and experience. But such general references, without more, are insufficient to establish the reliability of specific opinions." Dkt. 251 at 7. But there *is* more, as evidenced in the literature cited in his initial report, in the scores of additional articles provided to Somatics' counsel in response to her specific requests, the 26 articles and textbooks provided to the Court, and his reliance on Dr. Read and Dr. Castleman. And, as he explained in his deposition, Dr. Omalu relied on thousands of articles and texts from a library of previously reviewed medical literature in a database called EndNote.

The Court also questioned Dr. Omalu's experience in its Order. As Dr. Omalu explained in his expert report, his area of expertise is in brain patho-physiology, brain injuries and brain trauma. Ex. 7 at 2. Relying upon the reports of Plaintiff's other experts as well as his own extensive knowledge of the

workings of the human brain and brain trauma, including the "fundamental and foundation of electrical signaling and functioning of the human brain and nervous system" in its normal state (*see* Guyton & Hall textbook of Medical Physiology, Dkt. 198-12), Dr. Omalu concluded that ECT's "amounts of energy are exponentially outside the tolerable homeostatic ranges and thresholds of the human brain and nervous system" and "are expected to cause cellular physiologic, biochemical and anatomic injures to the human brain cells." Ex. 7 at 10. Dr. Omalu supported his opinions with scientific literature. *Id*. at 16; Dkt. 198 (highlighted literature); Ex. 6 at 173:20-175:3 (explaining his review of the medical and scientific literature over the years).

The Court states that Dr. Omalu "has not published on ECT, or conducted scientific studies on ECT, or autopsied patients to analyze the effects of ECT" and that he did not conduct a systematic review of the literature. Dkt. 251 at 7. *First*, Dr. Omalu *did* rely on Dr. Read who conducted a systematic literature review. *Second*, neither *Daubert* nor its progeny stand for the proposition that an expert must have conducted scientific studies or undertaken a systematic review of the literature. Experts may rely on "legitimate, preexisting research unrelated to the litigation" which "provides the most persuasive basis for concluding that the opinions expressed were 'derived by the scientific method'" *Monroe v. Zimmer U.S. Inc.*, 766 F. Supp. 2d 1012, 1028 (E.D. Cal. 2011); *Carroll v. Morgan*, 17 F.3d

787, 790 (5th Cir.1994) (expert's testimony based on thirty years of experience and his review of records and literature was "'ground[ed] in the methods and procedures of science' and was not mere 'unsupported speculation.'").

The Court notes that "Dr. Omalu has extensive experience with brain trauma but appears to have little experience with ECT in particular." Dkt. 251 at 7. However, "[t]he fact that the physician is not a specialist in the field in which he is giving his opinion affects not the admissibility of his opinion but the weight the jury may place on it." *Payton v. Abbott Labs*, 780 F.2d 147, 155 (1st Cir. 1985).

The Court states that, while Dr. Omalu acknowledged views contrary to his own, he did not explain why he came down on the side of ECT causing brain damage. Dkt. 251 at 7. Again, neither *Daubert* nor its progeny require such an explanation. To be admissible, Dr. Omalu was not required to show that whether ECT causes brain damage is a settled issue. *Daubert,* 509 U.S at 590; *see also*, *Loewen v. Wyeth*, 2011 WL 6942887, 3 (N.D. Ala. Nov. 14, 2011) (expert is "not required to show unanimity in science" and "the fact that another explanation might be right is not a sufficient basis for excluding the expert's testimony."); *Jones v. Otis Elevator Co*. 861 F. 2d 655, 662 (11th Cir.) (certainty is not required.)

The Court states that "Dr. Omalu conceded he did not rely on the cited literature in forming his opinions." Dkt. 251 at 7. However, in context, Dr. Omalu testified he "relied on the over 50,000 papers and textbooks I've read in

the past 30, 40 years." Ex. 5 at 126:8-10. And he identified approximately 90 citations to illustrate his opinions are supported and reliable. This literature not only supported Dr. Omalu's opinion but illustrates his opinion that ECT can cause brain damage has scientific support and does not simply constitute his say so. *See, e.g.*, Dkt. 198-16; 98-18; 198-7; 198-24; 198-25; 198-26; 198-2;198-8; 198-10.

V. The Court Improperly Limited Dr. Hannappel's Testimony

On May 5, 2023, the Court issued a *Daubert* order excluding the specific causation testimony of Dr. Mark Hannappel, Plaintiff's treating psychologist who performed neuropsychologist testing on Plaintiff in 2017 and continuously treated him for his neurocognitive disorder since 2020. *See* Dkt. 170 at 4-6.

In excluding Dr. Hannappel's testimony, the Court reasoned that he is not a medical doctor, has "no relevant training or experience" with ECT treatment or its risks and side effects, and he testified he is not qualified to offer medical opinions. *Id.* at 5. But the fact that Dr. Hannappel is not a *medical* doctor does not render him unqualified to offer specific causation opinion testimony under *Daubert*. Dr. Hannappel's specific causation testimony was based on the neuropsychological testing results of Thelen and his ongoing care of Thelen. Ex. 8 at 11:9-11, 142:4-22. Somatics' retained neuropsychologist, Dr. Bilder, who is also not a medical doctor, was permitted to testify as to medical causation at trial. Ex. 3 at 58:2-10. This is unsurprising because psychologists are routinely

permitted to offer causation opinions. *See* Dkt. 102 at 10-11 (collecting cases).

The Court also questioned Dr. Hannappel's methodology because "he did little to determine the existence of … possible alternative causes" and because in his 2017 testing report (which was not prepared for litigation) Dr. Hannappel stated that ECT treatment was "possibly related" to his condition and left it to Plaintiff's treating physicians to rule out medical explanations for cognitive declines. Dkt. 170 at 6. Dr. Hannappel's opinion, however, was not so limited. After treating Plaintiff continuously for two years, Dr. Hannappel unequivocally testified at his deposition that he believes that Mr. Thelen's "90 plus" ECT treatments were *more likely than not* a contributing factor to his diagnosis of neurocognitive disorder, and that the ECT treatments are a substantial factor in Mr. Thelen's diagnosis of neurocognitive disorder. Ex. 8 at 142:4-22. Dr. Hannappel's finding was confirmed by Plaintiff's treating psychiatrist, Dr. Heller (Ex. 6 at 91:13-93:21). Indeed, medical providers are routinely permitted to offer causation testimony. *Salas v. United States*, 165 F.R.D. 31 (W.D.N.Y. 1995); *Glasscock v. ABC Pro. Tree Servs., Inc*., 2022 WL 1910119 (N.D. Fla. June 4, 2022).

In its ruling, the Court improperly engaged in weighing the evidence, reasoning that Plaintiff did not show Dr. Hannappel was qualified to offer an opinion on "medical causation" because, for instance, he only read a couple of articles on ECT and relied on Plaintiff's self-reporting of his medical history.

Dkt. 170 at 5-6. This weighing of evidence was improper under *Daubert*. "The gatekeeper role … is not intended to supplant the adversary system or the role of the jury." *Allison v. McGhan Med. Corp.*, 184 F. 3d 1300, 1311 (11th Cir. 1999).

The Court's *Daubert* ruling had the effect of further improperly limiting Dr. Hannappel's testimony at trial. In ruling on deposition designations, the Court admitted testimony in which defense counsel questioned him about whether he had seen some medical records indicating Plaintiff's brain imagining was normal, but 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. *See* Dkt. 211-5 at 70; Dkt. 226. The Court also excluded Dr. 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. *See* Dkt. 211-5 at 109; Dkt. 211-6 at 36-37; Dkt. 226. In the eyes of a jury, the testimony of a non-retained, unbiased, treating expert's testimony carries significant weight. The Court's exclusion of Dr. Hannappel's specific causation testimony substantially affected Plaintiff's right to a fair trial.

VI. The Court Erroneously Dismissed Plaintiff's Design Defect Claim

The Court granted defendant's request to dismiss Thelen's design defect claim. Defendant's motion was primarily focused on the premise that, under Nebraska's consumer expectation test, the "ordinary users" of a medical device

are the prescribing physicians and that Thelen's prescribers purportedly were aware of the risk of brain damage and memory loss. Indeed, the *only* evidence defendant cited in support of dismissal of the design defect was the deposition of one of Thelen's treaters (Dr. Alsakaf). *See* Dkt. 93 at 15. The Court correctly rejected defendant's arguments finding that, under Nebraska law, the ordinary user is the patient (not the doctor); and further finding that a triable issue of fact existed as to whether Somatics had adequately warned about brain damage. *See* Dkt. 169 at 6-7, 14. However, the Court 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 is procedurally, factually, and legally flawed and warrants reversal under Rule 59(a) and 59(e).

Procedurally, in their motion for summary judgment, defendants did not focus on the consumer expectation test from the perspective of a patient and never met their 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 Dr. Alsakaf. Without any evidence in support of their motion, under established Circuit precedent, defendants did not meet their 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) ("The moving party bears the initial burden to show the district court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial. *Only when that burden has been met does the burden shift to the non-moving party to demonstrate that there is indeed a material issue of fact that precludes summary judgment*.") (emphasis added). In *Clark*, the 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.

Factually and *legally*, even if the burden had been shifted to Thelen, Thelen presented more than sufficient evidence for his design defect claim to proceed to trial. Specific to the issue of consumer expectation, Thelen's evidence was not limited to his own expectations, rather he submitted objective evidence, including: (a) copies of the ECT consent document (which did not warn of brain damage) (Dkt. 111-2); (b) a copy of the hospital patient information pamphlet for ECT (which did not warn of brain damage) (Dkt. 111-6); (c) Somatics' Thymatron ECT device manual (which did not warn of brain damage) (Dkt. 111-30); (d) Somatics' advertisements that its ECT device had "superior safety" (which did not warn of brain damage) (Dkt. 111-15); (e) testimony from treaters that

Somatics never warned about the risk of brain damage (Dkt. 111-5 at 105-106); (f) testimony from Thelen's parents that they were not informed of brain damage (Dkt. 111-3 at 54-55 & Dkt. 111-4 at 65-66); (g) testimony from Somatics' owner, Dr. Abrams, that the Patient Information Pamphlet Somatics wrote for ECT patients stated brain injury was not a risk (Dkt. 111-17 at 6 (pg. 154)); and (h) evidence that Somatics knew or should have known that ECT could cause brain injury and that it failed to warn of said risk (as the jury ultimately concluded) (Dkt. 105-107). These, 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*, 226 Neb. at 427 (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 (to establish design defect it is sufficient to assert that "[the drug] was more dangerous to [plaintiff] than was anticipated due to undisclosed side effects" and that these allegations can be supported by evidence that the drug was sold without warnings about life-threatening adverse events).

The Nebraska Supreme Court's decision in *Hancock v. Paccar, Inc.*, 204 Neb.

468 (1979), is further confirmation that Thelen's design defect claim should have gone to the jury. *Hancock* affirmed the jury's finding that defendant's car bumper was defectively designed and caused plaintiff's death and held:

> we find that there was sufficient evidence from which the jury could reasonably conclude that the design of the bumper was "unreasonably dangerous." Paccar knew the wheel was unprotected from the bumper. It also knew it had not designed the bumper to protect the wheel from large objects, likely to be struck by the truck at high speeds, which, upon impact, might bend the bumper impairing steering. Yet no action was taken by the manufacturer to protect the wheel from such impairments. That was sufficient to raise a question of fact as to whether the bumper in its present condition was unreasonably dangerous.

Hancock, 204 Neb. at 484. 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) ("the consumer expectation theory, rooted as it is in a warranty heritage, would seem necessarily to encompass a case in which it is alleged the product failed to perform in accordance with the representations contained in its own owner's manual.") (citations omitted); *Mariscal v. Graco, Inc*., 52 F. Supp. 3d 973 (N.D. Cal. 2014); *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").[7]

CONCLUSION

For the foregoing reasons, Thelen respectfully requests that his motion for a new trial be granted.

[7] The dismissal of the design defect claim is critical given that, under Nebraska law, the learned intermediary doctrine would not have been implicated in the design defect claim (as Nebraska views the patient (not the physician) as the consumer). *Freeman*, 260 Neb. at 567-68.

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Respectfully submitted,
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LOCAL RULES 3.01(G) CERTIFICATE

Pursuant to Middle District of Florida Rule 3.01(g), the undersigned counsel certifies that the parties met and conferred regarding this motion. Counsel for Somatics objects to Plaintiff's Motion.

CERTIFICATE OF SERVICE

I, Monique Alarcon, hereby certify that on this date, July 7, 2023, the foregoing was filed electronically via the Court's CM/ECF system, to be served on all counsel of record by operation of the Court's electronic filing system.

/s/ Monique Alarcon
Monique Alarcon