

1 David M. Karen, Esq.
State Bar No. 117883
2 dk@dk4law.com
Kimberly Offenbacher, Esq.
3 State Bar No. 166318
ko@dk4law.com
4 A. Scott Brown, Esq.
State Bar No. 221786
5 asb@dk4law.com

6 **DK LAW GROUP, LLP**
3155 Old Conejo Road
7 Thousand Oaks, CA 91320
Tel: (805) 498-1212
8 Fax: (805) 498-3030

9 Attorneys for Plaintiffs [REDACTED]
10 [REDACTED]

11 **UNITED STATES DISTRICT COURT**
12 **CENTRAL DISTRICT OF CALIFORNIA**

14 JOSE [REDACTED]
15 [REDACTED] individually, and on behalf of
16 all others similarly situated,
17 Plaintiffs,
18 v.
19 MECTA CORPORATION; SOMATICS,
LLC; and DOES 1 through 10, inclusive,
20 Defendants.
21

Case No.: 2:17-cv-06686 RGK(PJWx)
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

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24
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26 Plaintiffs [REDACTED]
27 [REDACTED] (collectively “Plaintiffs”), individually and on behalf of all
28 other similarly situated individuals, hereby complain against Defendants MECTA

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

3 **SUMMARY OF THE ACTION**

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

8 2. An ECT shock device is “a device used for treating severe psychiatric
9 disturbances (e.g., severe depression) by inducing in the patient a major motor
10 seizure by applying a brief intense electrical current to the patient's head.” 21
11 C.F.R. § 882.5940(a). An ECT shock device, in lay terms, is used to administer
12 ‘shock treatment.’

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

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

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

27 6. Despite statutory duties under the Food, Drug and Cosmetic Act

28 ¹ Also referred to as “shock therapy” or “shock treatment.”

1 (“FDCA”) and directives by the FDA, pursuant to the Medical Device Amendments
2 of 1976 (“MDA”) that ECT device manufacturers report information concerning
3 safety and effectiveness testing for their devices to the FDA,² no ECT device
4 manufacturer, including MECTA CORPORATION or SOMATICS, LLC, complied
5 with these statutory obligations. No ECT manufacturer, including either Defendant,
6 responded to the FDA’s first two orders requiring them to submit safety and
7 effectiveness data by May 28, 1982 and August 14, 1997, respectively. Defendants
8 only responded to a third FDA order, required by the Safe Medical Devices Act of
9 1990 (“SMDA”) requiring Defendants to submit “any information known or
10 otherwise available” about the safety and effectiveness of the device, *including*
11 *adverse safety or effectiveness information*. Defendants’ responses failed to include
12 *any* information relating to the majority of physiological, psychological, and
13 emotional injuries frequently suffered by those who receive ECT shock treatment.
14 Defendants also grossly understated the incidence of death resulting from ECT.
15 Such a response by Defendants failed to comply with their statutory reporting
16 requirements under the MDA and SMDA.

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

22 8. Because of the lack of testing rigor, the mechanism of action by which
23 ECT yields any alleged benefit to patients remains unascertained and unknown.
24 Testing over the years has not shown any conclusive benefit to receiving ECT
25 shock treatment past a brief bout of mania in the short-term, but the risks remain
26 apparent, and include but are not limited to permanent long-term memory loss,

27 ² 44 Fed. Reg. 172, at 51776-51777 (Sept.4, 1979) (“This action is being taken under the Medical
28 Device Amendments of 1976.”); *see* Medical Device Amendments of 1976, 21 U.S.C. § 351 *et.*
seq.

1 cognitive impairment, debilitating electrical brain trauma, seizures, acute and/or
2 chronic organic brain syndrome, complete neurological collapse, and death.

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

9 10. Defendants' failure to submit to the FDA all safety and effectiveness
10 data reasonably known and/or available relating to use of their ECT devices by
11 certain effective dates for premarket approval rendered their devices "adulterated"
12 under the FDCA.

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

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

19 13. Defendants' failure to warn the FDA of the latent dangers inherent in
20 ECT resulted in a lack of knowledge among the medical providers of members of
21 the putative class and the public in general about the latent dangers inherent in
22 administration of ECT shock treatment, but they nevertheless continued to market
23 their adulterated, misbranded, and defective ECT shock devices in the United
24 States. Because some form of physiological, psychological, or emotional injury
25 results universally from ECT shock treatment, Defendants' conduct directly and
26 proximately caused injuries to the putative class.

27 14. This class action seeks to remedy the damages caused by

28 ³ 21 U.S.C. § 331.

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

11 **PARTIES**

12 15. Plaintiff [REDACTED] is a citizen of the State of
13 California.

14 16. Plaintiff [REDACTED] is a citizen of the State of
15 California.

16 17. Plaintiff [REDACTED] is a citizen of the State of
17 California.

18 18. Plaintiff [REDACTED] is a citizen of the State of
19 California.

20 19. Plaintiffs are informed and believe and based thereon allege that, at all
21 relevant times, Defendant MECTA CORPORATION ("MECTA") is and was a
22 corporation formed and existing under the laws of the State of Oregon with its
23 principal place of business at 19799 SW 95th Place B, Tualatin, Oregon. Plaintiffs
24 are further informed and believe and based thereon allege that MECTA is an ECT
25 manufacturer and provider and, in that regard is authorized to conduct business in
26 the State of California and does conduct business in the State of California.

27 20. Plaintiffs are informed and believe and based thereon allege that, at all
28 relevant times, starting with its founding in 1984, Defendant SOMATICS, LLC

1 (“SOMATICS”) is and was a limited liability company formed and existing under
2 the laws of the State of Florida with its principal place of business at 710
3 Commerce Dr., Unit #101, Venice, FL 34292. Plaintiffs are further informed and
4 believe and based thereon allege that SOMATICS is an ECT manufacturer and
5 provider and, in that regard is authorized to conduct business in the State of
6 California and does conduct business in the State of California.

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

18 22. Plaintiffs are informed and believe, and, based upon such information
19 and belief allege that the Defendants named in this action as DOES 1 through 10,
20 and each of them, herein knowingly conspired together in various combinations,
21 and agreed amongst themselves to act in concert and in furtherance of a common
22 scheme, plan and design to commit, aid, abet and/or render substantial assistance in
23 the wrongs complained of herein below. Plaintiffs are further informed and believe,
24 and based upon such information and belief allege that Defendants knew as they
25 were conducting themselves that they were substantially assisting in the
26 accomplishment of wrongdoing, and had the right and ability to control the actions
27 of the remaining Defendants but did nothing to curb the activities described herein
28 below, or prevent others from engaging in such conduct. Plaintiffs are further

1 informed and believe, and based upon such information and belief allege, that
2 Defendants, and each of them, actively condoned, encouraged, participated in,
3 and/or instigated the conduct described herein below in furtherance of their
4 common scheme, plan and design which entailed, among other things: (a) aiding
5 and abetting the conspiracy and common course of conduct complained of herein;
6 (b) participating in and/or knowing and acquiescing in the acts complained of
7 herein, sufficient to categorize such conduct as conspiratorial; and (c) taking and/or
8 ratifying conduct to enrich themselves or their co-conspirators, at the expense of
9 Plaintiffs.

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

17 JURISDICTION AND VENUE

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

24 25. This Court has subject matter jurisdiction over the lawsuit under 28
25 U.S.C. § 1331 because the vindication of Plaintiffs' rights under state law
26 substantially and necessarily turn on a construction of federal law, specifically
27 21 U.S.C. § 360e with respect to premarket approval applications, 21 U.S.C. § 360i
28 with respect to medical device manufacturer reporting requirements, and 21 U.S.C.

1 § 351 with respect to the illegality of marketing adulterated or misbranded medical
2 devices.

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

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

9 28. Venue is proper in the Central District of California under 28 U.S.C.
10 § 1391 because a substantial part of the events or omissions giving rise to the
11 claims, including ECT shock treatment received by representative Class members,
12 occurred in this District.

13 **PLAINTIFF-SPECIFIC ALLEGATIONS**

14 29. Plaintiff [REDACTED], in seeking an effective treatment for severe
15 depression, underwent a series of six separate rounds of ECT shock treatment on
16 April 22, 2016, April 25, 2016, April 27, 2016, April 29, 2016, May 2, 2016, and
17 May 4, 2016 at Huntington Memorial Hospital in Pasadena, California. ECT did not
18 generate any improvement in [REDACTED] severe depression. Instead, it caused severe
19 physiological, psychological, and emotional injury.

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

26 31. [REDACTED] underwent over fifty-eight rounds of ECT shock treatment
27 in seeking to treat her bipolar disorder, beginning on March 28, 2012 and
28 continuing for about nine months. ECT shock treatment caused [REDACTED] severe

1 physiological, psychological, and emotional injury.

2 32. ██████ underwent ECT shock treatment over seven times in seeking
3 to treat her major depressive disorder and severe anxiety, between April of 2015
4 and Spring of 2016. ECT shock treatment caused ██████ severe physiological,
5 psychological, and emotional injury.

6 **CLASS ACTION ALLEGATIONS**

7 33. Plaintiffs bring this action on behalf of themselves and all others
8 similarly situated as this action satisfies the requirements of numerosity,
9 commonality, typicality, adequacy of representation, and predominance and
10 superiority⁴ requirements of Federal Rules of Civil Procedure, Rule 23.

11 34. The proposed Class is defined as follows:

12 **CLASS**

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

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

22 36. The members of the Class are so numerous that joinder is impractical.
23 The Class consists of thousands of individuals, as ECT shock treatment has been
24 available and administered to the described Class for more than 30 years, with the
25 annual estimate of ECT shock patients per year in California numbering in the
26 thousands. Although the exact number and identity of the class members is not
27 presently known, the class can be defined and ascertained by means of the objective

28 ⁴ Fed. R. Civ. P. 23(b)(3).

1 criteria, through strategic publication, and through coordinated discovery of the
2 identities of all purchasers of ECT shock devices as sold by and obtained from
3 MECTA and SOMATICS since the beginning of the class period.

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

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

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

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

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

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

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

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

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

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

25 j. Information known or knowable to Defendants regarding the
26 safety and effectiveness, or lack thereof, of the use of ECT shock
27 devices;

28 k. Whether Defendants' culpable state of mind in in failing to

1 comply with federal statutory duties and their parallel state counterparts
2 subjects Defendants to punitive damages.

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

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

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

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

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

26 43. To attempt to resolve the entirety of this claim by processing
27 individual cases would increase both the expenses and the delay, not only to class
28 members, but also to Defendants and the Court. In contrast, a class action will

1 avoid case management difficulties and provide multiple benefits to the litigating
2 parties, including efficiency, economy of scale, unitary adjudication with consistent
3 results and equal protection of the rights of each class member, all by way of the
4 comprehensive and efficient supervision of the litigation by a single court.

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

9 **SUBSTANTIVE ALLEGATIONS**

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

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

26 47. On September 4, 1979, the FDA published an Order in the Federal
27 Register (the “1979 FDA Order”) presenting its “final ruling” that ECT devices are
28 Class III “Premarket Approval” devices under the MDA and specifically ordered

1 manufacturers such as Defendants to prepare and submit a PMA for approval. The
2 FDA's ruling stated in relevant part:

3 The Food and Drug Administration (FDA) is issuing a
4 final ruling classifying electroconvulsive therapy devices
5 into Class III (premarket approval). The effect of
6 classifying a device into Class III is to require each
7 manufacturer of the device to submit to FDA a premarket
8 approval application ["PMA"] that includes information
9 concerning safety and effectiveness tests for the device."⁵

10 48. The FDA's Order followed the recommendation of the Neurological
11 Section of the Respiratory and Nervous System Devices empaneled by the FDA due
12 to the lack of available information regarding ECT devices and following public
13 comment. The FDA concluded that Class III placement was required as "there is
14 insufficient information to establish a standard to provide reasonable assurance of
15 the safety and effectiveness of the ECT device."⁶

16 49. As of September 4, 1979, Defendants herein, as manufacturers of ECT
17 devices, were specifically ordered to submit a PMA application to the FDA for
18 approval of this Class III device as a prerequisite to continued access to the market.
19 The PMA application was to contain "safety and effectiveness" information derived
20 from testing, e.g., from clinical trials. Moreover, PMA applications must include
21 "specimens of the labeling proposed to be used for such device,"⁷ to be submitted
22 for FDA approval.

23 50. Defendants, as manufacturers of ECT devices, were required to
24 perform clinical trials and submit their respective PMA applications by May 28,
25 1982.

26
27 ⁵ See 44 Fed. Reg. 172, at 51776-77 (Sept. 4, 1979) (reporting 21 C.F.R. § 882 [Docket No. 78N-1103]).

28 ⁶ See 21 C.F.R. § 882.5940.

⁷ 21 U.S.C. § 360e(c)(1)(F).

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

9 52. Plaintiffs are informed and believe and based thereon allege that
10 Defendants failed to submit reports to the FDA whenever the Defendants received
11 or otherwise became aware of information that reasonably suggested that one of
12 their marketed devices may have caused or contributed to a death or serious injury,
13 as required by federal law. Failure to submit such adverse event reports resulted in
14 Defendants' ECT devices being "misbranded" under federal law.⁹ Defendants
15 continued to manufacture, sell, and distribute their respective devices in the United
16 States, and otherwise enabled their continued use, despite being "misbranded"
17 under federal law.

18 53. The United States Congress enacted the Safe Medical Devices Act of
19 1990 ("SMDA"), effective November 28, 1990, amending the FDCA "to make
20 improvements in the regulation of medical devices." Thereafter, the FDA published
21 an Order in the Federal Register (the "1995 FDA Order") pursuant to the SMDA
22 requiring that the manufacturers of ECT devices, including Defendants, submit a
23 summary of, and a citation to, all information known or available about the safety
24 and effectiveness of their respective ECT devices to the FDA by August 14, 1997.¹⁰

25 54. Plaintiffs are informed and believe and based thereon allege that
26

27 ⁸ 21 U.S.C. § 351; *see id.* § 331 (prohibiting "introduction," "receipt," or "delivery" of adulterated
or misbranded devices into interstate commerce).

28 ⁹ 21 U.S.C. § 352(t).

¹⁰ 60 Fed. Reg. 156, at 41986-89 (Aug. 14, 1995).

1 Defendants violated the SMDA, and the 1995 FDA Order, by failing to submit a
2 summary of, and a citation to, all information known or available about the safety
3 and effectiveness of their respective ECT devices to the FDA by August 14, 1997.
4 Defendants continued to manufacture, sell and distribute their respective devices in
5 the United States, and otherwise enable their continued use.

6 55. On April 9, 2009, the FDA published a third Order in the Federal
7 Register (the “2009 FDA Order”) again requiring the manufacturers of ECT
8 devices, including Defendants, to comply with the SMDA by submitting all
9 information known or available about the safety and effectiveness of ECT devices
10 to the FDA by the deadline of August 7, 2009.¹¹ Defendants responded to this order,
11 but withheld a significant amount of information relating to adverse events from the
12 FDA. None of the information provided directly addressed the known issues of
13 permanent memory loss, cognitive impairment, or the certainty of brain damage
14 resulting from ECT.

15 56. The FDCA’s implementing regulations provide that manufacturers of
16 medical devices must report to the FDA within 30 calendar days after the day that
17 the manufacturer receives, or otherwise becomes aware of information, from any
18 source, that reasonably suggests that a device marketed by the manufacturer: “(1)
19 may have caused or contributed to a death or serious injury; or (2) has
20 malfunctioned and this device or a similar device that [the manufacturer has
21 marketed] would be likely to cause or contribute to a death or serious injury, if the
22 malfunction were to recur.”¹²

23 57. The regulations provide that manufacturers must submit all
24 information “reasonably known.” “Reasonably known” information is “(i) [a]ny
25 information that you can obtain by contacting a user facility, importer, or other
26 initial reporter; (ii) any information in your possession; or (iii) any information that

27
28 ¹¹ 74 Fed. Reg. 67, at 16214-17 (Apr. 9, 2009).

¹² 21 C.F.R. § 803.50(a).

1 you can obtain by analysis, testing, or other evaluation of the device.”¹³

2 58. Defendants continued to violate the SMDA, and related orders, by
3 failing to produce reasonably known information and by withholding a large
4 quantity of data from the FDA relating to the safety and effectiveness of their
5 respective ECT devices, including data relating to the devices’ collective propensity
6 to cause harm.

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

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

22 61. As a result of the Defendants’ conduct in violating statutory
23 requirements and selective withholding and manipulation of the data surrounding
24 ECT devices, and the duties under state law running parallel to such requirements,
25 the devices have continued to be manufactured, sold, distributed and have remained
26 in use without testing, public dissemination of reliable information and data as to
27 safety and effectiveness, warnings of inherent dangers, and without the requisite

28 ¹³ 21 C.F.R. § 803.50(b).

1 premarket FDA approval.

2 62. Defendants continue to manufacture, sell and distribute adulterated,
3 misbranded, and defective ECT devices to this day. Doing so violates both a duty
4 established under federal statute and parallel duties under state tort law.

5 63. The FDA's guidance document pertaining to medical device reporting
6 states that "a publicly disclosable version of the medical device reports that we have
7 received is available on the CDRH webpage at [http://www.accessdata.fda.gov/
8 scripts/cdrh/cfdocs/cfMAUDE/search.CFM](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)."¹⁴ Of the 49 reports posted on the
9 MAUDE database pertaining to ECT devices, the majority appear to have been
10 voluntarily submitted by patients, and none appear to have been submitted by
11 device manufacturers under their mandatory reporting duties. Had Defendants
12 complied with their federal and parallel state duties to report to the FDA all safety
13 and effectiveness data reasonably known or available for ECT, the FDA's MAUDE
14 database would have reflected the multitude of adverse events that routinely result
15 from administration of ECT shock treatment.

16 64. Adverse events have regularly resulted from administration of ECT
17 shock treatment since ECT's inception in 1938 such as to make it virtually
18 impossible that any ECT manufacturer could escape the FDCA's obligation to
19 investigate and report these events to the FDA. For example, from the 1940s to the
20 1980s, various psychiatric experts have documented brain damage correlated with
21 ECT. These adverse events were "reasonably known" to both MECTA and
22 SOMATICS, and therefore created a statutory duty to investigate and report them to
23 the FDA. However, there are no manufacturer-submitted adverse event reports in
24 FDA's MAUDE database, illustrating Defendants' continuous and intentional
25 failure to report adverse events to the FDA.

26 65. Multiple lawsuits were filed against MECTA corporation in the 1990s

27
28 ¹⁴ MEDICAL DEVICE REPORTING FOR MANUFACTURERS: GUIDANCE FOR INDUSTRY AND FOOD
AND DRUG ADMINISTRATION STAFF DOCUMENT 26 (2016).

1 by [REDACTED] 61, among
2 others. These lawsuits alleged serious injuries, including but not limited to brain
3 damage, permanent cognitive impairment, and ruptured bowels resulting from ECT
4 shock treatment. The CEO of MECTA, Ms. Robin Nicol, admits that these lawsuits
5 alleged that MECTA's devices caused brain damage to the patients. She testified
6 that she was not even curious why multiple people had sued her company for
7 causing them brain damage, assuming the lawsuits to be "frivolous."
8 Defendants intentionally evaded their duty to investigate these adverse events or
9 submit any adverse event reports to the FDA.

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

15 67. Had Defendants satisfied their reporting duties, ECT patients' medical
16 providers would have been properly informed by the FDA's MAUDE database, by
17 medical journals, and thereafter by direct warning from the FDA as to the inherent
18 risks associated with ECT. ECT is inherently harmful to the human brain, but this
19 fact is not publicly known because of Defendants' breach of their FDCA reporting
20 duties and all state common law duties running parallel to those FDCA reporting
21 requirements.

22 68. If the medical providers for members of the putative class or general
23 public had knowledge of the devices' inherent risk of permanent injury, members of
24 the putative class would have avoided receipt of ECT shock treatment, but for
25 Defendants' breach of their federal and state reporting duties that arose out of the
26 requirements imposed by the Food, Drug, and Cosmetic Act and the FDA's three
27 orders.

28 69. But for Defendants' marketing of adulterated, misbranded, and

1 defective medical devices, plaintiffs would not have had access to ECT shock
2 treatment, and would not have suffered the injuries alleged herein. Accordingly,
3 but for Defendants' conduct, ECT shock devices would not exist in their current
4 form, if at all.

5 70. ECT shock devices are defined in the FDA's regulations without
6 reference to particular manufacturers. Thus, any warning of adverse events by one
7 manufacturer would have been reported under the same category of "Device,
8 Electroconvulsive Therapy" on the FDA's MAUDE database. The same warning
9 and testing requirements applied to all manufacturers, and warnings submitted by
10 one manufacturer would have prevented injury caused by the other manufacturer's
11 devices. Accordingly, by failing to report adverse events to the FDA and failing to
12 furnish other required safety and effectiveness information to the FDA, each
13 Defendant actually and proximately caused the injuries suffered by every member
14 of the putative class without regard to which Defendant manufactured the particular
15 device that caused the particular injury.

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

23 72. There is such unity of interest and ownership within MECTA and
24 SOMATICS that the separate personalities of the corporations and relevant
25 individuals no longer exist. Moreover, if the acts described herein are treated as
26 those of the corporations alone, an inequitable result will follow, as the potential
27 judgments of the numerous putative class members cannot be satisfied by the assets
28 of the corporations alone.

1 duties and corresponding parallel state duties owed to the putative class when they
2 continued to market their adulterated and misbranded medical devices in the United
3 States after failing to submit premarket approval applications by the deadline of
4 May 28, 1982.

5 79. [REDACTED], as well as all other
6 members of the putative class, underwent ECT shock treatment delivered by ECT
7 shock devices placed into the stream of commerce by Defendants after May 28,
8 1982.

9 80. [REDACTED], as well as all other
10 members of the putative class, have suffered, and/or continue to suffer permanent
11 brain damage, cognitive impairment, severe permanent retrograde and anterograde
12 amnesia, and acute and/or chronic organic brain syndrome and related injuries
13 following ECT shock treatment. This harm is of the type sought to be prevented by
14 the passage of the FDCA, MDA, and SMDA.

15 81. Had Defendants complied with their state law duties to give a post-sale
16 warning to the FDA of all information the manufacturer becomes aware of, from
17 any source, that reasonably suggests that its device may have caused or contributed
18 to a serious injury (as was required by the FDCA), ECT in its current form would
19 not have been marketed to the medical providers of members of the putative class.
20 Accordingly, the negligent conduct of MECTA, SOMATICS, and DOES 1-10
21 actually caused, proximately caused, and was a substantial factor in causing the
22 harm suffered by members of the putative class. Accordingly, compensatory
23 damages are appropriate.

24 82. Alternatively, had Defendants complied with their state law duties to
25 give a post-sale warning to the FDA of all information the manufacturer becomes
26 aware of, from any source, that reasonably suggests that its device may have caused
27 or contributed to a serious injury (as was required by the FDCA), this information
28 would have appeared prominently and accessibly in the FDA's MAUDE database

1 and in medical journals and the FDA would have promulgated a warning to the end
2 users of ECT shock devices within the medical profession, who would have then
3 refrained from giving ECT shock treatment to members of the putative class.
4 Accordingly, the negligent conduct of MECTA, SOMATICS, and DOES 1-10
5 actually caused, proximately caused, and was a substantial factor in causing the
6 harm suffered by members of the putative class. Accordingly, compensatory
7 damages are appropriate.

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

10 84. Defendants acted with oppression, fraud and malice. As such, punitive
11 damages are appropriate.

12 **SECOND CLAIM FOR RELIEF**

13 **Strict Product Liability**

14 **Marketing and Information Defect– Failure to Warn**

15 **(By Plaintiffs against all Defendants)**

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

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

21 87. The ECT devices, at all times relevant to the causes of action alleged in
22 this Complaint, caused and continue to cause permanent brain damage, severe
23 permanent retrograde and anterograde amnesia, and acute and/or chronic organic
24 brain syndrome, and these facts were both known and knowable in light of the
25 scientific and medical knowledge available in the scientific community.
26 Defendants' failure to adequately warn plaintiffs and medical providers by warning
27 the FDA of these latent dangers renders the devices adulterated, misbranded, and
28 defective with respect to the marketing and information provided to the members of

1 the putative class alleged herein.

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

6 89. Ordinary consumers would not recognize these potential risks inherent
7 to ECT devices.

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

10 91. [REDACTED], as well as all other
11 members of the putative class, suffer permanent brain damage, severe permanent
12 retrograde and anterograde amnesia, and acute and/or chronic organic brain
13 syndrome as a direct result of administration of ECT shock treatment. Plaintiffs
14 and members of the putative class, had they been properly warned about the true
15 nature of ECT shock devices, would not have received ECT shock treatment.

16 92. Had Defendants complied with their state law duties to give a post-sale
17 warning to the FDA of all information the manufacturer becomes aware of, from
18 any source, that reasonably suggests that its device may have caused or contributed
19 to a serious injury (as was required by the FDCA), ECT shock devices in their
20 current form would not have been marketed to the medical providers of members of
21 the putative class. Accordingly, the conduct of MECTA, SOMATICS, and DOES
22 1-10 actually caused, proximately caused, and was a substantial factor in causing
23 the harm suffered by members of the putative class. Accordingly, compensatory
24 damages are appropriate.

25 93. Alternatively, had Defendants complied with their state law duties to
26 give a post-sale warning to the FDA of all information the manufacturer becomes
27 aware of, from any source, that reasonably suggests that its device may have caused
28 or contributed to a serious injury (as was required by the FDCA), this information

1 would have appeared prominently in the FDA's MAUDE database and in medical
2 journals and the FDA would have promulgated a warning to the end users of ECT
3 shock devices within the medical profession, who would have then refrained from
4 giving ECT shock treatment to members of the putative class. Accordingly, the
5 conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately
6 caused, and was a substantial factor in causing the harm suffered by members of the
7 putative class. Accordingly, compensatory damages are appropriate.

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

10 95. Defendants acted with oppression, fraud and malice. As such, punitive
11 damages are appropriate.

12 THIRD CLAIM FOR RELIEF

13 **Loss of Consortium**

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

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

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

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

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

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

