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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; DEBORAH CHASE,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-PJW
[Assigned to Hon. R. Gary Klausner, Court Room 850]

MEDIATION BRIEF FROM DEFENDANT, SOMATICS LLC

Date: September 11, 2018

Place: JAMS
1255 Treat Blvd.
Walnut Creek, CA 94597

Neutral: Hon. William J. Cahill (Ret.)

Reference: 1100090961

COMES NOW, Defendant SOMATICS LLC ("Somatics"), and submits its mediation brief, as follows:

I. INTRODUCTION

A. Procedural History

Plaintiffs' counsel filed its initial action against Somatics, LLC ("Somatics") and Mecta Corporation ("Mecta") with six named plaintiffs with the intent to establish a class action on behalf of all persons who underwent electroconvulsive therapy (ECT) in California. The class certification

motion was denied by the Court on March 19, 2018. Pursuant to motions to dismiss, four of the six named plaintiffs were dismissed with prejudice from the case on June 19, 2018. Mecta was also dismissed from the action. The remaining Plaintiffs, Jose Riera and Deborah Chase ("Plaintiffs"), filed a Fourth Amended Complaint (4AC) against Somatics on June 26, 2018.

The 4AC alleges six causes of action, all of which relate to Somatics' purported failure to warn of the known or knowable risks of ECT. Specifically, Plaintiffs contend that they are suffering from "brain damage" and that Somatics had a duty to disclose this potential risk to their treating physicians and to the FDA.

B. ECT

ECT is a medical procedure which administers a small amount of electricity to the scalp in order to produce a seizure in the brain. It has been used for over 75 years to treat severe illnesses such as depression, mania, and some forms of schizophrenia. ECT is typically recommended for patients who have not responded to other forms of treatment, or when other treatments appear to be less safe or tolerable. ECT is not considered a cure for these psychological conditions, but it can be effective in managing symptoms of said conditions, such as suicidal ideation and cognitive impairment brought on by depression.

C. Informed Consent

In California, **all** patients must provide written informed consent in order to undergo ECT. This process requires, at a minimum, an oral explanation of the risks and benefits of treatment by a licensed doctor, as well as the execution of a written consent form which highlights the known risks and complications of treatment.

D. Risks of ECT

The American Psychiatric Association publishes a practice guide known as the "APA Task Force Report" which goes over, in detail, the risks of ECT. Pertinent sections of the APA Task Force regarding the risks include:

> There is no evidence that ECT results in lasting impairments of executive functions (e.g. the capacity to shift mental sets), abstract reasoning, creativity, semantic memory, implicit memory, or skill acquisition or retention [citation omitted].

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> ECT selectively results in *anterograde* and *retrograde* amnesia. The anterograde amnesia is characterized by rapid forgetting of newly learned information … The extent and persistence of this rapid forgetting of newly learned information varies among patients … no study has documented anterograde amnestic effects of ECT more than a few weeks after the ECT course [citations omitted] … It is unlikely that ECT has any long-term effect on the capacity to learn and retain new information.
>
> Deficits in recalling both personal (autobiographical) and public information are usually evident and are typically greatest for events that occurred closest to treatment [citations omitted] … The retrograde amnesia over this time span is rarely complete. Rather, patients have gaps or spottiness in their memories of personal and public events … In some patients the recovery from retrograde amnesia will be incomplete, and evidence has shown that ECT can result in persistent or permanent memory loss [citations omitted]… profound and persistent retrograde amnesia may be more likely in patients with preexisting neurologic impairment and patients who receive large numbers of treatments using methods that accentuate acute cognitive side effects.
>
> A small minority of patients treated with ECT later report devastating cognitive consequences … Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations. Because these subjective reports of profound cognitive deficits are rare, determination of their absolute base rates is difficult. Multiple factors likely contribute to these perceptions by former patients.
>
> … in some patients self-reports of profound ECT-induced deficits may reflect objective loss of function. As noted, as with the adverse effects of any medical intervention, individual difference occur in the magnitude and persistence of ECT's cognitive effects. In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years before the treatment [citation omitted].
>
> … some of the psychiatric conditions treated with ECT result in cognitive deterioration as part of their natural history … Although cognitive deterioration would have occurred inevitably in such individuals, the experience of transient short-term side effects with ECT may sensitize patients to attribute the persistent changes to the ECT treatment [citation omitted].

Importantly, "brain damage" or <u>permanent</u> impairment to executive functions (e.g. anterograde amnesia) is not an acknowledged risk of ECT within the prevailing scientific and medical community.

E. <u>Brain Damage</u>

Plaintiffs have retained a number of experts who have provided unsupported opinions that ECT causes brain damage. At least two of these experts are known scientologists (Dr. Dolan and Dr. Castelman), and two others have close ties to scientology (Dr. Breggin and Mr. Emord.) Notwithstanding their inherent biases, none of these experts have provided credible proof that their position is supported in the prevailing scientific and medical community. To the contrary, they

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effectively point out that their position is an outlier view attributable to: (1) suppression through conspiracy within the psychiatric community; "methodological shortcomings" in studies that find ECT is safe and effective; and insufficient studies performed aimed at examining whether ECT causes brain damage. Conversely, Somatics' experts, Dr. Coffey and Dr. Kellner, are actual ECT practitioners with decades of experience in administering ECT, and who have each studied the effects of ECT in clinical settings. Neither Dr. Coffey or Dr. Kellner have found credible evidence in their practice or in scientific literature which would suggest that ECT causes brain damage.

F. Somatics

Somatics is a manufacturer of an electroconvulsive therapy device known as the "Thymatron." Somatics warns its customers of the potential risks of treatment in its Operator's Manual, as well as a separate Patient Information Pamphlet. Importantly, all users of the Thymatron device are advised to read and understand the APA Task Force Report, which highlights the prevailing scientific and medical consensus regarding the risks of ECT. Somatics only sells the Thymatron to sophisticated users such as medical hospitals who retain highly educated and licensed physicians to administer the treatment.

G. Plaintiffs

RIERA has been diagnosed with severe depression and has been hospitalized on at least two occasions for expressing suicidal ideation. RIERA comes from an affluent background but lost everything in the 2008 market crash, including his marriage and a relationship with his two daughters. *Prior to undergoing ECT treatment*, RIERA reported having concentration and memory issues. This type of complaint is not uncommon for people suffering from severe depression.

CHASE has also been diagnosed with severe depression and has been hospitalized on at least three occasions for expressing suicidal ideation. CHASE's medical records document a consistent history of reporting concentration and memory problems *prior to her ECT treatment*. CHASE has reported and testified that she was mentally abused by her ex-husband as well as her estranged current husband which caused her hospitalizations.

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II. ARGUMENT

Each of the six claims set forth in Plaintiffs' Fourth Amended Complaint is based on an alleged failure of Somatics to warn of certain risks of ECT. Plaintiffs' opposition to Somatics' motion fails completely because they have not created a triable issue of fact as to whether Somatics failed to warn of risks attendant to the use of ECT that were generally recognized as the known risks of ECT pursuant to the "prevailing best scientific medical knowledge" available at the time of manufacture and distribution of the device.

The undisputed evidence is that Somatics did warn of the very risks of memory loss and cognitive disfunction which constitute the primary complaints of both plaintiffs (and which, in fact, they both complained of prior to obtaining any ECT treatments). As to the allegation that both Plaintiffs also suffered "brain damage" and permanent impairment to executive functions, Plaintiffs have not produced any evidence that such risk of harm is generally recognized as the prevailing best scientific medical knowledge. Rather they offer the opinions of individuals who advocate for brain damage to be recognized as a resulting consequence of ECT but do not and cannot declare that their position is the prevailing view in the scientific medical community - because it is not.

A. Inability to Prove Causation

1. *Brain Damage is Not a Risk of ECT*

A device manufacturer may be liable on a failure to warn theory if it "did not adequately warn of a particular risk that was known or knowable in light of the **generally recognized and prevailing best scientific medical knowledge** available at the time of manufacture and distribution [emphasis added]." *Coleman v. Medtronic, Inc.*, 223 Cal.App.4th 416, 428 (2014), citing to *Anderson v. Owens-Corning Fiberglas Corp.*, 43 Cal.3d 987, 1002 (1991); see also *Carlin v. Superior Court*, 12 Cal.4th 1104 (1996).

Any opinion which purports to hold that brain damage is a risk of ECT is not generally accepted in the medical and scientific community, as made clear from two leading neuropsychiatrists, Dr. Coffey and Dr. Kellner, who are ECT practitioners with decades of experience in studying and administering ECT.

Significantly, Plaintiffs' experts do not represent that their position is generally recognized under the prevailing best scientific medical knowledge. Instead, they do just the opposite. They effectively point out that their position is an outlier view attributable to: (1) suppression through conspiracy within the psychiatric community; "methodological shortcomings" in studies that find ECT is safe and effective; and insufficient studies performed aimed at examining whether ECT causes brain damage.

What Plaintiffs' opposition fails to acknowledge is that this case is not a battle over whether their experts' views regarding brain damage are meritorious. It is not a forum in which this Court will decide that they are right, and the currently prevailing scientific medical community is wrong. This case is about whether Somatics disclosed the known and accepted risks of ECT, as defined by the prevailing scientific consensus – which it did. A manufacturer of a medical device is under no obligation to capitulate to a minority, unaccepted view in its warnings simply because some take issue with, and are attempting to challenge, the prevailing scientific consensus regarding ECT.

Plaintiffs' argument that "brain damage" is a risk of ECT has not been accepted by the scientific community or the FDA despite presenting this outlier opinion in multiple mediums, including the Citizen's Petition and complaints submitted to the FDA's 2009 public docket. Indeed, one of Plaintiffs' experts, Dr. Dolan, confirmed in her opposition declaration that she notified the FDA of her position regarding ECT and "brain damage" in 2009. In 2011, the FDA conducted an **independent** examination of the scientific literature, including 84 relevant studies, and found that Dr. Dolan's position is not supported. Specifically, "the FDA review of the literature identified no evidence of gross anatomical/histological, immunohistochemical, or biomarker of injury evidence to support this association [that ECT causes brain damage]." SOM 283. Leading practitioners in the field of ECT (Drs. Kellner and Coffey), as well as the FDA, have each concluded that "brain damage" is not a risk of ECT. Given this weight, Plaintiffs' position that Somatics was required to warn of Plaintiffs' experts' outlier, unsubstantiated position is entirely unfounded.

2. *Somatics' Warnings Are Consistent With Prevailing Scientific Knowledge*

Somatics' duty was to provide a warning to its customers that is consistent with the "prevailing best scientific knowledge." *Coleman*, 223 Cal.App.4th at 428. To that end, Somatics

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expressly directed its customers to the Task Force Report on ECT published by the American Psychiatric Association, which disclosed the prevailing accepted risks of ECT that are consistent within current scientific understanding. The Task Force Report was a collaborative effort from leading experts and practitioners in the field of ECT, who examined and compiled information from numerous studies on the safety and efficacy of ECT, as well as their own professional observations from administering ECT. It is considered to be the most comprehensive and authoritative report on ECT and is widely relied upon by ECT practitioners. Accordingly, Somatics met its burden to warn by directing every purchaser of its device to that report. It had no duty to warn of contrary, unsubstantiated positions which have not been accepted as known risks by the scientific medical community.

3. *Plaintiffs Cannot Establish that Their Purported Cognitive Deficits Were Caused by ECT*

Plaintiffs contend that they have current, quantifiable cognitive deficits based on the result of IQ tests performed by Richard Perrillo, Ph.D. on July 31, 2018 and August 2, 2018. Even assuming, *arguendo*, that the testing data is accurate and properly interpreted, Plaintiffs have failed to establish, and cannot establish, that their cognitive abilities were any better prior to receiving ECT. Plaintiffs have not submitted evidence of testing by which to compare Dr. Perrillo's recently obtained data. Importantly, Plaintiffs each reported cognitive deficits prior to receipt of ECT that were consistent with their current complaint of deficits.

Further, a current finding of cognitive deficits is consistent with the accumulated effect of the Plaintiffs' chronic depression and medication use. Accordingly, there is no possible way for Plaintiffs to meet their burden to establish that their current limitations, if any, have been affected by the administration of ECT.

4. *Plaintiffs Cannot Establish That Somatics Purported Failure to Report Adverse Events to the FDA Would Have Prevented Their Injuries*

Somatics disputes Plaintiffs' contention that it failed to report as required to the FDA. Notwithstanding, even assuming Plaintiffs were able to prove a failure to report on the part of

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Somatics, they will still be unable to establish that said violation had any impact on their ECT treatment.

> As the concurrence pointed out in *Stengel III*, construing this duty [to report adverse events to the FDA] in this way creates a causation hurdle that plaintiffs would not otherwise face. 'To prevail, they will have to ultimately prove that if [defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent his injuries.'

Coleman, 223 Cal.App.4th at 429, quoting *Stengel v. Medtronic Inc.* 704 F.3d 1224, 1234 (9th Cir. 2013.)

The FDA concedes that information populated on MAUDE has limitations which affect its reliability.[1] Perhaps most importantly, however, there is no evidence that Plaintiffs' treating physicians, or any treating physicians, actually review MAUDE in order to educate themselves on the risks associated with the medical devices they use in their practice. This missing link in causation is fatal to Plaintiffs' argument that a failure to report an adverse event would have precluded their treating physicians from recommending and administering ECT to Plaintiffs. It equally destroys Plaintiffs' argument that the treating physicians would have warned them of the risks revealed from the purported adverse event reports.

B. Somatics' Sells to Sophisticated Intermediaries

Somatics' duty to provide an additional warning to Plaintiffs is severed by the doctrine of Sophisticated Intermediary. A manufacturer may discharge its duty to warn end users about known or knowable risks in the use of its product if it: (1) provides adequate warnings to the product's immediate purchaser, or sells to a sophisticated purchaser that it knows is aware or should be aware of the specific danger; and (2) reasonably relies on the purchaser to convey appropriate warnings to downstream users who will encounter the product. *Webb v. Special Electric Co.*, 63 Cal.4th 167, 187 (2016). "Like the sophisticated user defense, the sophisticated intermediary defense applies to failure to warn claims sounding in either strict liability or negligence." *Ibid.*

Under the sophisticated intermediary doctrine, the first prong requires a manufacturer to establish that it provided adequate warnings to the intermediary about the particular hazard. *Id.* at

[1] FDA MAUDE Database website, available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

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188. In certain cases, the buyer's sophistication can be a substitute for actual warnings if the buyer was so knowledgeable about the material supplied that it knew or should have known about the particular danger. *Ibid.* "If a purchaser is so knowledgeable about a product that it should already be aware of the product's particular dangers, the seller is not required to give actual warnings telling the buyer what it already knows." *Ibid.* Accordingly, a manufacturer of a medical device does not have a duty to warn of "a risk known to the medical community." *Carlin v. Superior Ct.*, 13 Cal.4th 1104, 1116 (1996).

The second prong of the sophisticated intermediary test requires the manufacturer to show that it actually and reasonably relied on the intermediary to convey warnings to end users. *Webb, supra*, 63 Cal.4th at 189. This inquiry will typically raise questions of fact for the jury unless critical facts establishing reasonableness are undisputed. *Id.* at 189-190. Three categories of factors are relevant to this inquiry: (1) the gravity of the risks posed by the product, (2) the likelihood that the intermediary will convey the information to the ultimate user, and (3) the feasibility and effectiveness of giving a warning directly to the user." *Ibid.*

Here, Somatics only sells its devices to sophisticated users who are bound by state and local law to be knowledgeable of the risks and benefits of ECT treatment. Importantly, Plaintiffs are not attempting to argue that there is a flaw with the Thymatron device itself but are instead arguing a larger position that **all** ECT, regardless of the specific device used, causes brain damage. If this were true, evidence of such a position would necessarily be known to the physicians which administer and recommend ECT treatment to patients without an express warning from the manufacturer. Plaintiffs are arguing two inconsistent positions: (1) that brain damage was a knowable risk within the medical community from the scientific literature and patient complaints of injuries, and (2) that the medical community, who received direct complaints from patients and had an independent duty to stay current on scientific literature, could not know that ECT causes brain damage without a warning from Somatics.

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III. SETTLEMENT DISCUSSION

The parties have not had any meaningful settlement discussions. Plaintiffs have made a demand for policy limits at the outset of this litigation when it was potentially a class action lawsuit and involved four additional named plaintiffs.

IV. CONCLUSION

Because Plaintiffs will be unable to prove causation and because the sophisticated intermediary doctrine severs Somatics' liability, Plaintiffs cannot prevail in this matter.

DATED: September 4, 2018

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