

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

JEFFREY THELEN,

Plaintiff,

v.

Case No: 8:20-cv-1724-TPB-JSS

SOMATICS, LLC, and
ELEKTRIKA, INC.,

Defendants.

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ORDER ON DAUBERT MOTIONS

This cause is before the Court on the following motions: (1) “Elektrika, Inc. and Somatics, LLC’s Joint Motion to Exclude Opinion and Testimony of Doctor Mark Hannappel Regarding Causation” (Doc. 87), and (2) “Defendant Somatics, LLC’s Daubert Motion to Exclude the Testimony of Kenneth Castleman, Ph.D. and Bennet Omalu, M.D.” (Doc. 94). Plaintiff filed a response to the motion as to Hannappel on January 10, 2023. (Doc. 102). Plaintiff filed a response to the motion as to Castleman and Omalu on January 10, 2023. (Docs. 108; 115). The Court heard argument on the motions on April 17, 2023.¹ Upon review of the motions, responses, argument, court file, and record, the Court finds as follows:

¹ Defendants also filed a corrected motion seeking to exclude Hannappel’s causation opinions. (Doc. 92). Defendant Elektrika, Inc, also filed a *Daubert* motion as to Castleman and Omalu. *See* (Doc. 95). Elektrika, Inc. and Plaintiff have filed a notice of settlement, and Elektrika’s motion is therefore no longer at issue. However, because Somatics’ motion incorporates Elektrika’s arguments by reference, this Order addresses points made by Elektrika as well as by Somatics. This written opinion supplements the Endorsed Orders on these motions entered on May 3, 2023. (Docs. 155; 156).

Background

Plaintiff Jeffrey Thelen has suffered from severe depression and other mental health issues for many years, resulting in hospitalization on more than one occasion. From May 2014 to July 2016, he received over 90 electro-convulsive therapy (“ECT”) treatments at a CHI Health hospital in Omaha, Nebraska, using a Thymatron IV ECT device manufactured and sold by Defendant Somatics, LLC. Plaintiff alleges that despite knowing of the substantial risks associated with ECT treatment, Somatics failed to warn Plaintiff of these risks. Plaintiff alleges that the ECT treatments caused permanent neurological injury, including permanent memory loss and brain damage.

On July 24, 2020, Plaintiff filed this product liability suit under various legal theories. After the Court’s disposition of a number of claims, the remaining claims against Somatics are negligence (Count I) and strict liability (Count II). In support of his claims, Plaintiff seeks to offer expert testimony by Kenneth Castleman, Ph.D., and Bennett Omalu, M.D., on the issue of general causation, i.e., that ECT treatments can cause permanent memory loss and brain damage.² Plaintiff also intends to offer expert testimony by Mark Hannappel, Ph.D., and by Dr. Omalu on the issue of specific

² As discussed in the Court’s summary judgment order, “general causation,” i.e., whether the drug or other product can cause the injury in question, is typically established by expert testimony based on evidence such as the association between the product and injury shown in epidemiological studies, the strength and nature of the association, and the biological plausibility of a causal relationship. *See King v. Burlington N. Santa Fe Ry. Co.*, 762 N.W.2d 24, 34-42 (Neb. 2009). Specific causation, i.e., whether the product did in fact cause the plaintiff’s injury, is typically established by expert testimony employing a technique known as differential etiology by which the expert first “rules in” possible causes of the patient’s condition, and then “rules out” other potential causes, leading to a conclusion that the remaining possible cause more likely than not was the actual cause. *Id.* at 34, 49-50.

causation, i.e., that the ECT treatments administered to Plaintiff did in fact cause memory loss and brain damage. Somatics has moved to exclude these opinions as inadmissible under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), and its progeny.

Legal Standard

An expert witness may testify in the form of an opinion if “(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597 (1993). “The party offering the expert testimony bears the burden of establishing, by a preponderance of the evidence, the expert's qualification, reliability, and helpfulness.” *Payne v. C.R. Bard, Inc.*, 606 F. App'x 940, 942 (11th Cir. 2015) (citing *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc)).

Functioning as a gatekeeper, the district court plays an important role by ensuring that all expert testimony is reliable and relevant. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005). Although *Daubert* references specific factors for the district court to consider when evaluating relevancy and reliability, the inquiry is a flexible one, focusing on the principles and methodology employed by the expert, not on the conclusions reached. *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1305 (11th Cir. 2014); *see also Hanna v. Ward Mfg., Inc.*, 723 F. App'x 647, 649-50 (11th Cir. 2018) (outlining the criteria for the admissibility of expert witness

testimony). Essentially, the Court is simply asked to determine if the evidence “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597.

Analysis

Mark Hannappel

In August 2017, psychologist Mark Hannappel, Ph.D., prepared a neuropsychological evaluation of Plaintiff that concluded Plaintiff suffered from various cognitive deficits. His evaluation further stated that these deficits could possibly have resulted from the ECT treatments, but left it to Plaintiff’s treating physicians to rule out other medical explanations for this condition. Hannappel later treated Plaintiff for his condition. Plaintiff proposes to present testimony from Hannappel not only as to his neuropsychological evaluation of Plaintiff and later course of treatment, but also as to specific causation, i.e., on whether Plaintiff’s cognitive deficits were caused by the ECT treatments.

Somatics challenges the admissibility of specific causation testimony by Hannappel. Somatics first argues Hannappel is a clinical psychologist, not a medical doctor, and has no expertise by virtue of knowledge, training or experience in the risks or side effects of ECT. Second, Somatics argues that Hannappel based his opinion solely on the temporal connection between Plaintiff’s ECT treatments and his symptoms, which is not a reliable methodology for determining causation.

Plaintiff responds that Hannappel acquired his causation opinions in the course of treating Plaintiff and his opinions are therefore not subject to scrutiny under *Daubert*. Plaintiff argues Hannappel is qualified to offer a causation opinion based on his “significant experience interpreting and assessing neurocognitive disorders, as well

as the possible etiology of such disorders.” Finally, Plaintiff argues that Hannappel did not simply employ *post-hoc* reasoning in reaching his conclusion, but considered Plaintiff’s family history, medical history, and history of depression, as well as the results of neuropsychological testing. Plaintiff maintains that Hannappel also reviewed medical literature on ECT and considered other potential causes for Plaintiff’s symptoms, including depression, anxiety, and drug and alcohol use.

As a threshold matter, *Daubert* applies to Hannappel’s proposed medical causation testimony. In some cases, testimony by treating physicians may escape scrutiny under *Daubert* when it is related to treatment and necessary to explain the physician’s treatment decisions. *See, e.g., Wilson v. Taser Int’l*, 303 F. App’x 708, 712 (11th Cir. 2008). Here, however, at the time he formed his opinions, Hannappel was consulting with Plaintiff’s treating physicians rather than treating Plaintiff himself, and his recommendations for treatment focused on addressing Plaintiff’s symptoms, without regard to the cause. *See Wilson*, 303 F. App’x at 712-13 (*Daubert* applied to treating physician’s causation opinion where the physician did not need to know the cause of the injury in order to treat the plaintiff).

Applying *Daubert* and Rule 702, the Court concludes that Hannappel should not be allowed to offer medical causation opinions. Plaintiff has not shown by a preponderance of the evidence that Hannappel is qualified to render an opinion on medical causation. *In fact, Hannappel stated in deposition he did not consider himself qualified to render such an opinion.* He is not a medical doctor, has no relevant training or experience with ECT treatments, risks and side effects, and his background regarding ECT was acquired by reading “a couple of articles” on ECT (the

specifics of which he did not recall) and consulting a treatise on neuropsychology in 2017 when he performed his evaluation of Plaintiff.

As for the reliability of Hannappel's methodology, while he briefly considered whether Plaintiff's depression or other conditions might account for his memory issues, he did little to determine the existence of alternative possible alternative causes. In particular, Hannappel relied solely on Plaintiff's self-reporting as to his medical history, and did not even obtain or review Plaintiff's medical records. As noted above, he performed only cursory research into the risks and side effects of ECT treatments. It also appears that at the time he conducted his evaluation Hannappel himself understood that he could not reach a reliable conclusion on causation because his report stated only that ECT treatment was "possibly related" to his condition, and expressly left it to Plaintiff's treating physicians to "rule out medical explanations for the cognitive declines." The clear implication is that Hannappel had not done so.

Accordingly, Plaintiff has not demonstrated by a preponderance of the evidence that Hannappel is qualified or that his medical causation testimony is reliable. Moreover, his testimony on this point would be cumulative of that of Dr. Omalu, who purports to have conducted a differential etiology analysis that is not challenged by Defendants. Accordingly, Somatics' motion to preclude testimony by Hannappel that ECT caused Plaintiff's memory loss and other symptoms, or the admission of medical records setting forth his opinion on that point, is granted.

Kenneth Castleman

Somatics challenges the admissibility of opinions by biomedical engineer Kenneth Castleman that ECT causes brain damage or injury by generating excessive

heat inside the brain or by “electroporation,” that is, the creation of holes in brain cell membranes. At the April 17, 2023, hearing, Plaintiff agreed that Castleman would not offer these opinions and would limit his testimony to general principles of electricity relevant to Plaintiff’s ECT treatments. Based on this agreement, the *Daubert* motion as to Castleman is denied. To the extent Somatics has objections to the testimony of Castleman on issues other than general medical causation, the Court will hear and determine those at trial in the context of all the evidence.

Bennet Omalu

Dr. Omalu is a medical doctor and forensic pathologist with particular expertise in brain trauma. Plaintiff plans to present testimony from Dr. Omalu (1) that it is well-established in the medical and scientific community that ECT causes brain damage (general causation), and (2) that ECT treatment did in fact cause such damage in Plaintiff’s case (specific causation). Somatics’ challenges to Dr. Omalu’s testimony focus on general causation. To the extent Somatics argues Dr. Omalu cannot present specific causation testimony, its arguments turn on the absence of admissible evidence on general causation as a predicate for a specific causation analysis, rather than rather than deficiencies in Dr. Omalu’s specific causation methodology itself.

The record, however, contains sufficient evidence supporting general causation. Specifically, Plaintiff’s expert John Read will testify that ECT causes persistent or permanent memory loss and brain damage in from 12% to 55% of recipients. Somatics has not challenged the admissibility of Read’s opinions under Rule 702 or *Daubert*, and they provide a sufficient basis for Dr. Omalu to have “ruled in” ECT as a potential

cause as part of his differential etiology analysis. Since Somatics offers little else in the way of criticism of Dr. Omalu's differential etiology analysis, the Court will allow him to testify as to specific causation.

There remains for consideration whether Dr. Omalu will be permitted to testify regarding general causation. As to the specific mechanism of injury, Dr. Omalu relies in part on the opinions of Castleman as to how ECT causes brain damage through heating of the brain and electroporation. Plaintiff has agreed Castleman will not be offering opinions on that issue. Therefore, Dr. Omalu will not be able to refer to those opinions in his testimony. Doing so would allow Plaintiff to use Dr. Omalu as a conduit for opinions Plaintiff has agreed to keep out of the case.

Dr. Omalu, however, also opines that ECT causes brain damage based on his own training and experience, and asserts this proposition is well established. In support, he has referred generally to the medical and scientific literature and in particular to a list of citations provided to Defendants' counsel after the close of discovery. Although the Court allowed Defendants to conduct a brief deposition of Dr. Omalu regarding these citations, the Court is not convinced this issue has been sufficiently explored.³

³ At the April 17, 2023, motion hearing, Plaintiff repeatedly suggested Dr. Omalu could testify to general causation based on his training, education, and clinical experience in general, and he did not need to point to anything in the medical literature to support his opinion. Dr. Omalu's testimony, however, cannot be admitted based simply on his broad assertion that a proposition is widely accepted, or is correct, or is supported by the literature, simply because he says that is the case. As the Eleventh Circuit observed in *Frazier*, 387 F.3d at 1261, quoting the advisory committee notes to Rule 702, an expert relying primarily on experience "must explain *how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'"

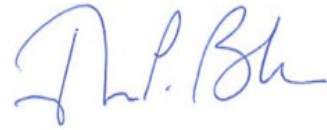
Accordingly, as directed at the April 17, 2023, hearing, Plaintiff will file on or before the May 15, 2023, pretrial conference, copies of all medical or scientific literature Dr. Omalu contends supports the opinions on general causation set forth in his expert report, including without limitation, his opinion on page 9 of his report that ECT causes brain injury and brain damage, his opinion on page 9 of his report that the primary objective of an ECT machine is to transmit electrical energy to the human brain to intentionally cause physiological, biochemical, and anatomic cellular injuries to human brain cells, and his discussion on pages 11-12 of his report regarding mechanisms of injury. On the filed copy of each text or article, Dr. Omalu will highlight or otherwise indicate the specific sentences and paragraphs he contends most strongly support his general causation opinions, including the specific opinions noted above. The highlighted portions *shall not* exceed ten sentences per article or text chapter.

Accordingly, it is hereby

ORDERED, ADJUDGED, and DECREED:

- (1) “Elektrika, Inc. and Somatics, LLC’s Joint Motion to Exclude Opinion and Testimony of Doctor Mark Hannappel Regarding Causation” (Doc. 87) is **GRANTED**.
- (2) “Defendant Somatics, LLC’s Daubert Motion to Exclude the Testimony of Kenneth Castleman, Ph.D. and Bennet Omalu, M.D.” (Doc. 94) is **DENIED IN PART** and **DEFERRED IN PART**.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 5th day of May,
2023.



TOM BARBER
UNITED STATES DISTRICT JUDGE