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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.:

COMPLAINT FOR:

1. NEGLIGENCE/NEGLIGENCE *PER SE*;
2. STRICT PRODUCT LIABILITY—MARKETING AND INFORMATION DEFECT—FAILURE TO WARN; and
3. LOSS OF CONSORTIUM.

CLASS ACTION

DEMAND FOR JURY TRIAL

Plaintiffs JOSE RIERA, MICHELLE HIMES, DIANE SCURRAH, and DEBORAH CHASE (collectively "Plaintiffs"), individually and on behalf of all other similarly situated individuals, hereby complain against Defendants MECTA

CORPORATION, SOMATICS, LLC and DOES 1 through 10, inclusive (collectively "Defendants") and, on information and belief, allege as follows:

SUMMARY OF THE ACTION

1. This is a class action brought by Plaintiffs, on behalf of themselves and other similarly situated electroconvulsive therapy ("ECT")[1] patients, who have sustained injuries resulting from Defendants' conduct. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 & 1332.

2. 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 and members of the putative class are individuals suffering from various degrees of physiological, psychological and emotional trauma including, but not limited to skin burns, permanent brain damage, severe permanent cognitive and memory impairment, broken teeth, prolonged seizures, myocardial infarction, ruptured bowels, acute and/or chronic organic brain syndrome, complete neurological collapse, and sometimes death, secondary to ECT shock treatment.

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[1] Also referred to as "shock therapy" or "shock treatment."

6. Despite statutory duties under the Food, Drug and Cosmetic Act ("FDCA") and directives by the FDA, pursuant to the Medical Device Amendments of 1976 ("MDA") that ECT device manufacturers report information concerning safety and effectiveness testing for their devices to the FDA,[2] no ECT device manufacturer, including MECTA CORPORATION or SOMATICS, LLC, complied with these statutory obligations. No ECT manufacturer, including either Defendant, responded to the FDA's first two orders requiring them to submit safety and effectiveness data by May 28, 1982 and August 14, 1997, respectively. Defendants only responded to a third FDA order, mandated by the Safe Medical Devices Act of 1990 ("SMDA") requiring Defendants to submit "any information known or otherwise available" about the safety and effectiveness of the device, *including adverse safety or effectiveness information*. Defendants' responses failed to include *any* information relating to the majority of physiological, psychological, and emotional injuries frequently suffered by those who receive ECT shock treatment. Defendants also grossly understated the incidence of death resulting from ECT. Such a response by Defendants failed to comply with their statutory reporting requirements under the MDA and SMDA.

7. As a direct and proximate result of Defendants' refusal to comply with multiple orders by the FDA and satisfy their state duties running parallel to their statutory duties, as of the time of this filing, ECT devices have never satisfied the stringent premarket approval standards that Class III medical devices are required to meet.

8. Because of the lack of testing rigor, the mechanism of action by which ECT yields any alleged benefit to patients remains unascertained and unknown. Testing over the years has not shown any conclusive benefit to receiving ECT shock treatment past a brief bout of mania in the short-term, but the risks remain

[2] 44 Fed. Reg. 172, at 51776-51777 (Sept.4, 1979) ("This action is being taken under the Medical Device Amendments of 1976."); *see* Medical Device Amendments of 1976, 21 U.S.C. § 351 *et. seq.*

apparent, and include but are not limited to permanent long-term memory loss, cognitive impairment, debilitating electrical brain trauma, seizures, acute and/or chronic organic brain syndrome, complete neurological collapse, and death.

9. But for Defendants' failure to comply with the FDCA, MDA, and SMDA, the putative class members would not have suffered the serious injuries alleged in this complaint, since compliance would require that the Defendants investigate, solicit, and report information when they learn that their ECT devices may have contributed to a death or serious injury and specifically warn the FDA of adverse safety and effectiveness information.

10. Defendants' 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 their devices "adulterated" under the FDCA.

11. Defendants' failure to furnish statutorily mandated material or information pertaining to occasions on which their devices may have contributed to a death or serious injury rendered their devices "misbranded" under the FDCA.

12. The manufacture, introduction, or receipt of an adulterated or misbranded medical device through interstate commerce is prohibited under the FDCA.[3]

13. Defendants' failure to warn the FDA of the latent dangers inherent in ECT resulted in a lack of knowledge among the medical providers of members of the putative class and the public in general about the latent dangers 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, Defendants' conduct directly and proximately caused injuries to the putative class.

[3] 21 U.S.C. § 331.

14. This class action seeks to remedy the damages caused by Defendants' conduct: violating the state warning duties running parallel to the Food, Drug & Cosmetic Act and causing harm by placing a defective product into the stream of commerce. Defendants' violation of federal statutory duties, as demonstrated by Defendants' failure to comply with three separate administrative orders by the United States Food and Drug Administration ("FDA"), which required Defendants to submit to the FDA all safety and effectiveness data reasonably known and/or available for their ECT shock devices by certain effective dates, resulted in a lack of knowledge among the medical providers of members of the putative class and the public in general about the latent dangers inherent in ECT shock treatment.

PARTIES

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

16. Plaintiff MICHELLE HIMES ("HIMES") is a citizen of the State of California.

17. Plaintiff DIANE SCURRAH ("SCURRAH") is a citizen of the State of California.

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

19. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, Defendant MECTA CORPORATION ("MECTA") is and was a corporation formed and existing under the laws of the State of Oregon with its principal place of business at 19799 SW 95th Place B, Tualatin, Oregon. Plaintiffs are further informed and believe and based thereon allege that MECTA 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.

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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.

21. Plaintiffs are not presently aware of the true names and capacities, whether individual, corporate, associate or otherwise, of Defendants named in this action as DOES 1 through 10, and each of them, and therefore sue such Defendants, and each of them, by such fictitious names. Plaintiffs are informed and believe, and on the basis of such information and belief allege, that each fictitiously named Defendant is legally responsible for the acts alleged herein, and/or is liable to Plaintiffs as hereinafter alleged. Plaintiffs are informed and believe, and on the basis of such information and belief allege, that at all times mentioned herein, that such fictitiously named Defendants, and each of them, were participants in the stream of commerce and/or necessary marketing agents that played a role in delivering ECT shock devices to their end users.

22. Plaintiffs are informed and believe, and, based upon such information and belief allege that the Defendants named in this action as DOES 1 through 10, and each of them, herein knowingly conspired together in various combinations, and agreed amongst themselves to act in concert and in furtherance of a common scheme, plan and design to commit, aid, abet and/or render substantial assistance in the wrongs complained of herein below. Plaintiffs are further informed and believe, and based upon such information and belief allege that Defendants knew as they were conducting themselves that they were substantially assisting in the accomplishment of wrongdoing, and had the right and ability to control the actions

of the remaining Defendants but did nothing to curb the activities described herein below, or prevent others from engaging in such conduct. Plaintiffs are further informed and believe, and based upon such information and belief allege, that Defendants, and each of them, actively condoned, encouraged, participated in, and/or instigated the conduct described herein below in furtherance of their common scheme, plan and design which entailed, among other things: (a) aiding and abetting the conspiracy and common course of conduct complained of herein; (b) participating in and/or knowing and acquiescing in the acts complained of herein, sufficient to categorize such conduct as conspiratorial; and (c) taking and/or ratifying conduct to enrich themselves or their co-conspirators, at the expense of Plaintiffs.

23. Plaintiffs are informed and believe that Defendants, and each of them, are in some manner legally responsible for the events alleged in this Complaint. Plaintiffs are further informed and believe that each of the Defendants acted in all respects pertinent to this action as the agent of the other Defendants, carried out a joint scheme, business plan, policy, or enterprise, or aided and abetted the acts and omissions alleged herein, and that the acts and omissions of each Defendant are legally attributable to the other Defendants.

JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction over the lawsuit under the Class Action Fairness Act, 28 U.S.C. § 1332, because this is a proposed class action in which: (1) there are at least 100 Class members; (2) the combined claims of Class members exceed $5,000,000, exclusive of interest, attorney's fees, and costs; and (3) Plaintiffs and Defendants are citizens of different states to the extent required by statute.

25. 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.

26. This Court has personal jurisdiction over Defendant MECTA because it has sufficient minimum contacts in California to render the exercise of jurisdiction by this Court proper.

27. 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.

28. 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 representative Class members, occurred in this District.

PLAINTIFF-SPECIFIC ALLEGATIONS

29. 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, California. ECT did not generate any improvement in RIERA's severe depression. Instead, it caused severe physiological, psychological, and emotional injury.

30. Plaintiff HIMES obtained over twenty rounds of ECT shock treatment between about April 2011 and about July 2012 at Sharp Mesa Vista Hospital in San Diego, California. As a result of receiving ECT shock treatment, HIMES suffers severe physiological, psychological, and emotional injury. Plaintiff HIMES's husband suffers a loss of the consortium that HIMES offered during the course of their marriage as a result of HIMES's receipt of ECT shock treatment.

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31. Plaintiff SCURRAH underwent over fifty-eight rounds of ECT shock treatment in seeking to treat her bipolar disorder, beginning on March 28, 2012 and continuing for about nine months. ECT shock treatment caused SCURRAH severe physiological, psychological, and emotional injury.

32. Plaintiff CHASE underwent ECT shock treatment at least seven times in seeking to treat her major depressive disorder and severe anxiety, between April of 2015 and Spring of 2016. ECT shock treatment caused CHASE severe physiological, psychological, and emotional injury.

CLASS ACTION ALLEGATIONS

33. Plaintiffs bring this action on behalf of themselves and all others similarly situated as this action satisfies the requirements of numerosity, commonality, typicality, adequacy of representation, and predominance and superiority[4] requirements of Federal Rules of Civil Procedure, Rule 23.

34. The proposed Class is defined as follows:

CLASS

> All individuals in the United States who received ECT shock treatment in California after May 28, 1982, administered by an ECT shock device that was manufactured, sold and/or distributed by Defendants after May 28, 1982, and who suffered an injury as a result thereof, with the exception of paragraph 35 below.

35. Excluded from the Class are government entities, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members.

36. The members of the Class are so numerous that joinder is impractical. The Class consists of thousands of individuals, as ECT shock treatment has been available and administered to the described Class for more than 30 years, with the

[4] Fed. R. Civ. P. 23(b)(3).

annual estimate of ECT shock patients per year in California numbering in the thousands. Although the exact number and identity of the class members is not presently known, the class can be defined and ascertained by means of the objective criteria, through strategic publication, and through coordinated discovery of the identities of all purchasers of ECT shock devices as sold by and obtained from MECTA and SOMATICS since the beginning of the class period.

37. There are questions of law and fact that are common to the Class, and these common questions predominate over any questions affecting only individual Class members. Among the questions common to the Class are:

a. Defendants' statutory obligation not to market an adulterated or misbranded medical device and/or reporting requirements imposed by the FDCA;

b. Whether the FDCA gives rise to a duty to warn;

c. Whether Defendants violated statutory obligations and/or reporting requirements and/or breached their duty to warn;

d. The dates of said violations and/or breaches;

e. Whether, had Defendants complied with their statutory duties, their ECT devices would have been on the market;

f. Defendants' efforts to comply and/or justifications for non-compliance with the reporting requirements and/or duty to avoid marketing an adulterated or misbranded medical device as may be offered by Defendants in their defense;

g. Whether Defendants' violations and/or breaches can give rise to liability under the state laws running parallel to the federal laws;

h. Information as to the safety and effectiveness, or lack thereof, for the use of ECT shock devices;

i. The inherent dangers of the use of ECT shock devices;

j. Information known or knowable to Defendants regarding the

safety and effectiveness, or lack thereof, of the use of ECT shock devices;

k. Whether Defendants' culpable state of mind in in failing to comply with federal statutory duties and their parallel state counterparts subjects Defendants to punitive damages.

38. Common questions of fact and law predominate over any questions affecting only individual Class members with respect to liability, and damages may be properly bifurcated for separate determination.

39. The claims of Plaintiffs are typical of the claims of Class in that they underwent ECT shock treatment using an ECT shock device manufactured, sold and/or distributed by Defendants that, like the Class members, they would not have undergone had Defendants not violated the FDCA or had not manufactured, sold and/or distributed an adulterated, misbranded, and defective ECT shock device within the stream of commerce, and would therefore not have been injured by ECT shock treatment.

40. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have no interests antagonistic to the interest of any of the other Class members.

41. Plaintiffs are committed to the vigorous pursuit of this action and have retained competent counsel with the necessary experience and skill to prosecute this action on behalf of the Class.

42. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The issues that may be jointly tried, when compared to those requiring separate adjudication, are so numerous and substantial that the maintenance of a class action would be advantageous to the judicial process and to the litigants. In light of the allegations made, individual litigation to resolve the whole of this matter would be unnecessarily costly and burdensome and would deter individual claims.

43. To attempt to resolve the entirety of this claim by processing individual cases would increase both the expenses and the delay, not only to class members, but also to Defendants and the Court. In contrast, a class action will avoid case management difficulties and provide multiple benefits to the litigating parties, including efficiency, economy of scale, unitary adjudication with consistent results and equal protection of the rights of each class member, all by way of the comprehensive and efficient supervision of the litigation by a single court.

44. Without class certification, the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the proposed class that would establish incompatible standards of conduct for Defendants.

SUBSTANTIVE ALLEGATIONS

45. 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."

46. 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.

47. 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 Defendants 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."[5]

48. 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 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."[6]

49. As of September 4, 1979, Defendants herein, as manufacturers of ECT devices, were specifically ordered to 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 must include "specimens of the labeling proposed to be used for such device,"[7] to be submitted for FDA approval.

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[5] *See* 44 Fed. Reg. 172, at 51776-77 (Sept. 4, 1979) (reporting 21 C.F.R. § 882 [Docket No. 78N-1103]).
[6] *See* 21 C.F.R. § 882.5940.
[7] 21 U.S.C. § 360e(c)(1)(F).

50. Defendants, as manufacturers of ECT devices, were required to perform clinical trials and submit their respective PMA applications by May 28, 1982.

51. Plaintiffs are informed and believe and based thereon allege that Defendants thereafter violated the MDA, and the 1979 FDA Order, and specifically failed to conduct human trials and/or submit PMA applications with safety and effectiveness information then available to date to the FDA by May 1982, or at all. Failure to timely submit PMAs resulted in Defendants' ECT devices being "adulterated" under federal law. Defendants continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enabled their continued use, despite being "adulterated" under federal law.[8]

52. Plaintiffs are informed and believe and based thereon allege that Defendants failed to submit reports to the FDA whenever the Defendants received or otherwise became aware of information that reasonably suggested that one of their marketed 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 Defendants' ECT devices being "misbranded" under federal law.[9] Defendants 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.

53. 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 Defendants, submit a summary of, and a citation to, all information known or available about the safety

[8] 21 U.S.C. § 351; *see id.* § 331 (prohibiting "introduction," "receipt," or "delivery" of adulterated or misbranded devices into interstate commerce).
[9] 21 U.S.C. § 352(t).

and effectiveness of their respective ECT devices to the FDA by August 14, 1997.[10]

54. Plaintiffs are informed and believe and based thereon allege that Defendants 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. Defendants continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enable their continued use.

55. On April 9, 2009, the FDA published a third Order in the Federal Register (the "2009 FDA Order") again requiring the manufacturers of ECT devices, including Defendants, 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.[11] Defendants responded to this order, but withheld a significant amount of information relating to adverse events from the FDA. None of the information provided directly addressed the known issues of permanent memory loss, cognitive impairment, or the certainty of brain damage resulting from ECT.

56. 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."[12]

57. The regulations provide that manufacturers must submit all information "reasonably known." "Reasonably known" information is "(i) [a]ny

[10] 60 Fed. Reg. 156, at 41986-89 (Aug. 14, 1995).
[11] 74 Fed. Reg. 67, at 16214-17 (Apr. 9, 2009).
[12] 21 C.F.R. § 803.50(a).

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."[13]

58. Defendants continued to violate the SMDA, and related orders, by failing to produce reasonably known information and by withholding a large quantity of 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.

59. Plaintiffs are informed and believe and based thereon allege that when the FDA, pursuant to statutory duty, scheduled hearings before its Neurological Devices Panel in 2011 to discuss the safety and effectiveness of ECT shock treatment, Defendants hired numerous psychiatrists with conflicts of interest to perform a skewed culling of data points (from about 60 studies out of 1,200) so as to suggest that ECT shock treatment posed minimal risks and had significant short-term benefits, and had a death rate hundreds of times lower than the actual death rate of those who undergo ECT shock treatment.

60. 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.

61. As a result of the Defendants' 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

[13] 21 C.F.R. § 803.50(b).

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.

62. Defendants 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.

63. 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."[14] Of the 49 reports posted on the MAUDE database pertaining to ECT devices, the majority appear to have been voluntarily submitted by patients, and none appear to have been submitted by device manufacturers under their mandatory reporting duties. Had Defendants 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 reflected the multitude of adverse events that routinely result from administration of ECT shock treatment.

64. 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. These adverse events were "reasonably known" to both MECTA and SOMATICS, and therefore created a statutory duty to investigate and report them to the FDA. However, there are no manufacturer-submitted adverse event reports in FDA's MAUDE database, illustrating Defendants' continuous and intentional

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

failure to report adverse events to the FDA.

65. Multiple lawsuits were filed against MECTA corporation in the 1990s. These lawsuits alleged serious injuries, including but not limited to brain damage, permanent cognitive impairment, and ruptured bowels resulting from ECT shock treatment. The CEO of MECTA, Ms. Robin Nicol, admits that these lawsuits alleged that MECTA's devices caused brain damage to the patients. She testified that she was not even curious why multiple people had sued her company for causing them brain damage, assuming the lawsuits to be "frivolous." Defendants intentionally evaded their duty to investigate these adverse events or submit any adverse event reports to the FDA.

66. In sworn deposition testimony in 2004, in an unrelated suit, Robin Nicol, was asked if she or anyone from her company had "made any effort to solicit information from persons who have received ECT to see whether or not they have been harmed." She responded "no . . . that is not in the purview of our company's responsibilities."

67. Had Defendants satisfied their reporting duties, ECT patients' medical providers would have been properly informed by the FDA's MAUDE database, by medical journals, 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 Defendants' breach of their FDCA reporting duties and all state common law duties running parallel to those FDCA reporting requirements.

68. If the medical providers for members of the putative class or general public had knowledge of the devices' inherent risk of permanent injury, members of the putative class would not have undergone ECT shock treatment, but for Defendants' breach of their federal and state reporting duties that arose out of the requirements imposed by the Food, Drug, and Cosmetic Act and the FDA's three orders.

69. But for Defendants' marketing of adulterated, misbranded, and defective medical devices, plaintiffs would not have had access to ECT shock treatment, and would not have suffered the injuries alleged herein. Accordingly, but for Defendants' conduct, 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. 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, each Defendant actually and proximately caused the injuries suffered by every member of the putative class without regard to which Defendant manufactured the particular device that caused the particular injury.

71. Defendants concealed the facts such that no plaintiff reasonably would have known of facts giving rise to this suit: namely, that MECTA CORPORATION, SOMATICS, LLC and DOES 1-10 comprehensively failed to investigate adverse events, conduct human clinical trials, and report all safety and effectiveness data known or available relating to the use of their ECT devices to the FDA, as was required by the three FDA orders and the state medical device warning duties running parallel thereto.

72. Because of Defendants' fraudulent concealment of facts, no member of the putative class knew or should have known that Defendants failed to comply with federal statutory requirements or of the dangers inherent in use of ECT shock devices that gave rise to their claims asserted herein.

73. Plaintiffs diligently filed this suit in a timely fashion upon discovering the facts giving rise to the claims asserted herein, namely that Defendants failed to satisfy the reporting requirements imposed by the FDCA, MDA and SMDA.

FIRST CLAIM FOR RELIEF

Negligence/Negligence *Per Se*

(By Plaintiffs against all Defendants)

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

75. MECTA, SOMATICS and DOES 1-10 were the manufacturers of ECT devices, classified as Class III medical devices, and as such owed a duty of care to the putative class and to public at large to use that degree of care in the manufacturing of such Class III medical devices as would be used in similar circumstances to avoid exposing others to a foreseeable risk of harm. Congress enacted the MDA and the SMDA to protect individuals in the United States with respect to risks posed by medical devices, including Class III medical devices, and specifically required premarket approval, testing, investigation, solicitation of information relative to injuries, and submission of any and all safety and effectiveness data reasonably known or available to the FDA for the purpose of ensuring the safety of psychiatric and medical patients from products and medical devices that have not been adequately tested and screened for dangers.

76. MECTA, SOMATICS, and DOES 1-10 breached those duties owed to the putative class and to the public at large by continuously failing to contact user facilities, conduct testing, and report safety and effectiveness data to the FDA from May 28, 1982 to the present.

77. MECTA, SOMATICS, and DOES 1-10 breached additional statutory duties and corresponding parallel state duties owed to the putative class when they continued to market their adulterated and misbranded medical devices after failing to submit premarket approval applications by the deadline of May 28, 1982.

78. RIERA, HIMES, SCURRAH, and CHASE, as well as all other members of the putative class, underwent ECT shock treatment delivered by ECT shock devices placed into the stream of commerce by Defendants after May 28, 1982.

79. RIERA, HIMES, SCURRAH, and CHASE, as well as all other members of the putative class, have suffered, and/or continue to suffer permanent brain damage, cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome and related injuries following ECT shock treatment. This harm is of the type sought to be prevented by the passage of the FDCA, MDA, and SMDA.

80. Had Defendants 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), ECT in its current form would not have been marketed to the medical providers of members of the putative class. Accordingly, the negligent conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

81. Alternatively, had Defendants 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 and accessibly 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 latent dangers inherent in providing ECT shock treatment to members of the putative class in time to prevent their injuries.

Accordingly, the negligent conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

82. Alternatively, Defendants had a duty not to market their defective, adulterated, and misbranded devices after failing to comply with their reporting requirements.

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

SECOND CLAIM FOR RELIEF

Strict Product Liability

Marketing and Information Defect– Failure to Warn

(By Plaintiffs against all Defendants)

84. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 83 of this Complaint.

85. Defendants MECTA, SOMATICS, and DOES 1-10 manufactured, distributed, and sold their ECT devices in the stream of commerce within the United States, knowing that it was to be used without inspection for defect.

86. 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 scientific community. Defendants' failure to adequately warn plaintiffs and medical providers by warning the FDA of these latent dangers renders the devices adulterated, misbranded, and defective with respect to the marketing and information provided to the members of the putative class alleged herein.

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87. Permanent brain damage, cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome present a substantial danger to patients when "electroconvulsive therapy" devices are used as intended or misused in a foreseeable way.

88. Ordinary consumers would not recognize these potential risks inherent to ECT devices.

89. MECTA, SOMATICS, and DOES 1-10 failed to investigate and provide adequate warnings of these risks.

90. RIERA, HIMES, SCURRAH, and CHASE, as well as all other members of the putative class, 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 and members of the putative class, had they been properly warned about the true nature of ECT shock devices, would not have received ECT shock treatment.

91. Had Defendants 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), ECT shock devices in their current form would not have been marketed to the medical providers of members of the putative class. Accordingly, the conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

92. Alternatively, had Defendants 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 latent dangers inherent in providing ECT shock treatment to members of the putative class in time to prevent their injuries. Accordingly, the conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

93. Alternatively, Defendants had a duty not to market their defective devices after failing to comply with their reporting requirements.

94. Defendants acted with oppression, fraud and malice. As such, punitive damages are appropriate.

THIRD CLAIM FOR RELIEF

Loss of Consortium

95. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 94 of this Complaint.

96. Some members of the putative class are spouses of patients who underwent ECT shock treatment, and as a result have suffered a loss of consortium.

97. Such members of the putative class were in valid and lawful marriages to persons injured by ECT shock treatment.

98. Those injured by ECT shock treatment suffered tortious injuries as a result of Defendant's actions.

99. Those members of the putative class in marriages to those that have suffered injury resulting from ECT shock treatment have suffered a loss of consortium.

100. That loss of consortium was a direct and proximate result of the Defendant's acts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. For compensatory damages in light of the pain and suffering, emotional distress, loss of consortium, wrongful deaths, and other damages suffered by members of the putative class;

2. For punitive damages in light of Defendants' oppression, fraud, and malice;

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

4. For reasonable attorney's fees and such other nontaxable costs, subject to court approval, as provided by Rule 23(h) of the Federal Rules of Civil Procedure;

5. 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: September 11, 2017

Respectfully submitted,

DK LAW GROUP, LLP

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