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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; DEBORAH CHASE,

Plaintiffs,

v.

SOMATICS, LLC,

Defendant.

Case No.: 2:17-cv-06686 RGK-PJW

Assigned to: Hon. R. Gary Klausner
Courtroom: 850

**PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

Date: September 4, 2018
Time: 9:00 a.m.

Trial Date: October 2, 2018

Plaintiff Jose Riera and Deborah Chase hereby submit their Opposition to Defendant's Motion for Summary Judgment.

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# MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

## I. INTRODUCTION

Plaintiffs DEBORAH CHASE ("Chase") and JOSE RIERA ("Riera") were recommended electroconvulsive shock therapy ("ECT") to treat "treatment-resistant depression." Unfortunately, they were never adequately informed of the risk of **brain damage ("brain trauma", "traumatic brain injury", or "structural brain damage")** – the cause of the oft-reported memory loss and cognitive impairment resulting from ECT -- prior to receiving ECT.

Unaware of the all of the risks, Plaintiffs underwent electroconvulsive shock therapy with Defendant Somatics, LLC's ECT devices. The result, confirmed by a neuropsychologist: both Riera and Chase suffered ***structural brain damage*** resulting in severe, persistent loss of memory and cognitive impairment of a type and magnitude they had not experienced prior to treatment.

At all times relevant to this action, the risk of **structural brain damage** resulting from electroconvulsive shock therapy administered through ECT devices as intended or in a foreseeably mistaken manner, has been known and knowable to ECT device manufacturer Somatics, LLC, in light of the generally accepted and prevailing best scientific and medical knowledge available to the medical community, within and outside the cohort of ECT-administering psychiatrists. As such, Somatics, LLC had a duty to adequately warn Plaintiffs and their medical providers of the risks of using their ECT devices.

Additionally, the FDA's post-market surveillance obligations require that manufacturers of medical devices study their devices and scrutinize complaints of injury, and then report to a centralized database accessible by medical providers. *See* 21 C.F.R. § 803.3, 803.50 et. seq.; *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 n.5. The purpose of post-marketing surveillance is to collect and distribute risk information in order to allow medical providers to better understand the medical

devices they are using, so that they can better inform patients. Patients can then, in turn, make educated decisions in the interest of their own care. Plaintiffs assert that had Defendant complied with its duties, Plaintiffs would have had adequate warning of the risks of ECT and could have avoided their injuries.

As discussed further below, Defendant Somatics, LLC's motion for summary judgment should be denied because there are triable issues of material fact as follows:

1. Whether Plaintiffs can establish that their injuries were caused by Somatics's ECT Devices;
2. Whether Plaintiffs can establish that Somatics's failure to report adverse events caused their injuries;
3. Whether Plaintiffs can establish that Somatics's warnings were inadequate;
4. Whether Plaintiffs can establish that their injuries were known or knowable risks necessitating a warning by Somatics;
5. Whether Somatics can rely on the doctrine of sophisticated intermediary as a defense to their failure to warn.

## II. SUMMARY OF PERTINENT FACTS

### *A. Regulatory History of ECT Devices*

"Partly in response to an ongoing concern about radio and newspaper advertising making false therapeutic claims for both 'quack machines' and legitimate devices such as surgical instruments and orthopedic shoes, in 1938 Congress broadened the coverage of the 1906 [Food, Drug and Cosmetic] Act to include [prohibition of manufacture or distribution of] misbranded or adulterated medical devices and cosmetics." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996), *citing* Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), §§ 501, 502, 52 Stat. 1049–1051.

In response to advances in medical technology and the advent of various artificial and technologically advanced medical devices, Congress enacted the

Medical Device Amendments of 1976 (MDA or Act), 90 Stat. 539 to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), §§ 501, 502, 52 Stat. 1049-1051. The Act classifies medical devices in three categories based on the risk that they pose to the public. The highest-risk devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. 21 U.S.C. § 360c(a)(1)(C). Ordinarily, manufacturers of Class III devices must pass the FDA's rigorous "premarket approval" or "PMA" process by submitting detailed information regarding the safety and effectiveness of their device prior to accessing the market. *See Medtronic, supra*, 518 U.S. at 477.

However, a loophole exists by which Class III devices that are "substantially equivalent" to "preamendments devices" (or medical devices introduced to market prior to May of 1976) access the market without demonstrating safety or effectiveness to the FDA, until the FDA either formally requires a PMA or reclassifies the device into Class I or Class II. *See* 80 Fed. Reg. 81224 (Dec. 10, 2015). It is this loophole that has allowed ECT devices onto the market. *See* FDA's Final Rule dated September 04, 1979, 44 Fed. Reg. 51776-51777, Stewart Decl., Ex.A, Docket Entry No. 46-2.

The Federal Register, at 80 Fed. Reg. 81225-26 (December 10, 2015), recounts the following regulatory history of ECT devices:

> "[I]n 1979 (44 FR 51776, September 4, 1979), FDA classified ECT into class III after receiving several comments [on a proposed rule to the contrary], and reconvening the [Neurological Devices Classification] Panel to discuss these comments (May 29, 1979). The Panel discussed whether there was sufficient evidence to establish a performance standard for ECT. Several panel members expressed doubt that such information was available, and the Panel voted to recommend that ECT be classified into class III. FDA agreed with the Panel stating that FDA did not believe that the characteristics of ECT devices had been identified precisely enough such that special controls could be established that would provide reasonable assurance of the safety and effectiveness of the device. . .

> [In 1982]. . . Several comments received by the Agency argued that research and data did not support that ECT is an effective therapy for schizophrenia, and after careful review of the scientific literature and the APA's petition, FDA agreed with the comments. In the subsequent proposed rule (55 FR 36578, September 5, 1990), FDA determined that the evidence of effectiveness for schizophrenia was inconclusive, and proposed that ECT be reclassified to class II only for severe depression and remain class III for all other indications.
>
> In 1995, FDA published an order for the submission of safety and effectiveness information on ECT devices (60 FR 41986, August 14, 1995)."

The FDA's 1995 Order required the submission of a summary of *any and all* safety and effectiveness data *known or otherwise available* concerning the safety and effectiveness of ECT by 1997, but Somatics, LLC never responded and simply let the deadline pass. *See* Email Chain Between Somatics, LLC and FDA, Karen Decl. Ex. G. at SOM00442, Docket Entry No. 79-12; 60 Fed. Reg. 41986 (August 14, 1995); Emord Supp. Dec., at ¶2. [A1]Docket Entry No. 38-1. The Federal Register continues:

> "In 2009, FDA published an order for the submission of safety and effectiveness information on ECT devices by August 7, 2009 (74 FR 16214, April 9, 2009). In response to that order, FDA received two submissions from ECT manufacturers suggesting that ECT devices could be reclassified to class II. The manufacturers stated that safety and effectiveness of these devices may be assured by reducing the frequency of treatments, temporary or permanent interruption of treatments, reduction of stimulus dose, electrode placement, dosage or type of anesthetic (or other) medications, including minimizing psychotropic medications, brief pulse or ultra-brief pulse waveform stimulus, EEG monitoring, proper preparation (including conductive gel) and contact of the electrodes to the skin, changing anesthetic medications or doses, and changing concurrent medications."

Somatics, LLC's 2009 submission to the FDA feigned ignorance about deaths or serious injuries resulting from ECT, claiming that in the 25 years since the Thymatron's 510(k) market access, there has never been the occurrence of a "reported adverse event." *Compare Somatics, LLC's 2009 Response to the FDA's Order for Submission of Safety and Effectiveness Data* ("2009 Response"), at SOM 00446, Docket Entry No. 79-9; with *Establishment Inspection Report of Somatics,*

*LLC*, dated 4/20/2016 to 4/22/2016, Karen Decl., Ex. A., p. 0036, Docket Entry No. 79-6; *Somatics, LLC's responses to Plaintiffs' Requests for Admission Nos. 30, 36, 40, 41, 42*, Karen Decl., Ex. C, Docket Entry No. 79-8; and 80 Fed. Reg. 81226-81228, Karen Decl., Ex. E, Docket Entry No. 79-10. The Federal Register continues further:

> "In 2009, FDA also opened a public docket to receive information and comments regarding the current classification process for ECT by January 8, 2010 (74 FR 46607, September 10, 2009). FDA received over 3,000 submissions to the docket, with the majority of respondents, approximately 80 percent, opposing reclassification of ECT. The majority of those opposing reclassification of ECT cited adverse events from ECT treatment as the basis for their opposition. The most common type of adverse event mentioned in the public docket were **memory adverse events, followed by other cognitive complaints, brain damage, and death**."

Defendant Somatics, LLC became aware of these comments alleging death, permanent memory loss, and brain damage. Yet, it conducted no testing or investigation of its devices, made no attempt to follow-up on the complaints pursuant to 21 C.F.R. Part 803, and has generally failed to make a good-faith effort to satisfy its postmarket surveillance obligations to the FDA and, more broadly, the public health. *See Arrowsmith Decl.*, ¶¶3-4, 8-9, 14, Docket Entry No. 79-3. *See also Somatics, LLC's responses to Plaintiffs' Requests for Admission Nos. 30, 36, 40, 41, 42*, Karen Decl., Ex. C, Docket Entry No. 79-8. *See FDA Executive Summary Prepared for the January 27-28, 2011 Meeting of the Neurological Devices Panel* (Executive Summary) at SOM 00263, Karen Decl., Ex. F, Docket Entry No. 79-11.

Had Defendant Somatics, LLC met its post-market surveillance obligations, the MAUDE database would have been populated by – at the very least – case reports corresponding to the comments in the FDA's public docket, consisting of the four hundred and thirteen (413) complaints of cognitive impairment, two hundred and ninety-eight (298) complaints of brain damage, and one hundred three (103) complaints of death resulting from ECT. *See Executive Summary* at SOM 00262, Karen Decl., Ex. F, Docket Entry No. 79-11; 80 Fed. Reg. 81226-81228, Karen

Decl., Ex. E, Docket Entry No. 79-10; *Arrowsmith Decl*., ¶¶ 7-9, Docket Entry No. 79-3.

Regardless of any proposed risk/benefit determination of ECT for narrowly specified populations,[1] medical device manufacturers have a duty to adequately warn medical providers of risks that reasonably prudent manufacturers would know and warn about, and also risks that are knowable in light of the best available generally accepted medical knowledge at the time it manufactured its product. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112-1113 (1996). The adequacy of a warning is generally a question of fact for the jury. *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1158 (E.D.Cal. 2010).

### *B. Structural Brain Trauma – the Known and Knowable Risk of ECT Treatment*

Somatics, LLC, as one of two ECT device manufacturers, admitted to the FDA that structural brain injury, including hippocampal damage and cell death, is a risk associated with electroconvulsive shock therapy. Executive Summary at SOM00262, Karen Decl., Ex. F, Docket Entry No. 79-11. At all times relevant to this action, structural brain trauma resulting from electrically-induced grand mal seizures was known or knowable by Somatics in light of available medical knowledge. *See, e.g.* Breggin Decl., ¶¶ 12, 14, PA080, Docket Entry No. 26-2; Declaration of Moira Dolan, M.D. (Dolan Decl.), ¶¶ 61-64, Docket Entry No. 84-19; Declaration of Kenneth Castleman, PhD (Castleman Decl.), ¶¶ 6-16, Docket Entry No. 84-12; Declaration of Richard Perillo, PhD (Perillo Decl.), ¶ 23, Docket Entry No. 84-23; See also *See FDA Executive Summary* (Executive Summary) at SOM 00262, Karen Decl., Ex. F, Docket Entry No. 79-11. Yet, Somatics, LLC disseminated no warning of structural brain trauma resulting from ECT to any medical provider, but rather merely warned of the *sequelae* of structural brain

[1] *See* 80 Fed. Reg. 81225-81226 (December 29, 2015).

trauma, like cognitive impairment and memory loss. *See Kellner Decl.*, ¶¶ 9-11, Docket Entry No. 80-2; *APA Task Force Report*, Kellner Decl. ¶11, Ex. F, pp. 70-71, Docket Entry 80-8; *Patient Information Pamphlet*, p. 2, Kellner Decl., Ex. D, Docket Entry 80-6; *see also* Dolan Decl., ¶ 62, Docket Entry No. 84-19.

1. The Task Force Report

The American Psychiatric Association ("APA")'s *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training and Privileging* ("Task Force Report") discusses ECT side-effects of anterograde and retrograde amnesia and deficits in recalling personal and public information. The Task Force Report also indicates that "evidence has shown that ECT can result in persistent or permanent memory loss" but persistent amnesia extending several years before ECT is an "uncommon" effect. APA Task Force Report, Kellner Decl. ¶11, Ex. F, pp. 70-71, Docket Entry 80-8.

Somatics contends that its reference to the Task Force Report, coupled with the disclosures in its instruction manual and patient pamphlet that accompany its ECT devices, provide an adequate warning to medical providers. However, a warning of a procedure must explain, in lay terms, the nature of any material risk of serious injury that can result from use of a product. *Cobbs v. Grant*, 8 Cal.3d 229, 244 (1972). It is not sufficient to merely state the sequelae of the risk – in order to properly warn a patient, the actual, objective risk, if known or knowable, must be described to the patient. Dolan Decl., ¶ 62, Docket Entry No. 84-19. An illustrative example of an insufficient warning is, in the case of electroconvulsive shock therapy, warning of memory loss and cognitive impairment without reference to the structural brain trauma that causes it. *Id.*

While the Task Force Report warns of the *sequelae* of traumatic brain injury, it fails to warn patients of the *cause* of memory loss and cognitive impairment, and the true knowable risk of ECT: structural brain trauma such as electroporation of their brain tissue resulting from ECT. *See, e.g., Declaration of Peter Breggin, M.D.* at ¶27,

PA088, Docket Entry No 26-2; Castleman Decl. at ¶¶6-16, 18, Docket Entry No. 84-12; Dolan Decl. at ¶ 62; Docket Entry No. 84-19; Perillo Decl., at ¶ 23, Docket Entry No. 84-23. Somatics LLC's warnings for its devices are therefore completely inadequate as a warning to medical providers and patients, for its failure to disclose the known or knowable risk of structural brain trauma resulting from electroconvulsive shock therapy. *Carlin, supra,* 13 Cal.4th at 1109.

To further illustrate the point that brain damage has been a knowable risk of electroconvulsive shock therapy for decades, the APA issued a Task Force Report relating to ECT in 1978 ("1978 Task Force Report"). In the report, the member ECT practitioners of the APA were asked whether they believed ECT caused at least slight or subtle brain damage. ***Forty-one (41) percent of the practitioners said "yes" and only twenty-six (26) percent of ECT practitioners disagreed with the conclusion that ECT causes at least slight or subtle brain damage.*** *1978 ECT Task Force Report of the American Psychiatric Association,* Karen Oppo Decl., Ex. H, Docket Entry No. 84-10. Coming from this pro-ECT source, the fact of brain injury resulting from ECT should be deemed conceded, especially in light of the fact that modern ECT devices access the market on the purported ground that they present no difference in safety and effectiveness from those marketed prior to May 28, 1976. *See Separate Statement in Opposition to Motion for Summary Judgment,* at p. 10, No. 20, Docket Entry No. 84-1.

2. Somatics' Disclosures

Somatics also distributes a pamphlet to every medical provider which drastically downplays the side effects of ECT, calling them mere "memory disturbances" that are "not needed for ECT to work" but which will go away within a few days or weeks, or "occasionally continues in a mild form" for longer. See Somatics' *Patient Information Pamphlet*, p. 2, Kellner Decl., Ex. D, Docket Entry 80-6. With regard to the question of whether ECT can cause brain damage, Defendant's pamphlet also deceptively and equivocatingly states that the "available

evidence speaks against this possibility" and then goes on to confuse the reader as to whether it could cause brain damage or not by comparing ECT patients to stroke victims, pointing to lack of evidence of brain damage in animals from "brief seizures as given with ECT" and the lack of data from brain-imaging studies, and concluding that the amount of electricity cannot cause electrical injury. *Id.* Nowhere does the pamphlet definitively answer the question it poses: "Can ECT Cause Brain Damage?" Somatics' pamphlet plays similar word acrobatics around the question of "Does ECT Cause Permanent Memory Loss?" Again, instead of answering its own question and clearly and adequately conveying the potential risk, the pamphlet downplays and fails to elaborate on the answer "Not in most people" by immediately jumping to the misleading, falsely equivalent, and unsupported conclusion that "ECT does not interfere with the ability to learn" and "memory problems in patients with psychiatric illness result more often from medication, incompletely- treated illness, and aging." *Id.*

As with the Task Force Report, Somatics, LLC's warnings were and are inadequate and should have clearly and affirmatively stated in layman's terms that structural brain trauma, brain damage, and irreversible memory loss are potential risks associated with the use of its devices. Executive Summary at SOM00262, Karen Decl., Ex. F, Docket Entry No. 79-11; See *Carlin, supra,* 13 Cal.4th at 1109; *see also Cobbs, supra,* 8 Cal.3d at 244. Moreover, it should have warned that the commonly-reported symptoms of memory and cognitive impairment are sequelae of structural brain trauma, including electroporation. *See, e.g.,* Dolan Decl., ¶62, Docket Entry No. 84-19, Breggin Decl, ¶¶ 27-28, Docket Entry No. 26-2, PA088; Castleman Decl., ¶ 18, Docket Entry No. 84-12. *See also* Executive Summary at SOM00262, Karen Decl., Ex. F, Docket Entry No. 79-11; Perillo Decl., ¶ 23; Docket Entry No. 84-23.

### *C. Plaintiffs' ECT and Brain Trauma*

1. Jose Riera

Plaintiff Jose Riera was a successful fund manager, until the market crashed in

2008 putting him out of business, throwing his relationships and finances into disarray, and sending him into a severe state of depression for several years. *Deposition of Jose Riera* (Riera Depo), Karen Decl., Ex. A, at 40:11-45:17, 62:8-14, 102:24-103:18; 112:24-113:11; 116:21-118:3, Docket Entry No. 84-3. At a low point, he became suicidal, which led to a family member hospitalizing him. Riera Depo at 116:21-118:3, 124:6-125:10, Docket Entry No. 84-3. Subsequently, Mr. Riera was diagnosed with pharmacologically treatment-resistant depression and prescribed electroconvulsive shock therapy. Deposition of Viguen G. Movsesian, M.D. (Movsesian Depo) at 27:6-24; Docket Entry No. 84-4. However, Mr. Riera was not adequately warned of the risks of cognitive impairment, long-term memory loss or brain damage that could result from ECT. *Declaration of Jose Riera (Riera Decl.)* ¶ 3, Appendix of Evidence in Support of Class Certification at PA 182-183, Docket Entry No. 26-2.

Mr. Riera was given ECT using Defendant Somatics, LLC's Thymatron ECT device. *See, e.g., Medical Records of Jose Riera,* Karen Decl., Ex. C, at 0045, Docket Entry No. 84-5. Jose Riera suffers severe damages as a result of unwarned structural brain trauma caused by ECT, including **a 24-point IQ loss from baseline in the prefrontal/frontal area, 25 IQ loss in the Temporal area and 19 IQ loss in the Occipital area**. **His verbal learning and memory, as well as visual memory, are still compromised.** Perillo Decl., ¶¶ 15,16. Docket Entry No. 84-23. **He is at higher risk for early dementia because of ECT.** *Id* at ¶23. Had Mr. Riera been adequately warned of the risks of brain injury, he never would have agreed to undergo ECT treatment. Riera Decl. ¶ 4, Appendix of Evidence in Support of Class Certification at PA 183, Docket Entry No. 26-2.

2. Deborah Chase

Plaintiff Deborah Chase's history of psychiatric care dates back to approximately 1992-1994 when she was first admitted to a mental health facility around the time she split with her first ex-husband, and 1995, when she first started

seeing a psychiatrist and regularly taking medication for depression. Deposition of Deborah Chase (Chase Depo) 39:9-15, 40:5-24; 43:7-44:9, 50:20-24, Docket Entry No. 84-6. Since that time Ms. Chase was admitted to mental facilities two more times during her marriage to her second ex-husband around 2000, and also involuntarily in 2015, both times for severe depression related to her relationship with her husband. Chase Depo 46:6-47:12, 49:7-50:10, Docket Entry No. 84-6. It was following her 2015 involuntary hospitalization that she was first administered ECT. *Id*. However, Ms. Chase was not adequately warned of the risks of cognitive impairment, long-term memory loss or brain damage that could result from ECT. Declaration of Deborah Chase (Chase Decl.) ¶ 3, Appendix of Evidence in Support of Class Certification at PA 178-179, Docket Entry No. 26-2.

Ms. Chase was treated on at least two different occasions with ECT using Defendant Somatics, LLC's Thymatron ECT device. Chase Depo. at 74:3-76:17, *Medical Records for Deborah Chase* ("Chase records"), Docket Entry No. 84-7. As a result, Ms. Chase sustained quantifiable and measureable brain damage which was caused with a reasonable medical probability by the ECT treatments administered by Defendant's ECT device. Perillo Decl. ¶¶ 16, Docket Entry No. 84-23. **As a result, Ms. Chase has suffered a 31 IQ-point loss in the Prefrontal/Frontal area and a 40-point loss in the right hippocampal and Occipital area.** *Id* at ¶12. **Deborah Chase may be vulnerable to accelerated aging and/or at risk of further cognitive compromise as a result of ECT.** *Id* at ¶ 13. **She shows present signs of early dementia resulting from ECT.** *Id* at ¶ 23. Had Ms. Chase been adequately warned of the risks of injury, she never would have agreed to undergo ECT treatment. Chase Decl. ¶ 4, Appendix of Evidence in Support of Class Certification at PA 179, Docket Entry No. 26-2.

## III. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate if there is no genuine issue as to any material fact, so the movant is entitled to judgment as a matter of law. *See* FED. R. CIV.P. 56(a).

## IV. LEGAL ARGUMENT

### *A. Plaintiffs Have Introduced Admissible Scientific Evidence Showing Brain Damage Resulting From ECT*

Despite Defendant's averments to the contrary, methodologically sound, peer-reviewed medical literature supports the assertion that application of electricity to the cranium, including ECT, can and does cause structural injury to the brain. *See, e.g.*, Dolan Decl., ¶63, Docket Entry No. 84-19, Breggin Decl, ¶¶ 27-28, Docket Entry No. 26-2, PA088; Castleman Decl., ¶ 18, Docket Entry No. 84-12. *See also* Executive Summary at SOM00262, Karen Decl., Ex. F, Docket Entry No. 79-11; Perillo Decl., ¶23; Docket Entry No. 84-23.

#### 1. Plaintiffs Display the Objective Signs of Structural Brain Trauma Resulting From Electric Shock.

As confirmed by neuropsychological evaluation, Plaintiff Jose Riera displays objective and quantifiable symptoms of brain damage caused by the shock therapy administered using Defendant's ECT device. Perillo Decl. at ¶¶ 16, 20, Docket Entry No. 84-23. Plaintiff Deborah Chase also displays objective and quantifiable symptoms of structural brain trauma of brain damage caused by the shock therapy administered using Defendant's ECT device. *Id.*

### *B. Somatics, LLC Failed to Warn Plaintiffs' Medical Providers of Brain Trauma*

#### 2. Somatics Failed to Adequately Disclose Structural Brain Trauma from Its ECT Devices to the Psychiatric Community

While Somatics, LLC has privately identified structural brain trauma, including hippocampal damage and cell death, as a risk associated with their devices, none of Somatics's device warnings or the APA's Task Force Report adequately warn of structural brain trauma. *See Kellner Decl.*, ¶¶ 9-11, Docket Entry No. 80-2; *APA Task Force Report*, Kellner Decl. ¶11, Ex. F, pp. 70-71, Docket Entry 80-8; *Patient*

*Information Pamphlet*, p. 2, Kellner Decl., Ex. D, Docket Entry 80-6; *see also* Executive Summary at SOM 00262, Karen Decl., Ex. F, Docket Entry No. 79-11. Memory loss and cognitive impairment is a known consequence of structural brain trauma. *See* Perillo Decl., ¶ 23, Docket Entry No. 84-23. As such, these risks were known or knowable to Somatics. Therefore, Somatics, LLC's warning is inadequate. *See* Dolan Decl., ¶ 62, Docket Entry No. 84-19.

Had Somatics, LLC warned Plaintiffs' treating physicians that brain injury results from ECT, Plaintiffs' treating physicians would have conveyed that warning to Plaintiffs according to their duties under California law. *See Carlin*, *supra*, 13 Cal.4th at 1109; *Cobbs*, *supra*, 8 Cal.3d at 244; At the very least, there is a genuine issue of triable fact.

### *C. Somatics's Failure to Conduct Postmarket Surveillance Caused Plaintiffs' Brain Damage*

#### 1. Adverse Event Data is Automatically Made Public

Defendant insists that there is no guarantee that the FDA would have made adverse events public, but this is untrue. The FDA automatically makes MAUDE data public upon receipt of adverse event reports. *See* Arrowsmith Decl., ¶10, Docket Entry No. 79-3; *see also Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 n.5; *Stengel v. Medtronic, Inc*. 704 F.3d 1224, 1233 (9th Cir. 2013) (adopting the reasoning of *Hughes*).

#### 2. The Whole Point of The MAUDE is to Assist Health Care Providers In Drawing Conclusions

Defendants claim that MDR data has "extremely limited value" based on an excerpt from the FDA's website cautioning against far-reaching conclusions based on potentially insufficiently-reported MDR data *in isolation*. Motion at p.14. The conclusion that MDR data generally has "extremely limited value" does not follow, **as *even one* well-documented adverse event report can help reasonably establish causation between use of a medical device and a resulting type of injury.** *See*

*Declaration of Janet Arrowsmith in Support of Oppositon to Defendant's Motion For Summary Judgment* ("Arrowsmith Oppo. Decl."), ¶ 12, Docket Entry No. 84-17.

When considered in the context of the rest of the information available about use of a device, including known side effects and risks, multiple well-documented adverse event reports, collectively, can highlight crucial details and provide support for important inferences in understanding the full set of risks, short and long-term, associated with use of a medical device. *See* Arrowsmith Decl., ¶¶ 10-14, Docket Entry No. 79-3.

The postmarket surveillance regulations are designed to help identify and assess root causes of medical device and radiation-emitting device problems following market introduction, including detection of unforeseen and unlabeled risks and product failures. *Id.at* ¶ 3. The MAUDE reporting regulations are intended to provide a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. *Id.* The goals of the regulation are to detect and correct problems in a timely manner. *Id.* Manufacturers and FDA are to use problem reports and adverse event reports to correct real and potential device-related problems to better serve the public health. *Id.* Information from medical device reports is used by manufacturers, user facilities, and providers to help insure that patients and other stakeholders are properly informed of all material risks associated with use of medical devices. *Id.* The manufacturer's cooperation in this process is crucial. The FDA states:

> The MDR regulation provides a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner. . . **FDA relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation**.[2]

[2]https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ucm127985.htm (emphasis added).

Therefore, Defendants cannot plausibly claim that MAUDE data has "extremely limited value".

3. Plaintiffs Have a Right to Presume the Federal Post-Market Surveillance System Will Work As Designed

Directly referencing the MAUDE database is not the only manner in which conclusions drawn from MAUDE data and analysis thereof might reach a medical provider. *Id at ¶¶10-14; see also Hughes v. Boston Scientific Corp.,* 631 F.3d 762, 770 n.5. ("[T]he FDA then disseminates the reports to the public, and the reports are then relied upon by physicians and authors of medical journals in comparing the relative safety of medical devices.") Everyone has a right to assume that others will perform their duties and obey the law. *T.H. v. Novartis Pharmaceuticals Corporation,* 4 Cal. 5th 145 184 (2017). *See also Webb v. Special Elec. Corp.*, 63 Cal. 4th 167, 191 (2016) ("[M]odern life would be intolerable unless one were permitted to rely to a certain extent on others' doing what they normally do, particularly if it is their duty to do so."), *citing* RESTATEMENT (2D) OF TORTS, § 388, cmt. n. By the same token, recipients of procedures involving use of Class III medical devices have a right to assume that the federal government's medical device postmarket surveillance system will function as intended. *See* Arrowsmith Decl., at ¶¶ 3, 14, Docket Entry No. 79-3.

Manufacturers must investigate, evaluate, and report allegations of death and serious injury associated with their devices. *See* 21 C.F.R. §§ 803; 820 *et seq*. The MAUDE data is made public, and scientific and regulatory personnel at FDA, as well as outside clinicians, researchers, and other resources, in ensuring public safety and health, may analyze properly-submitted MAUDE data. *See* Arrowsmith Decl, at ¶¶ 10-11, Docket Entry No. 79-3.[3] Health care providers, bearing a duty to remain

[3] *See also Hughes v. Boston Scientific Corp.,* 631 F.3d 762, 770 n.5; *FDA's Description of the Function of the Office of Surveillance and Biometrics* (https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandToba

knowledgeable about the devices they use, must intercept sound conclusions drawn through MAUDE data and analysis thereof, and convey it to a patient where it suggests a material risk associated with a device to a reasonable medical certainty. *Id.* (" . . . it is incumbent upon health care providers to communicate that risk to patients before use of the device"); *see also T.H. v. Novartis Pharmaceuticals Corporation,* 4 Cal. 5th 145 184 (2017) ("[W]e have never allowed a defendant to excuse its own negligence as a matter of law simply by asserting that *someone else* should have picked up the slack and discharged the duty at issue.").

Whether Plaintiffs' medical providers specifically reviewed the MAUDE database is irrelevant. Plaintiffs had a right to expect that the federal regulatory post-market surveillance mechanism would function as designed.

***D. The Sophisticated Intermediary Doctrine Does Not Apply***

California applies the "sophisticated" or "learned intermediary" doctrine which provides that the duty to warn in the case of medical devices runs to the physician, not the patient. *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158 (S.D. Cal. 2015) However, the manufacturer may defend itself from liability through the sophisticated intermediary doctrine *only where* the manufacturer (1) adequately warned or sold to a knowledgeable intermediary *and* (2) *actually and reasonably* relied on an intermediary to deliver a warning. *Webb v. Special Elec. Corp.*, 63 Cal. 4th 167, 189-90 (2016). "This inquiry will typically raise questions of fact for the jury to resolve unless critical facts establishing reasonableness are undisputed." *Id.*

1. <u>Somatics Did Not Adequately Warn Plaintiffs' Medical Providers of Structural Brain Trauma Resulting from ECT</u>

Somatics admitted to the FDA that structural brain trauma, including hippocampal damage and cell death, is a risk associated with use of its devices. Executive Summary at SOM 00262, Docket Entry No. 79-11. Methodologically

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cco/CDRH/CDRHOffices/ucm116002.htm).

sound, peer-reviewed medical literature supports a conclusion that ECT-induced brain damage results in the commonly-reported cognitive impairment and memory loss. *See* Dolan Decl., ¶ 63, Docket Entry No. 84-19. Yet, Somatics does not warn of brain injury resulting from ECT but instead specifically suggests to medical providers that it does not happen. *See Defendant's Statement of Uncontroverted Facts and Conclusions of Law*, at p. 8, Nos. 22-23, Docket Entry No. 80-1; *Kellner Decl.*, ¶¶ 9-11, Docket Entry No. 80-2; *APA Task Force Report*, Kellner Decl. ¶11, Ex. F, pp. 70-71, Docket Entry 80-8; *Patient Information Pamphlet*, p. 2, Kellner Decl., Ex. D, Docket Entry 80-6. Had Somatics adequately informed Plaintiffs' medical providers of the risks of permanent memory loss or brain injury from ECT, they would have warned their patients. See Deposition of Navin Adatia, M.D. (Adatia Depo), Karen Decl, Ex. F, 68:14-69:3, 96:16-19, 131:13-132:14, Docket Entry No. 84-8; Movsesian Depo 61:23-62:5, Karen Decl., Ex.B., Docket Entry No. 84-4.

2. Somatics Did Not Actually or Reasonably Rely On Any Intermediaries, Including Plaintiff's Treating Psychiatrists

In addition to failing to provide adequate warnings to ECT providers such as Plaintiffs' medical providers, Somatics makes no effort to interface with those who promulgate informed consent forms, nor does Somatics keep a postmarket surveillance system in place to help alert psychiatrists to unforeseen risks associated with electroconvulsive shock therapy. See Id., Deposition of David Mirkovich (Mirkovich Depo) 222:9-223:20, Docket Entry No. 79-7. [A2]Under these circumstances, Somatics, LLC does not come close to establishing application of the sophisticated intermediary doctrine as a matter of law.

***E. Despite Triable Issuse Relating to Causation, Plaintiffs Do Not Have the Burden of Proving Causation At Trial.***

In the case of negligence *per se* actions involving violations of federal safety statutes (like the FDCA), a shift in the burden of proving causation onto a civil

defendant is warranted where a paucity of evidence on the issue of proximate causation results from the defendant's violation of said statute. *See Haft v. Lone Palm Hotel*, 3 Cal. 3d 756, 771-72 (1970). "The plaintiff has the burden of producing some evidence before the burden of proof is shifted to the defendant to prove the failure to preserve the evidence did not cause damage to plaintiff." *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal. App. 4th 1336, 1346-47 (2003). In negligence per se actions premised on FDCA violations, the plaintiff must produce evidence of a violation of a statute and a substantial probability that the plaintiff's injury was caused by the violation in order to shift the burden. *In re Bendectin Litigation*, 857 F.2d 290, 312-13 (6th Cir. 1988) (Burden shift requires a lack of evidence on causation resulting from a statutory violation, and that it is "at least reasonably conceivable" that injury results from the violation), *citing Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689 (1967).

In such circumstances, "it is more appropriate to hold the defendant liable than to deny an innocent plaintiff recovery, unless the defendant can prove that his negligence was not a cause of the injury." *Haft*, 3 Cal. 3d 756, 774, n. 19.

3. A Paucity of Data Relating to ECT's Adverse Safety Risks Exists Because of Defendant's FDCA Violations, and it is Likely these Violations Caused Injury to Plaintiffs

Proper compliance with the FDA's Medical Device Reporting ("MDR") regulations would have required Somatics, LLC to investigate and *evaluate the cause* of each adverse event complaint, and submit to the FDA *all information that can be gathered through analysis, testing, or other evaluation of the device.* 21 C.F.R. 803.3, 803.50 et. seq.

Richard Abrams, a director of Somatics, LLC and the author of "ELECTROCONVULSIVE THERAPY" (1982) claims that Somatics, LLC is not in the business of testing or studying long term side effects of its own devices. *See Excerpt*

*from Rough Draft of Deposition of Richard Abrams* ("Abrams Depo"), Karen Decl., Ex. G, Docket Entry No. 84-9. But federal law mandates that Somatics, LLC be in the business of testing and studying its own device. 21 C.F.R. 803.3, 803.50 et. seq. Somatics has therefore never conducted the testing continuously required by the FDA's adverse event reporting regulations (*See, e.g.*, 21 C.F.R. Parts 803; 820). Nor did it properly gather, analyze, and submit the information required by the FDA's 1995 Order (60 Fed. Reg. 41986), or the FDA's 2009 Order (74 Fed. Reg. 16214).

As far as Somatics, LLC is concerned, the **mechanism of action for ECT shock treatment remains unknown to this day, despite decades of use.** *See* Mirkovich Depo., at 160:5-15, Docket Entry No. 79-7. **The history of medical literature purporting to show ECT's safety and/or effectiveness is riddled with methodological flaws and epistemological deficits.** *See* Castleman Decl., ¶¶ 13, 16-18, Docket Entry No. 84-12; Dolan Decl; ¶ 61, Docket Entry No. 84-19. Regulatory compliance by Somatics would have forced it to conduct studies and testing, in a good-faith attempt to produce results of testing without methodological flaws and epistemological deficits. (*See, e.g.*, 21 C.F.R. § 803.50; 820 *et seq.*), the FDA's 1995 Order (60 Fed. Reg. 41986), or the FDA's 2009 Order (74 Fed. Reg. 16214).

Had Defendant complied with the Food, Drug and Cosmetic Act, they would have addressed the epistemological difficulties in objectively identifying ECT-induced brain trauma as effectively as would be feasible, and medical literature would have been populated by thousands of good-faith case-report-style studies on the adverse events associated with ECT. *See* Arrowsmith Decl., ¶¶7-13, Docket Entry No. 79-3. *See also* 21 C.F.R. § 803.3(b) ("*any* information *you can obtain through analysis, testing, or other evaluation* . . .")[emphasis added]; *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 n.5.

Accordingly, a paucity of evidence results from Defendant's statutory violations, and it is likely that Plaintiff's injuries were caused by Defendant's

violations in failing to report adverse events and by manufacturing and distributing its misbranded devices. California law mandates that Defendant prove a lack of causation.

## V. CONCLUSION

Somatics, LLC unequivocally failed to inform Plaintiffs' treating physicians of the material risk of brain trauma resulting from electroconvulsive shock therapy, both through failure to issue direct warning and through failure to conduct post-market surveillance. Proper regulatory compliance by Somatics, LLC would have effectively informed Plaintiffs' treating psychiatrists that the oft-reported cognitive impairment and memory loss resulting from ECT, in fact, is a consequence of electrically-induced structural brain damage. Had Plaintiffs' treating physicians received such a warning, they would have been required to convey to Plaintiffs a lay-terms warning of ECT-induced brain trauma prior to treatment.

A neuropsychologist has confirmed that both Plaintiffs suffered unwarned brain trauma as a result of ECT, and that they both have suffered significant IQ losses as a direct result of ECT. Both Plaintiffs have a heightened risk of early dementia as a result of electrically-induced brain damage. Due to electroconvulsive shock therapy, Deborah Chase faces the prospect of accelerated aging, and Jose Riera is now unemployable in his chosen career.

Defendant's motion should be denied. All six of Plaintiffs' product liability causes of action, premised on all three theories of causation (failure to report, failure to warn, and distribution of misbranded devices) should proceed to trial.

Dated August 14, 2018

Respectfully Submitted,

*/s/ David M. Karen*
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