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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**

FOURTH AMENDED COMPLAINT FOR:

1. NEGLIGENCE/NEGLIGENCE *PER SE* (Adulteration & Misbranding);
2. NEGLIGENCE/NEGLIGENCE *PER SE* (Failure to Timely Investigate, Evaluate, and Report Adverse Event Complaints);
3. NEGLIGENCE – PRODUCT LIABILITY (Failure to Warn Treating Physician Directly)
4. STRICT LIABILITY—FAILURE TO WARN (Failure to Timely Investigate, Evaluate, and Report Adverse Event Complaints);
5. STRICT LIABILITY (Adulteration & Misbranding); and
6. STRICT LIABILITY – FAILURE TO WARN (Failure to Warn Treating Physician Directly)

DEMAND FOR JURY TRIAL

Plaintiffs JOSE RIERA and DEBORAH CHASE, (collectively "Plaintiffs"), hereby complain against Defendant SOMATICS, LLC ("Defendant") and, on information and belief, allege as follows:

SUMMARY OF THE ACTION

1. This action brought by Plaintiffs JOSE RIERA and DEBORAH CHASE, who have sustained injuries resulting from Defendant's conduct. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 & 1332.

2. SOMATICS, LLC manufactures the "Thymatron" ECT shock device. An ECT shock device is "a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head." 21 C.F.R. § 882.5940(a). An ECT shock device, in lay terms, is used to administer 'shock treatment.'

3. The California Department of Mental Health reported 3,302 patients given ECT in 2001 alone. The number of patients given ECT shock treatment in California per year is likely to have increased since that time.

4. The primary demographic for ECT shock treatment is comprised of patients suffering from bipolar disorder ("BPD") and/or severe depression. ECT shock treatment is liberally prescribed for a variety of psychological disorders including, but not limited to schizophrenia and catatonia. ECT shock treatment is used on patients of all ages, including children and the elderly.

5. Plaintiffs are individuals suffering from ECT-induced brain trauma and ensuing physiological, psychological and emotional injury including, but not limited to permanent brain dysfunction, severe permanent cognitive and memory impairment, lasting short-term memory difficulties, and acute and/or chronic organic brain syndrome.

6. Despite statutory duties under the Food, Drug and Cosmetic Act ("FDCA") and directives by the Food & Drug Administration ("FDA") that ECT

device manufacturers report information concerning safety and effectiveness testing for their devices to the FDA, no ECT device manufacturer, including SOMATICS, LLC, complied with these statutory obligations. SOMATICS, LLC failed to respond to the FDA's order requiring submission of a summary of, and a citation to, all safety and effectiveness data known or available concerning the use of their devices by August 14, 1997.

7. Prior to the filing of the Complaint in this action, the only order by the FDA to which Defendant responded was one mandated by the Safe Medical Devices Act of 1990 ("SMDA") requiring Defendant's submission of a summary of, and citation to, any information known or otherwise available about the safety and effectiveness of their ECT devices by August 7, 2009. Defendant's responses failed to include nearly all adverse safety and effectiveness information relating to use of ECT shock devices. Defendant also grossly understated the incidence of death resulting from ECT. Such a response by Defendant failed to comply with its statutory reporting requirements under the MDA and SMDA.

8. As a direct and proximate result of Defendant's refusal to comply with multiple orders by the FDA and satisfy their state duties running parallel to their federal statutory duties, as of the time of this filing, Defendant has not provided the FDA with the information it has requested in order to determine whether submission of a PMA should be required, as is typical for Class III medical devices. To this day, ECT devices have never satisfied the stringent premarket approval standards that Class III medical devices are required to meet.

9. Because of the lack of testing rigor, the mechanism of action by which ECT may provide any benefit to patients, if indeed it does, remains unascertained and unknown. Testing over the years has not shown any conclusive benefit to those receiving ECT shock treatment beyond those that may be associated with a brief bout of mania in the short-term. Conversely, the risks of ECT use remain apparent and include but are not limited to concussive brain injury and debilitating electrical

brain trauma, resulting in permanent long-term memory loss, lasting cognitive impairment, seizures, acute and/or chronic organic brain syndrome, complete neurological collapse, and death.

10. But for Defendant's failure to comply with the FDCA, MDA, and SMDA, Plaintiffs would not have suffered the injuries alleged in this complaint. Compliance required Defendant to investigate, solicit, and report information upon learning that their ECT devices may have contributed to a death or serious injury and specifically report all "reasonably known" information to the FDA. The FDA makes all such information public in order to warn patients, medical providers and the general public of risks inherent in certain medical devices, through their Medical and User Facility Device Experience ("MAUDE") database.

11. Defendant's failure to submit to the FDA all safety and effectiveness data reasonably known and/or available relating to use of their ECT devices by certain effective dates for premarket approval rendered its "Thymatron" devices (as well as any other ECT device it may have manufactured) "misbranded" under the FDCA.

12. Defendant's failure to investigate, evaluate, and file adverse event reports pertaining to occasions on which their devices may have caused or contributed to a death or serious injury also rendered SOMATICS, LLC's devices "misbranded" under the FDCA.

13. SOMATICS, LLC has utilized a contract manufacturer unregistered with the FDA to manufacture all of its "Thymatron" devices for decades. A device manufactured by an unregistered contract manufacturer is "misbranded" under the FDCA.

14. Moreover, all modern ECT devices are marketed as "substantially equivalent" to pre-1976 "predicate" devices, but the predicate devices were not legally marketed for failure to timely investigate and report adverse events. According to Defendant's contentions, modern ECT devices have different intended

uses than predicate devices and differ in design and function. Although the contention is unestablished, if it were proven true the "different" modern devices would not meet the requirement that they be "substantially equivalent" to their predicate devices, and the 510(k) clearance for all modern ECT devices is invalid. To the extent Class III devices are not substantially equivalent to a predicate, a PMA would be required for modern ECT device, as the modern device would raise new questions of safety and effectiveness. As Defendant have submitted no PMA application relative to the allegedly different, modern ECT devices, these devices are "adulterated" and are being manufactured and marketed in violation of the FDCA.

15. The manufacture, introduction, or receipt of an adulterated or misbranded medical device through interstate commerce is prohibited under the FDCA.[1]

16. Defendant's failure to comply with federal medical device regulations by investigating, evaluating, and reporting information reasonably suggesting death or serious injury with which their devices may have been associated resulted in a lack of knowledge among Plaintiffs' medical providers and the public in general about the risk of craniocerebral trauma inherent in administration of ECT shock treatment, but they nevertheless continued to market their adulterated, misbranded, and defective ECT shock devices in the United States. Because some form of physiological, psychological, or emotional injury results universally from ECT shock treatment, Defendant's conduct directly and proximately caused injury to Plaintiffs.

17. This action seeks to remedy the damages caused by Defendant's conduct: violating the state law reporting duties running parallel to the Food, Drug & Cosmetic Act and causing harm by placing an adulterated, misbranded, and defective product into the stream of commerce. Defendant's violation of federal

[1] 21 U.S.C. § 331.

statutory duties, as demonstrated by: (1) Defendant's failure to comply with all administrative orders by the FDA requiring Defendant to submit to the FDA all safety and effectiveness data reasonably known and/or available for its "Thymatron" ECT shock devices by certain effective dates; and (2) failure to maintain systems for the timely investigation, evaluation, and reporting of adverse events to the FDA, resulted in the decades-long circulation of misbranded and adulterated medical devices in the stream of commerce as well as a lack of knowledge among Plaintiffs' medical providers, and the public in general about craniocerebral trauma caused by ECT shock treatment. Moreover, SOMATICS, LLC violated its common law duties to warn Plaintiffs' psychiatrists directly of the risk of craniocerebral trauma resulting from electroconvulsive therapy.

PARTIES

18. Plaintiff JOSE RIERA ("RIERA") is a citizen of the State of California.

19. Plaintiff DEBORAH CHASE ("CHASE") is a citizen of the State of California.

20. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, starting with its founding in 1984, Defendant SOMATICS, LLC ("SOMATICS") is and was a limited liability company formed and existing under the laws of the State of Florida with its principal place of business at 710 Commerce Dr., Unit #101, Venice, FL 34292. Plaintiffs are further informed and believe and based thereon allege that SOMATICS is an ECT manufacturer and provider and, in that regard is authorized to conduct business in the State of California and does conduct business in the State of California.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over the lawsuit under the U.S.C. § 1332, because the claims of Plaintifss exceed $75,000, exclusive of

interest, attorney's fees, and costs; and (3) Plaintiffs and Defendant are citizens of different states to the extent required by statute.

22. This Court has subject matter jurisdiction over the lawsuit under 28 U.S.C. § 1331 because the vindication of Plaintiffs' rights under state law substantially and necessarily turn on a construction of federal law, specifically 21 U.S.C. § 360e with respect to premarket approval applications, 21 U.S.C. § 360i with respect to medical device manufacturer reporting requirements, and 21 U.S.C. § 351 with respect to the illegality of marketing adulterated or misbranded medical devices.

23. This Court has personal jurisdiction over Defendant SOMATICS because it has sufficient minimum contact in California to render the exercise of jurisdiction by this Court proper.

24. Venue is proper in the Central District of California under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims, including ECT shock treatment received by Plaintiffs, occurred in this District.

PLAINTIFF-SPECIFIC ALLEGATIONS

25. Plaintiff RIERA, in seeking an effective treatment for severe depression, underwent a series of six separate rounds of ECT shock treatment on April 22, 2016, April 25, 2016, April 27, 2016, April 29, 2016, May 2, 2016, and May 4, 2016 at Huntington Memorial Hospital in Pasadena, using a "Thymatron" ECT device manufactured by SOMATICS, LLC. ECT did not generate any improvement in RIERA's severe depression. Instead, it caused severe physiological, psychological, and emotional injury, including brain injury. Following treatment, RIERA did not know and had no reason to know that he had sustained a concussive brain injury from ECT use, or that the symptoms he was experiencing post-treatment were the result of a concussive brain injury, or that they would be long-term or permanent. RIERA incorrectly but reasonably believed that

he was experiencing only minor short-term side effects from ECT use that would improve over time, as no information to the contrary was given to him by his medical providers. Following treatment, RIERA also did not know and had no reason to know or suspect that wrongful conduct had caused him concussive brain injury or was attributable to the noncompliance with federal regulation by ECT manufacturers causing ECT devices to be available and recommended for use, without warning of the true risks of brain trauma as inadequate informed consent.

26. Towards the end of 2016, in the course of having conferred with counsel, RIERA learned for the first time that Defendant had failed to comply with multiple administrative orders by the FDA, had never obtained FDA approval for their ECT devices, and had never maintained a system for the timely investigation, evaluation, and reporting of adverse events and that this wrongful conduct on the part of Defendant had caused ECT to be available as a recommended treatment, caused him to be a recommended candidate and caused him to undergo ECT treatment and to sustain the concussive brain injury without warning.

27. Prior to the end of 2016, when the Citizen Petition for reclassification and/or banning of ECT devices became public, he had no reason to suspect, or inquire as to, the wrongful conduct or the nature of his injuries caused by that conduct. However, even if he had inquired earlier, no amount of inquiry would have revealed the danger of concussive brain injury likely to result from ECT shock treatment, or the wrongful conduct of Defendant in having failed to comply with regulatory requirements. This information was unavailable to the medical community at large and to these plaintiffs in particular, specifically because of Defendant's noncompliance with regulations, including failure to report adverse events attributable to ECT use in the MAUDE data base at any time prior to filing the within litigation.

28. Plaintiff RIERA's treating psychiatrist, unaware of electroconvulsive therapy's unavoidable risk of injuring the brain, gave him no warning of brain

trauma prior to electroconvulsive therapy. Moreover, the informed consent form RIERA signed merely warned of "headaches, confusion, nausea, and short-term memory loss" and advised that "oxygen will be administered to minimize the small risk of brain, heart or lung dysfunction, permanent spotty memory loss, or death as a result of the anesthesia or the treatment." This warning was grossly inadequate, as ECT presents a material, unavoidable risk of causing structural brain trauma including cell death, hippocampal damage, and subdural hematoma, in a way that wholly debilitates the patient such that many patients cannot live normal lives after receiving ECT shock treatment.

29. Plaintiff CHASE underwent ECT shock treatment at the Kaiser Foundation Hospital at least seven times in seeking to treat her major depressive disorder and severe anxiety, between April of 2015 and Spring of 2016, using a "Thymatron" electroconvulsive therapy device manufactured by Defendant SOMATICS, LLC. ECT shock treatment caused CHASE severe physiological, psychological, and emotional injury, including brain injury. Following treatment, CHASE did not know and had no reason to know that she had sustained a concussive brain injury from ECT use or that the symptoms she was experiencing post treatment were the result of a concussive brain injury, or would be long term or permanent. CHASE incorrectly but reasonably believed that she was experiencing only minor short term side effects from ECT use that would improve over time as no information to the contrary was given to her by her medical providers. Following treatment, CHASE also did not know and had no reason to know or suspect that wrongful conduct had caused her concussive brain injury, or that it was attributable to ECT manufacturers' violation of federal regulations, which caused ECT device to be available and recommended for use on her, without warning of the true risks of brain trauma and therefore without adequate informed consent.

30. In the early part of 2017, in the course of having conferred with counsel, CHASE learned for the first time that Defendant had failed to comply with

multiple administrative orders by the FDA, had never obtained FDA approval for their ECT devices, and had never maintained a system for the timely investigation, evaluation, and reporting of adverse events, and that this wrongful conduct on the part of Defendant had caused ECT to be available as a recommended treatment, caused her to be a recommended candidate and caused her to undergo ECT treatment and to sustain the concussive brain injury.

31. Prior to the end of 2016, when the Citizen Petition for reclassification and/or banning of ECT devices became public, she had no reason to suspect, or inquire as to, the wrongful conduct or the nature of her injuries caused by that conduct. However, even if she had inquired earlier, no amount of inquiry would have revealed the danger of concussive brain injury likely to result from ECT shock treatment or the wrongful conduct of Defendant in having failed to comply with regulatory requirements. This information was unavailable to the medical community at large and to these plaintiffs in particular, specifically because of Defendant's noncompliance with regulations, including failure to report adverse events attributable to ECT use in the MAUDE data base at any time prior to filing the within litigation.

32. Plaintiff CHASE's treating psychiatrist, unaware of electroconvulsive therapy's unavoidable risk of injuring the brain, gave her no warning of brain injury or permanent memory loss prior to electroconvulsive therapy. Moreover, the informed consent provided merely generally advised of headaches, confusion, nausea, and short-term memory issues. The warning provided was grossly inadequate, as ECT presents a material, unavoidable risk of causing structural brain trauma including cell death, hippocampal damage, and subdural hematoma, in a way that wholly debilitates the patient such that many patients cannot live normal lives after receiving ECT shock treatment.

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FACTUAL ALLEGATIONS

33. The regulation of devices, including ECT devices, is relatively new. The United States Congress enacted the Medical Device Amendments of 1976 (the "MDA"), effective May 28, 1976, amending the FDCA "to provide for the safety and effectiveness of medical devices intended for human use."

34. Pursuant to the MDA, the FDA was required to review all existing medical devices and, by regulation, divide each into one of three classes of devices established to control access to the market depending on the intended use, the indications for use, and the risks that the particular device posed to the user. A Class I ("General Controls"), device was subject to general post-market or after-sale controls including good manufacturing practices. A Class II ("Performance Standards") device was to be subject to FDA established regulations for performance standards as well as post-market controls. A Class III ("Premarket Approval") device required a premarket approval application ("PMA") and approval before sale, or a product development protocol, and adherence to post-market controls. By way of contrast, a wheelchair is an example of a Class I device while an implantable pacemaker is an example of a Class III device.

35. On September 4, 1979, the FDA published an Order in the Federal Register (the "1979 FDA Order") presenting its "final ruling" that ECT devices are Class III "Premarket Approval" devices under the MDA and specifically ordered manufacturers such as Defendant to prepare and submit a PMA for approval. The FDA's ruling stated in relevant part:

> "The Food and Drug Administration (FDA) is issuing a final ruling classifying electroconvulsive therapy devices into Class III (premarket approval). The effect of classifying a device into Class III is to require each manufacturer of the device to submit to FDA a premarket approval application ["PMA"] that includes information concerning safety and effectiveness tests for the device."[2]

[2] *See* 44 Fed. Reg. 172, at 51776-77 (Sept. 4, 1979) (reporting 21 C.F.R. § 882 [Docket No. 78N-1103]).

36. The FDA's Order followed the recommendation of the Neurological Section of the Respiratory and Nervous System Devices empaneled by the FDA, due to the lack of available information regarding the safety of ECT devices and following public comment. The FDA concluded that Class III placement was required as "there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the ECT device."[3]

37. As of September 4, 1979, Congress intended that Defendant herein, as a manufacturer of ECT devices, submit a PMA application to the FDA for approval of this Class III device as a prerequisite to continued access to the market. The PMA application was to contain "safety and effectiveness" information derived from testing, e.g., from clinical trials. Moreover, PMA applications are required to include "specimens of the labeling proposed to be used for such device,"[4] to be submitted for FDA approval.

38. Defendant has been one of two ECT device manufacturers in the United States market since at least 1985, and SOMATICS, along with the other manufacturer, have held 100% of the US market share since that time. Defendant has never submitted a premarket approval application, nor have any ECT devices ever been granted premarket approval, which is the FDA's official (and only) determination of "safety and effectiveness" for Class III medical devices.

39. Plaintiffs are informed and believe and based thereon allege that Defendant has never conducted human trials in order to support their continued claims of their devices' "safety and effectiveness." Defendant continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enabled their continued use, despite a lack clinical proof of safety or effectiveness and Congress's intent that they prove such to the FDA.

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[3] *See* 21 C.F.R. § 882.5940.
[4] 21 U.S.C. § 360e(c)(1)(F).

40. Plaintiffs are informed and believe and based thereon allege that prior to the filing of the Complaint in this action, Defendant failed to investigate, evaluate injury, and submit reports to the FDA whenever the Defendant received or otherwise became aware of information that reasonably suggested that one of their marketed ECT devices may have caused or contributed to a death or serious injury, as required by federal law. Failure to submit such adverse event reports resulted in Defendant's ECT devices being "misbranded" under federal law.[5] Defendant continued to manufacture, sell, and distribute their respective devices in the United States, and otherwise enabled their continued use, despite being "misbranded" under federal law.

41. The United States Congress enacted the Safe Medical Devices Act of 1990 ("SMDA"), effective November 28, 1990, amending the FDCA "to make improvements in the regulation of medical devices." Thereafter, the FDA published an Order in the Federal Register (the "1995 FDA Order") pursuant to the SMDA requiring that the manufacturers of ECT devices, including Defendant, submit a summary of, and a citation to, all information known or available about the safety and effectiveness of their respective ECT devices to the FDA by August 14, 1997.[6]

42. Plaintiffs are informed and believe and based thereon allege that Defendant violated the SMDA, and the 1995 FDA Order, by failing to submit a summary of, and a citation to, all information known or available about the safety and effectiveness of their respective ECT devices to the FDA by August 14, 1997. Defendant continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enable their continued use. This rendered all of Defendant's ECT devices misbranded on separate legal grounds.

43. On April 9, 2009, the FDA published a third Order in the Federal Register (the "2009 FDA Order") again requiring the manufacturers of ECT

[5] 21 U.S.C. § 352(t).
[6] 60 Fed. Reg. 156, at 41986-89 (Aug. 14, 1995).

devices, including Defendant, to comply with the SMDA by submitting all information known or available about the safety and effectiveness of ECT devices to the FDA by the deadline of August 7, 2009.[7] Defendant responded to this order, but withheld a significant amount of information relating to adverse events from the FDA. None of the information provided directly or adequately addressed the known issues of permanent memory loss, cognitive impairment, or the certainty of electrically-induced brain injury and other intracranial insults resulting from ECT. Thus, Defendant rendered their own devices misbranded on yet another ground.

44. The FDCA's implementing regulations provide that manufacturers of medical devices must report to the FDA within 30 calendar days after the day that the manufacturer receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer: "(1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that [the manufacturer has marketed] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."[8]

45. The regulations provide that manufacturers must submit all information "reasonably known." "Reasonably known" information is: "(i) [a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) any information in your possession; or (iii) any information that you can obtain by analysis, testing, or other evaluation of the device."[9]

46. Defendant continued to violate the SMDA, and related orders, by failing to produce reasonably known information and by withholding data from the FDA relating to the safety and effectiveness of their respective ECT devices, including data relating to the devices' collective propensity to cause harm. In response to each and every one of the thousands of instances of Defendant's

[7] 74 Fed. Reg. 67, at 16214-17 (Apr. 9, 2009).
[8] 21 C.F.R. § 803.50(a).
[9] 21 C.F.R. § 803.50(b).

becoming aware of information reasonably suggesting death or serious injury with which their devices may be associated, Defendant conducted no investigation and reflexively rationalized, with no scientific justification at all, any alleged harm as resulting from an "underlying psychiatric condition" rather than the true obvious cause: the inducement of a major motor seizure through application of electricity to the crania of patients.[10] All devices designed to cause a major motor seizure through application of electricity to the cranium, regardless of design or technical specifications, present an unavoidable risk of serious trauma to the brain.

47. Plaintiffs are informed and believe and based thereon allege that the overwhelming weight of scientific evidence relating to ECT shock treatment suggests that there is no long-term benefit to receiving ECT shock treatment at all, that the alleged short-term benefits are transient and are little more than a bout of mania following brain damage, that ECT shock treatment inherently damages the brain, and that any mechanism of action by which it is said to 'treat' depression or mental illness is hypothetical.

48. As a result of the Defendant's conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, and the duties under state law running parallel to such requirements, the devices have continued to be manufactured, sold, distributed and have remained in use without testing, public dissemination of reliable information and data as to safety and effectiveness, warnings of inherent dangers, and without the requisite premarket FDA approval.

49. As evidenced by the warnings and consent forms that patients encounter prior to ECT, all or nearly all psychiatrists that administer ECT in the United States are under the impression that they have found a way to induce a major motor seizure in patients through application of electricity to the cranium with no

[10] 21 C.F.R. § 882.5940 (regulatory definition for electroconvulsive therapy devices, the predicate device type for all modern ECT devices).

risk of causing craniocerebral trauma at all. Proper compliance by Defendant with the pre-market screening and post-market surveillance obligations imposed on medical device manufacturers by the FDCA would have corrected this misperception among the psychiatric community and ensured conveyance of an adequate warning to patients, potentially ultimately resulting in a drastic curtailment or even non-use of Defendant's ECT devices on all or virtually all patients.

50. Defendant continue to manufacture, sell and distribute adulterated, misbranded, and defective ECT devices to this day. Doing so violates both a duty established under federal statute and parallel duties under state tort law. Had Defendant refrained from marketing adulterated and/or misbranded medical devices as was required by the FDCA, they would have stopped manufacturing and/or distributing their devices when the FDCA begun to prohibit the introduction into interstate commerce of adulterated and/or misbranded medical devices, or the introduction into interstate commerce of devices without a system in place for the timely investigation, evaluation, and reporting of adverse events.

51. The FDA's guidance document pertaining to medical device reporting states that "a publicly disclosable version of the medical device reports that we have received is available on the CDRH webpage at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM."[11] At the time of the original filing of this action, of the 49 reports that were posted on the MAUDE database pertaining to ECT devices, the majority were voluntarily submitted by patients, and none were submitted by device manufacturers under their mandatory reporting duties. Had Defendant complied with their federal and parallel state duties to report to the FDA all safety and effectiveness data reasonably known or available for ECT, the FDA's MAUDE database would have, for decades, reflected the multitude of adverse events that routinely result from administration of ECT shock treatment.

[11] MEDICAL DEVICE REPORTING FOR MANUFACTURERS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF DOCUMENT 26 (2016).

52. By way of contrast, the MAUDE entry for "Floss, Dental" contains hundreds of adverse event reports submitted by manufacturers, for malfunctions such as the breaking of packaging or adverse events such as the loss of a tooth.

53. Adverse events have regularly resulted from administration of ECT shock treatment since ECT's inception in 1938 such as to make it virtually impossible that any ECT manufacturer could escape the FDCA's obligation to investigate and report these events to the FDA. For example, from the 1940s to the 1980s, various psychiatric experts have documented brain damage correlated with ECT. A vocal "ECT survivor community" has been voicing their objection to the continued use of shock treatment for decades. Moreover, during FDA hearings between 2009 and 2011 in which the FDA opened a public docket seeking reports of adverse event complaints, ECT patients submitted thousands of adverse event complaints, hundreds of which alleged serious brain injury. SOMATICS became aware of these adverse event allegations by virtue of participating in those hearings, and therefore the hearings invoked their statutory duty to investigate, evaluate, and report the complaints to the FDA so that they are fully researched and reflected in the MAUDE database. However, there are no manufacturer-submitted adverse event reports in FDA's MAUDE database corresponding to those adverse event allegations, illustrating Defendant's continuous and intentional failure to investigate and/or report adverse events to the FDA.

54. "The Electroshock Quotationary" was published in 2006.[12] It recounts an eighty-year history of serious adverse events including permanent brain damage resulting from ECT shock treatment, as well as the formation of patient advocate groups united in their continued opposition to ECT shock treatment. Moreover, it references testimony and studies by U.S. psychiatrists, in which the psychiatrists opine that ECT inherently damages the brain. No account of injury resulting from

[12] LEONARD ROY FRANK, THE ELECTROSHOCK QUOTATIONARY (2006), http://www.endofshock.com/102C_ECT.PDF.

ECT shock treatment referenced in the Electroshock Quotationary went investigated and reported by Defendant.

55. Many studies have suggested or documented reasonably known brain injury resulting from ECT shock treatment. For example, a study in Archives of General Psychiatry documented that cerebral atrophy was significantly more common in those patients who had ever received ECT.[13]

56. A brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.[14]

57. A study relating MRI scans of patients demonstrated a strong correlation between the numbers of previous ECT treatments to loss of brain tissue.[15]

58. Another study found that ECT recipients were twice as likely to have a measurable loss of brain tissue in the front area of the brain and a tripling of the incidence of a loss of brain tissue in the back of the brain.[16]

59. Finally, a particularly graphic study documented intra-cranial bleeding resulting from ECT shock treatment administered using current ECT devices.[17] Defendant remained willfully ignorant of the adverse events in these and other reasonably known studies in an attempt to evade their FDCA reporting duties.

60. ECT is covered by numerous federal programs including Medicare and is sufficiently remunerative to keep entire psychiatric facilities in business.

61. Defendant conducted no investigation corresponding to the allegations in the original Complaint in this action, or the medical literature cited herein, within thirty days of its filing on September 11, 2017.

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[13] Weinberger et al., *Structural Abnormalities in the Cerebral Cortex of Chronic Schizophrenic Patients*, 36 ARCHIVES GEN. PSYCHIATRY, 935-39 (1979).
[14] Calloway et al., *ECT and Cerebral Atrophy: A CT Study*, 64 ACTA PSYCHIATRICA SCANDINAVICA 442-45 (1981).
[15] Andreasen et al., *MRI of the Brain in Schizophrenia*, 47 ARCHIVES GEN. PSYCHIATRY, 35-41 (1990).
[16] R.J. Dolan et al., *The Cerebral Appearance in Depressed Subjects*, 16 PSYCHOL. MED., 775-79 (1986).
[17] Kulkarni & Melkundi, *Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review*, CASE REPORTS IN PSYCHIATRY (2012).

62. The FDA brought specific reportable events to the attention of both Defendant during facility inspections. Defendant did not timely investigate and/or report those specific events.

63. In SOMATICS, LLC's 2009 response to the FDA's third Order, the manufacturer states: "[t]he Somatics Thymatron ECT device has already been in functional class II during its entire lifetime of 25 years . . . ." Since ECT devices are officially classified into Class III based on their potential risk to human health and safety, and because Class II devices are generally safer than Class III devices, such a statement is misleading to health care providers and to patients, who may be led to believe that ECT is safer than it actually is. The only senses in which ECT devices are "functionally in Class II" is in that ECT devices have managed to reach the market without the submission of a premarket approval application, and have otherwise entirely evaded the FDA's pre- and post- market regulatory requirements. Premarket approval is a safeguard applied only to Class III devices by virtue of their unreasonable risk of causing injury, and the only reason ECT devices have managed to stay on the market without submission of premarket approval applications is because Defendant failed to submit them when due. Accordingly, in attempting to demonstrate the safety of SOMATICS' ECT devices, SOMATICS instead draws attention to their regulatory noncompliance.

64. Also, in their 2009 submission to the FDA, SOMATICS states: "[i]n the ensuing 25 years [since clearance of the Thymatron] there has been no occurrence of a reported adverse event." Given the multitude of adverse events that regularly result, and have resulted, from ECT shock treatment, this statement is an admission that SOMATICS, LLC has not reported any of the adverse events that have occurred as a result of use of their Thymatron devices in 25 years. In the same submission to the FDA, SOMATICS, LLC claimed a lack of evidence of any ECT-induced permanent memory loss in patients past the six-month mark after the procedure. Simultaneously, SOMATICS, LLC in briefs in this action, has claimed

that permanent memory loss is now a ubiquitously known adverse event associated with ECT devices.

65. SOMATICS, LLC has used a contract manufacturer unregistered by the FDA, Elektrika, Inc., to manufacture its devices for decades.

66. Had the FDA's MAUDE database accurately reflected manufacturer reporting on the multitude of adverse events that result routinely from ECT treatment, those adverse events would have been noticed by professionals in the psychiatric field, addressed in academic and medical literature, discussed at meetings and conferences attended by psychiatrists within California and the United States generally, and altogether well-known by the general public.

67. Had Defendant satisfied their reporting duties, ECT patients' medical providers would have been properly informed by the FDA's MAUDE database, by medical and academic literature discussing the adverse events in the MAUDE database, by meetings they attended at which the adverse events resulting from ECT would have been discussed, by general public discussion, and thereafter by direct warning from the FDA as to the inherent risks associated with ECT. ECT is inherently harmful to the human brain, but this fact is not publicly known because of Defendant's breach of their FDCA reporting duties and all state common law duties running parallel to those FDCA reporting requirements.

68. But for Defendant's breach of their federal and state reporting duties that arose out of the requirements imposed by the FDCA and the FDA's multiple orders, the Plaintiffs' medical providers would have had knowledge of the risk inherent in ECT shock treatment in time to prevent the Plaintiffs' injuries. Plaintiffs' medical providers, with knowledge that modern ECT devices actually have not managed to mitigate the risk of brain trauma resulting from induced seizures through application of electricity to the cranium, would have conveyed a warning to patients, as common law principles of informed consent require such warning of unavoidable risks of serious harm. Plaintiffs would then have been in a position to

either give informed consent or refuse the treatment entirely. Moreover, medical providers would have acted different, including severely limiting recommendations, or ceasing to recommend ECT shock treatment altogether for all or virtually all patients.

69. But for Defendant's marketing of adulterated, misbranded, and defective medical devices, plaintiffs would not have had access to ECT shock treatment, would not have consented to undergo ECT treatment, and would not have suffered the injuries alleged herein. Accordingly, but for Defendant's conduct in manufacturing and marketing their devices, ECT shock devices would not exist in their current form, if at all.

70. ECT shock devices are defined in the FDA's regulations without reference to particular manufacturers, and use of any device meeting the regulatory definition presents an unavoidable risk of craniocerebral trauma to patients. Thus, any warning of adverse events by one manufacturer would have been reported under the same category of "Device, Electroconvulsive Therapy" on the FDA's MAUDE database. The same warning and testing requirements applied to all manufacturers, and warnings submitted by one manufacturer would have by definition alerted all healthcare providers of the dangers posed by any manufacturer's ECT devices. Accordingly, by failing to report adverse events to the FDA and failing to furnish other required safety and effectiveness information to the FDA, Defendant actually and proximately caused the injuries suffered by the Plaintiffs.

71. Medical literature and studies purporting to prove that ECT does not cause brain injury is methodologically flawed. Researchers seeking to study the adverse safety risks presented by ECT have difficulty obtaining funding in the United States. Defendant, holding a strong interest in preventing public revelation of the unavoidable risk of intracranial insult and/or craniocerebral trauma presented by ECT, have maintained improper ties and provided kickbacks and/or honoraria to

opinion leaders and those responsible for determining who gets funding for research into ECT's safety and effectiveness in an attempt to prevent public revelation of ECT's adverse safety risks. Plaintiffs believe the primary motive behind this behavior is to ensure that funds from federal programs keep numerous psychiatric units financially afloat.

72. Finally, SOMATICS, LLC delivered no direct warning of craniocerebral trauma, brain injury and permanent memory loss as risks of ECT to the either the facilities where the ECT was provided or the physicians responsible for prescribing ECT to JOSE RIERA, including his doctors, Dr. Rajan and Dr. Adatia. SOMATICS, LLC delivered no direct warning of craniocerebral trauma, brain injury and permanent memory loss as risks of ECT to the either the facilities where the ECT was provided or the physicians responsible for prescribing ECT to DEBORAH CHASE, including her doctors, Dr. Movsesian and Dr. Jaglkar. Had SOMATICS, LLC done so, the physicians would have conveyed the warnings of the risks of craniocerebral trauma, brain injury and permanent memory loss as risks of ECT to JOSE RIERA and DEBORAH CHASE, as such a conveyance would be legally required under California principles of informed consent. Plaintiffs RIERA and CHASE then would have refused the treatment entirely.

FIRST CLAIM FOR RELIEF

Negligence/Negligence *Per Se* (Adulteration and Misbranding)

73. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 72 of this Complaint.

74. SOMATICS had a duty and failed to respond to the FDA's Order requiring submission of a summary of, and a citation to, all data known or available concerning the safety and effectiveness of their ECT devices by August 14, 1997, and August 7, 2009, respectively. Failure to furnish such information rendered all of their devices misbranded.

75. SOMATICS, according to their own contentions, manufacture and introduce into interstate commerce devices that have different intended uses, and different technical characteristics that raise new questions of safety and effectiveness when compared to their predicate devices. Moreover, their predicate devices were not legally marketed. This renders all of Defendant's devices adulterated.

76. SOMATICS has never had in place a system for the timely investigation, evaluation, and reporting of adverse event complaints to the FDA, and they have never reported an adverse event despite countless instances of becoming aware of information reasonably suggesting death or serious injury associated with their devices.

77. SOMATICS utilizes an unregistered contract manufacturer to manufacture all of their devices. This renders SOMATICS' devices misbranded.

78. Defendant has had and continue to have a duty of reasonable care under California state common law to refrain from the manufacture, delivery, or introduction into interstate commerce of adulterated and/or misbranded devices. Such devices are legally defective.

79. SOMATICS breached those state common law duties owed to the Plaintiffs when they continued to market their adulterated and misbranded medical devices for decades.

80. RIERA and CHASE underwent ECT shock treatment delivered by ECT shock devices placed into the stream of commerce by the Defendant, and during the time that adulterated and misbranded ECT devices were being manufactured, sold and distributed.

81. RIERA and CHASE have suffered, and/or continue to suffer concussive brain injury and ensuing cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome and related injuries following and as a proximate result of ECT shock

treatment and Defendant's breach of duty owed to plaintiffs. This harm is of the type sought to be prevented by the passage of the FDCA, MDA, and SMDA, and Plaintiffs, as recipients of Class III medical devices, are of the class of plaintiffs the applicable statutes and regulations are intended to protect.

82. Had Defendant complied with their state law duties requiring them to refrain from manufacturing, delivering, or introducing into interstate commerce their misbranded and adulterated devices, those devices would never have reached or injured Plaintiffs and Plaintiffs would not have undergone such treatment.

83. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

SECOND CLAIM FOR RELIEF

Negligence/Negligence *Per Se* (Failure to Timely Investigate, Evaluate, and Report Adverse Events)

84. Plaintiffs re-allege and incorporate by reference paragraphs 1- 83 as if fully set forth herein.

85. Defendant has and has had a continuous duty since the early 1980s to investigate, evaluate, and report information reasonably suggesting death or serious injury associated with their devices to the FDA within 30 days of discovering such information.

86. In breach of said duty, Defendant encountered countless adverse event complaints and other information reasonably suggesting death or serious injury resulting from ECT, but never maintained a system for the timely reporting of adverse safety information and never submitted a single adverse event report to the FDA prior to the filing of this action.

87. Had Defendant complied with their state law duties to report to the FDA all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), this information would have appeared

prominently and accessibly in the FDA's MAUDE database and in medical journals, and would have been discussed at conferences attended by the psychiatric profession at large. The FDA also would have promulgated a warning to the end users of ECT shock devices within the medical profession, who would have been on constructive notice of the latent dangers inherent in providing ECT shock treatment to Plaintiffs in time to alter their conduct and their recommendations, and to convey a warning of craniocerebral trauma, thereby preventing a deprivation of informed consent and associated injuries as Plaintiff would not have undergone such ECT treatment. Accordingly, the negligent conduct of SOMATICS actually caused, proximately caused, and was a substantial factor in causing the harm suffered by Plaintiffs. Accordingly, compensatory damages are appropriate.

88. Defendant acted with oppression, fraud, and malice. Accordingly, punitive damages are appropriate.

THIRD CLAIM FOR RELIEF

Negligence – Failure to Warn (Failure to Warn Plaintiffs' Medical Providers Directly)

89. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 88 of this Complaint.

90. Defendant SOMATICS manufactured, distributed, and sold their ECT devices in the stream of commerce within the United States, knowing that they would be used without inspection for defect.

91. The ECT devices, at all times relevant to the causes of action alleged in this Complaint, caused and continue to cause permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome, and these facts were both known and knowable in light of the scientific and medical knowledge available in the medical and scientific communities. Defendant's failure, at the time of manufacture and distribution, to adequately warn plaintiffs' medical providers of the "Thymatron" device's risk of

causing craniocerebral trauma, brain injury and/or permanent memory loss rendered their devices defective with respect to the marketing and information provided to the Plaintiffs alleged herein.

92. Craniocerebral trauma and ensuing cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome present a substantial danger to patients when ECT devices are used as intended or misused in a foreseeable way.

93. Ordinary consumers would not recognize these potential risks inherent to ECT devices, especially in light of Defendant's aggressive marketing and promotion campaigns.

94. SOMATICS, LLC had a duty to warn Plaintiffs' medical providers directly of the "Thymatron" device's risk of causing craniocerebral trauma to patients.

95. SOMATICS failed to investigate and provide adequate warnings of these risks directly to Plaintiffs' medical providers, in breach of their duty under California law.

96. RIERA and CHASE were not advised of these risks of ECT treatment and suffer permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome as a direct result of administration of ECT shock treatment. Plaintiffs, had they been properly warned about the true nature of ECT shock devices, would not have consented or received ECT treatment.

97. Had Defendant complied with their state law duties to directly warn and thereby inform Plaintiffs RIERA and CHASE's psychiatrists of ECT's risk of causing brain trauma, those treating psychiatrists would have been legally required to convey warning of the risk of brain trauma to Plaintiffs under California principles of informed consent. Plaintiffs then would have refused to consent to undergo ECT shock treatment administered by SOMATICS, LLC's "Thymatron"

device and not have received the ECT treatment. The conduct of SOMATICS actually caused, proximately caused, and was a substantial factor in causing the harm suffered by Plaintiffs. Therefore, compensatory damages are appropriate.

98. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

FOURTH CLAIM FOR RELIEF

Strict Product Liability– Failure to Warn (Failure to Timely Investigate, Evaluate, and Report Adverse Event Complaints)

99. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 98 of this Complaint.

100. Defendant SOMATICS manufactured, distributed, and sold their ECT devices in the stream of commerce within the United States, knowing that they would be used without inspection for defect.

101. The ECT devices, at all times relevant to the causes of action alleged in this Complaint, caused and continue to cause permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome, and these facts were both known and knowable in light of the scientific and medical knowledge available in the medical and scientific communities. Defendant's failure, at the time of manufacture and distribution, to adequately warn plaintiffs and medical providers by reporting to the FDA of these latent dangers and risks renders the devices adulterated, misbranded, and defective with respect to the marketing and information provided to the Plaintiffs.

102. Craniocerebral trauma and ensuing cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome present a substantial danger to patients when ECT devices are used as intended or misused in a foreseeable way.

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103. Ordinary consumers would not recognize these potential risks inherent to ECT devices, especially in light of Defendant's aggressive marketing and promotion campaigns.

104. SOMATICS failed to investigate and provide adequate warnings of these risks.

105. RIERA and CHASE, suffer permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome as a direct result of administration of ECT shock treatment. Plaintiffs, had they been properly warned about the true nature of ECT shock devices, would not have received ECT treatment.

106. Had Defendant complied with their state law duties to give a post-sale warning to the FDA of all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), this information would have appeared prominently in the FDA's MAUDE database and in medical journals and the FDA would have promulgated a warning to the end users of ECT shock devices within the medical profession, who would have been on constructive notice of the unavoidable risk of intracranial insult to patients as a known risk in providing ECT shock treatment to Plaintiffs and would have conveyed a warning of craniocerebral trauma, brain injury and/or permanent memory loss in time to prevent their injuries. Accordingly, the conduct of SOMATICS actually caused, proximately caused, and was a substantial factor in causing the harm suffered by Plaintiffs. Therefore, compensatory damages are appropriate.

107. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

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FIFTH CLAIM FOR RELIEF

Strict Product Liability (Adulteration and Misbranding)

108. Plaintiff incorporates by reference paragraphs 1-107 as if fully set forth herein.

109. All of Defendant's ECT shock devices have been adulterated and/or misbranded for their entire life on the market. This regulatory noncompliance rendered all ECT defective for purposes of strict liability under California common law.

110. But for Defendant's introduction of defective medical devices into interstate commerce, ECT shock devices would never have reached Plaintiffs who therefore would not have undergone ECT treatment and suffered unwarned craniocerebral trauma, brain injury and/or permanent memory loss secondary to ECT treatment. Therefore, compensatory damages are appropriate.

111. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

SIXTH CLAIM FOR RELIEF

Strict Product Liability – Failure to Warn (Failure to Warn Plaintiffs' Medical Providers Directly)

112. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 111 of this Complaint.

113. Defendant SOMATICS manufactured, distributed, and sold their ECT devices in the stream of commerce within the United States, knowing that they would be used without inspection for defect.

114. The ECT devices, at all times relevant to the causes of action alleged in this Complaint, caused and continue to cause permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome, and these facts were both known and knowable in light of the scientific and medical knowledge available in the medical and scientific

communities. Defendant's failure, at the time of manufacture and distribution, to adequately warn plaintiffs' medical providers of the "Thymatron" device's risk of causing craniocerebral trauma rendered their devices defective with respect to the marketing and information provided to the Plaintiffs as alleged herein.

115. Craniocerebral trauma and ensuing cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome present a substantial danger to patients when ECT devices are used as intended or misused in a foreseeable way.

116. Ordinary consumers would not recognize these potential risks inherent to ECT devices, especially in light of Defendant's aggressive marketing and promotion campaigns.

117. SOMATICS failed to investigate and provide adequate warnings of these risks.

118. RIERA and CHASE suffer permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome as a direct result of administration of ECT shock treatment. Plaintiffs, had they been properly warned about the true nature of ECT shock devices, would not have received ECT treatment.

119. Had Defendant complied with their state law duties to directly warn and thereby inform Plaintiffs RIERA and CHASE's psychiatrists of ECT's risk of causing brain trauma, those treating psychiatrists would have been legally required to convey warning of brain trauma to Plaintiffs under California principles of informed consent. Accordingly, the conduct of SOMATICS actually caused, proximately caused, and was a substantial factor in causing the harm suffered by Plaintiffs. Therefore, compensatory damages are appropriate.

120. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. For compensatory damages for the special medical expenses incurred and necessary to treat the damages caused to Plaintiffs;

2. For general damages for the pain and suffering, inconvenience, emotional distress, loss of earnings, and lost earning capacity as suffered by Plaintiffs;

3. For punitive damages in light of Defendant's oppression, fraud, and malice;

4. For costs of suit and expenses incurred herein, including expert fees;

5. For reasonable attorney's fees and such other nontaxable costs, subject to court approval, as warranted;

6. For injunctive relief; and

7. For all such other and further relief that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all claims so triable.

Dated: June 26, 2018

Respectfully submitted,

DK LAW GROUP, LLP

By: /s/ *David M. Karen*
David M. Karen, Esq.
Attorneys for Plaintiffs

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Jose Riera, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-PJW

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 3155 Old Conejo Road, Thousand Oaks, CA 91320.

On June 26, 2018, I served the foregoing document described as: **[Fourth Amended Complaint)** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Los Angeles, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below.

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on June 26, 2018, at Thousand Oaks, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

/S/ David M. Karen
David M. Karen, Declarant

SERVICE LIST

Jose Riera, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-PJW

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