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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN and DANIEL BENJAMIN; individually, and on behalf of all others similarly situated, Plaintiffs, v. MECTA CORPORATION; SOMATICS LLC; and DOES 1 through 10, inclusive, Defendants.	Case No. 2:17-cv-06686-RGK-PJW Hon. R. Gary Klausner Courtroom 850 **Rule 26(f) Joint Report** Action Filed: September 11, 2017

TO THE HONORABLE JUDGE OF SAID COURT:

Named Plaintiffs Jose Riera, Michelle Himes, Diane Scurrah, Deborah Chase, Marcia Benjamin, Daniel Benjamin, and appearing Defendants MECTA Corporation ("MECTA") and Somatics, LLC ("Somatics") hereby jointly submit their Report of the early meeting of counsel, as required by FED. R. CIV. P. 26(f), LOCAL RULE 26-1, and this Court's October 20, 2017 Order (Doc. 16).

1. Statement of the Case

Plaintiffs

Plaintiffs are suing MECTA Corporation, Somatics, LLC and DOES 1-10, on theories of common law negligence *per se* and strict liability for failure to warn. Plaintiffs are suing under California state law for damages caused by Defendants' failure to satisfy their state common law duties that run parallel to the Food, Drug and Cosmetic Act's medical device regulatory reporting requirements. They seek recovery for injuries caused by Defendants' failure to submit adverse event reports and other information to the Food & Drug Administration (FDA), leading to a lack of adverse event information relating to ECT in the FDA's Medical and User Facility Device Experience ("MAUDE") database, resulting in a lack of warning to patients of knowable risks of ECT including concussive brain injury, chronic traumatic encephalopathy, permanent brain dysfunction, lasting cognitive impairment, and long-term retrograde and anterograde amnesia.

Plaintiffs seek to bifurcate for class determination the three outcome-determinative common issues in this action: 1) Defendants' regulatory noncompliance; 2) general causation of brain injury from ECT; and 3) federal preemption, along with the other common issues, from the individual issues: 1) extent of compensatory damages; and 2) assumption of risk. This will materially advance the disposition of the litigation and render it manageable. Since individual actions in the past have not deterred Defendants' continuous regulatory violations, the public policy interest of deterrence weighs in favor of a bifurcated

class action.

An ECT 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). In 1979, pursuant to Congressional mandate, The Food & Drug Administration, by issuing an order classifying ECT devices into Class III, placed the burden on ECT device manufacturers to submit premarket approval applications and thereby prove the safety and effectiveness of their devices by May 28, 1982.

After 1979, Defendants did not respond to the FDA's order requiring submission of a premarket approval application for their ECT devices by May 28, 1982. Nor did Defendants respond to the FDA's 1995 order requiring submission of any and all information known or available concerning the safety and effectiveness of their devices by August 14, 1997. In response to a third order from the FDA in 2009, requiring the same as the 1995 order, Defendants omitted significant amounts of required information relating to injury resulting from electroconvulsive therapy.

Moreover, instead of complying with FDA Medical Device Reporting regulations which would have ensured the public revelation of the injurious nature of their devices under 21 C.F.R. 20.20(b), Defendants chose to turn a blind eye to, *inter alia*, thousands of adverse events described in complaints in public dockets, complaints sent directly to the manufacturers, victims recounting their stories in youtube videos, quotationaries recounting eighty years of human suffering resulting from ECT, and even medical literature discussing intracranial insults cited directly in the First Amended Complaint. Instead of correcting this warning defect through regulatory compliance, Defendants decided to shirk the FDA's regulatory requirements for nearly 40 years, ignoring entirely the FDA's first two orders to submit safety and effectiveness data, omitting large amounts of adverse

safety and effectiveness information from the third order, submitting not a single adverse event report to the FDA despite the Medical Device Reporting (MDR) regulations applicable to their devices, and continuing to manufacture and deliver their misbranded devices. To this day ECT devices have never been subject to the FDA's premarket approval ("PMA") requirements applicable to Class III devices.

ECT victims, to the extent they have been capable, have been voicing their opposition to the continued administration of ECT shock treatment in an increasingly organized fashion since 1938. A public docket opened by the FDA in 2010 collected public comments in preparation for a 2011 hearing before the FDA's Advisory Committee. The docket collected over two thousand adverse comments, including 103 reports of deaths, 529 reports of significant memory impairment, 413 reports of significant cognitive impairment and 298 reports of brain damage. A brief 2016 petition on Twitter urging the FDA to ban ECT devices collected 2,200 signatures and over 800 comments. The sixth, seventh, and eighth most common words used in the comments submitted to the Twitter petition were "damage", "barbaric" and "torture."

All ECT devices are defective with respect to the warnings given, as neither patient consent forms, including State and APA-approved consent forms, nor warnings given directly by psychiatrists warn patients of concussive brain injury, encephalopathy, subdural hematoma, or any other intracranial insult resulting from ECT. Nor do patients receive warning of ECT's likelihood of causing cognitive impairment, anterograde amnesia, and retrograde amnesia that does not recover in time. Patients receive warning of headaches, confusion, and short-term memory loss, and sometimes a "small risk" of "heart, lung or brain dysfunction" that is "mitigated by administration of oxygen during the treatment." Patients are not informed that these "side effects" are the expected result of electrically-induced concussive brain injury, often will not get better in time, and are often so

debilitating that they will interfere with the patient's ability to plan, organize, recall significant past life events, or live a normal life.

FDA's medical device regulatory requirements, including the obligation to submit adverse event reports, refrain from adulteration and/or misbranding, and comply with FDA orders, are designed to bring to light this type of warning defect by ensuring medical device manufacturers properly investigate and report allegations of adverse events associated with their devices. Defendants did not comply with those regulations. If they had, the fact that ECT is a electrical or lightning injury to the brain, and information of all of the associated consequences, would have been prominently displayed in the Medical and User Facility Device Experience ("MAUDE") database and otherwise widely discussed in the psychiatric profession, effectively warning the psychiatric profession in time to prevent electrical injury to the brains of the putative class. The FDA is mandated by law to publish all such information it receives from reporters, and it does so in the MAUDE database.

Discussion of the adverse events associated with ECT devices, a crucial element in determining the safety of any medical device, is conspicuously underrepresented in the current medical literature, largely because Defendants have not upheld their regulatory duty to conduct such research and submit their findings to the FDA. Moreover, researchers interested in studying the adverse events associated with ECT administration such as concussive brain injury have difficulty obtaining funding in the United States.

Extensive research from within the US and elsewhere, dating back to the 1940s, shows traumatic brain injury to reliably result from ECT. Recent comprehensive literature review of the medical research relating to ECT administration in treating psychiatric disturbances (particularly major depression) has acknowledged the strong evidence of permanent brain injury resulting from ECT as made manifest in the form of retrograde and anterograde amnesia, as well

as the evidence of a significant increased risk of death resulting from ECT.

Newer approaches to ECT administration do not address the issue of electrical injury to the brain inherent in ECT administration. General anesthesia renders the procedure less safe, as it raises the amount of electricity necessary to induce a major motor seizure. As ECT is only considered to have taken effect once it has induced a major motor seizure, general anesthesia results in the patient being subject to even more harmful electricity.

Since ECT devices cause the aforementioned injuries as they are legally defined in 21 C.F.R. § 882.5940(a), rather than as manufactured by any particular manufacturer, proper regulatory compliance by either defendant would have revealed the warning defect in all ECT devices. Each manufacturer therefore substantially contributed to the harm suffered by members of the putative class, and each manufacturer is liable for harm caused by any ECT device regardless of whether it manufactured the particular device that caused injuries at issue.

Defendants fraudulently concealed the fact that ECT causes concussive brain injury, concealed all of the complaints they received from ECT victims by failing to submit adverse event reports, concealed the seriousness of the injuries inflicted upon members of the putative class, and concealed their regulatory noncompliance, tolling the statute of limitations for all Plaintiffs. Moreover, many putative class members did not know, nor should they reasonably have known, about the conduct giving rise to this suit – namely Defendants' comprehensive failure to comply with the Medical Device Reporting obligation of the Food, Drug and Cosmetic Act, failure to comply with the adulteration and misbranding obligations of the Food, Drug and Cosmetic Act, and failure to submit all safety and effectiveness data to the FDA in response to its three orders. Finally, Defendants are equitably estopped from asserting the statute of limitations.

Plaintiffs and counsel for Plaintiffs were uninvolved in *Akkerman v. Mecta Corp., Inc*. This action is appropriate for class certification, while *Akkerman v.*

Mecta Corp, Inc. was not. Ascertainability of the class is not an element of class certification in the federal system like it is in California. *Akkerman* arose out of misleading advertising; this state law action is premised on regulatory violations. *See Akkerman v. Mecta Corp., Inc.*, 152 Cal. App. 4th 1094 (2007).

Defendants

This case was brought by six named Plaintiffs, five of which allegedly received electroconvulsive therapy ("ECT") in California and sustained injuries on behalf of a putative class consisting of all patients who received ECT in California after May 28, 1982 and sustained injuries as a result thereof. The named Plaintiffs brought this suit against only two ECT device manufacturers, appearing Defendants MECTA and Somatics. The named Plaintiffs also named Does 1-10 as additional fictitious defendants.

ECT is a medical procedure performed under general anesthesia in which small electric pulses are passed through the brain intentionally triggering short, brief, and controlled seizures. ECT is most commonly used in patients with severe major depression, bipolar disorder, mania, and patients with severe suicide ideations that have not responded to other treatments. Extensive medical research supports that ECT is highly effective for patients with major depression and other conditions as discussed above. It is also used for other severe mental illnesses, such as schizophrenia. ECT is sometimes used in treating patients with catatonia, a condition in which a patient can become increasingly agitated and unresponsive. A patient with catatonia can seriously injure themselves or develop severe dehydration from not eating or drinking. ECT is typically used when other treatments including medications and psychotherapy have failed. ECT is also used for patients who require a rapid treatment response because of the severity of their condition including the risk for suicide.

ECT has been used for over 70 years. In the United States, over one million patients are estimated to receive ECT each year. ECT is routinely performed at

hundreds if not thousands of health care facilities in the United States including, but not limited to, some of the most prestigious health care facilities in the world: the Mayo Clinic, the Cleveland Clinic, Mount Sinai Hospital, the NYU Hospital, John Hopkins Hospital, Houston Methodist Hospital, Yale New Haven Psychiatric Hospital, Duke University Hospital, Baylor University Medical Center, the Menninger Clinic, and UT Southwestern Hospital.[1]

In their First Amended Complaint, the named Plaintiffs improperly bootstrap Defendants' alleged violations of the Food and Drug Administration's ("FDA") regulations into causes of action for negligence, strict products liability for failure to warn, and loss of consortium. The named Plaintiffs allege that because Defendants allegedly did not comply with FDA regulations by submitting safety and effectiveness data reasonably known and/or available for their ECT devices by "certain effective dates," it resulted in a lack of knowledge among medical providers, the putative class, and the public about the "latent dangers inherent in" ECT. Furthermore, the named Plaintiffs allege that if Defendants would have submitted safety and effectiveness data to the FDA then the named Plaintiffs would not have had access to ECT and would not have sustained their alleged injuries. These allegations are not specific as to the relevant time period, and appear to cover the entire purported class time period of 1982 to the present.

Based on the First Amended Complaint, the five named Plaintiffs that allegedly received ECT have no knowledge of the company that manufactured the device used to administer ECT on them and therefore have also named Does 1-10 as fictitious Defendants in this case. Nevertheless, the named Plaintiffs strangely allege that even if the ECT devices were not manufactured by MECTA or Somatics, both Defendants are still liable to that named Plaintiffs and putative

[1] ECT's effectiveness in treating severe mental illnesses is recognized by the American Psychiatric Association, the American Medical Association, the National Institute of Mental Health, and similar organizations in Canada, Great Britain and many other countries.

class for allegedly failing to submit safety and effectiveness data to the FDA. The remaining named Plaintiff is the alleged spouse of one of the other five named Plaintiffs and brings a claim for loss of consortium.

Despite purporting to represent a putative class going back to May 29, 1982, the named Plaintiffs allegedly received their ECT beginning in 2011 and ending in 2016. Only two named Plaintiffs allegedly received their ECT within the two year statute of limitations of when this case was filed. The named Plaintiffs allege that ECT caused them "severe physiological, psychological, and emotional injury," dental trauma, brain injury, and loss of consortium. The named Plaintiffs seek compensatory and punitive damages, expert fees, and attorney's fees.

The named Plaintiffs are further seeking to bifurcate this case and certify the class to determine only specific questions of law and fact as to MECTA's and Somatics' conduct in relation to its compliance with FDA regulations, which is wholly inappropriate given the fact that these specific questions are wholly predominated by the individualized questions that are not common to the class (e.g., whether the named Plaintiffs' received ECT from Defendants' ECT devices, the specific nature of the named Plaintiffs' alleged injuries, medical histories and treatments, whether the named Plaintiffs' claims are barred by the statute of limitations, the learned intermediary defense, and the informed consent doctrine). Also problematic is the fact that the purported class is not ascertainable. The named Defendants have no knowledge of, or access to, the identity of any purported class members. Even if third party mental health institutions and providers could be forced to disclose the identity of their patients, sending class notice to this group of highly at-risk mental health patients is not only dangerous, but violates numerous state and federal privacy laws. The named Plaintiffs are attempting to simply relitigate a class action against MECTA in particular even though their prior attempt at class certification was denied by the trial and

appellate state courts. *See Akkerman v. Mecta Corp.*, 152 Cal. App. 4th 1094, 62 Cal. Rptr. 3d 39 (Cal. Ct. App. 2007).

2. Complexity of the Case

Plaintiffs

As this case was appropriately brought as a class action complaint seeking bifurcation of the outcome-determinative common issues from the individual issues of compensatory damages and assumption of risk, there is one procedurally complex issue -- whether this Court should certify common issues for class treatment so as to materially advance the disposition of the litigation. As such, the Plaintiffs consent to the use of the section of the Manual for Complex Litigation (Fourth) titled "Class Actions in Mass Tort Cases" beginning on page 413 of the Manual to the extent it assists the Court in managing this case.

Defendants

As this case was brought as a class action complaint seeking bifurcation of class certification as to MECTA's and Somatics' conduct only, there are certain issues that are procedurally complex. Namely, whether bifurcation of class certification is appropriate in this case (it is not). As such, the parties consent to the use of the Manual for Complex Litigation (Fourth) to the extent it assists the Court in managing this case.

3. Motion Schedule

Plaintiffs

The named Plaintiffs filed a Motion for Class Certification on December 10, 2017 (Doc. 26). The hearing on the motion was initially set for January 22, 2018, but it has been continued to March 12, 2018. (Doc. 31). Plaintiffs have submitted sufficient evidence to support class certification with their Motion for Class Certification, and no discovery is needed prior to a decision on class certification. Once a determination on class certification is made, Plaintiffs may move to strike affirmative defenses and for summary judgment, or in the

alternative, summary adjudication. Since the First Amended Complaint contains a narrower Class Definition than that in the Motion for Class Certification, in that the Motion contains a putative spousal loss of consortium subclass, Plaintiffs plan to stipulate with Defendants for leave and then move the court to file a Second Amended Complaint with the putative loss of consortium subclass listed in the Class Definition.

Defendants

The named Plaintiffs filed a Motion for Class Certification on December 10, 2017 (Doc. 26). The hearing on the motion was initially set for January 22, 2018. The parties have submitted a joint stipulation to continue the hearing now ordered continued to March 12, 2018. (Doc. 31). As noted in the discovery plan section 8 below, extensive discovery is needed to provide Defendants with a fair and adequate opportunity to respond to the Motion for Class Certification. Therefore, the Defense requests that the hearing on the Motion for Class Certification be reset at the Court's convenience to a date in November 2018 or December 2018 so that the parties can perform such discovery.

4. ADR

Plaintiffs

The parties select ADR PROCEDURE NO. 3: "The parties shall participate in a private dispute resolution proceeding."

Neither Plaintiffs nor Counsel are affiliated, in any way, officially or informally, with the "Church of Scientology." Plaintiffs merely seek to ensure an adequate warning of potential adverse events to ECT patients.

Defendants

This case was brought as a class action on behalf of a purported class of any patient who received ECT in California after May 28, 1982 who suffered an injury as a result thereof. Because of the individualized nature of the putative class' alleged damages, the Court lacks the ability to approve and certify any potential

class action settlement. Furthermore, even if the Court could approve and certify a potential class action settlement, the Church of Scientology under its affiliated "nonprofit organization" the Citizens Commission on Human Rights International which has funded these types of lawsuits in the past, would object to any such settlement as its goal is to stop the administration of ECT and put ECT device manufacturers out of business. Therefore, as long as this case is based on a class action complaint, this case cannot be resolved through an alternative dispute resolution procedure.

Nevertheless, to comply with the Local Rules, the parties select ADR PROCEDURE NO. 3: "The parties shall participate in a private dispute resolution proceeding."

5. Trial Estimate

The parties anticipate that a trial in this matter of the six named Plaintiffs will take approximately four to six weeks.

6. Additional Parties

Plaintiffs

Plaintiffs do not anticipate that any other manufacturer of ECT devices will be named as a codefendant.

Since the individuals administering ECT in California to the named Plaintiffs are not proper defendants in a product liability suit, nor would their negligence be a superseding cause of Plaintiffs' injuries, Plaintiffs do not anticipate that individuals administering ECT in California to the named Plaintiffs after May 28, 1982 will be named as codefendants. To the extent that the negligence and/or fraud of those individuals contributed to the injuries of the putative class, Defendants can pursue those individuals for contribution and/or indemnity during each Plaintiff's mini-trial or separately.

Defendants

The parties anticipate that there will be an appearance of numerous

additional codefendants, including, but not limited to, (1) all other manufacturers of ECT devices whereby such devices were used in California after May 28, 1982, and (2) all individuals administering ECT in California to the named Plaintiffs after May 28, 1982.

7. Expert Witnesses

Plaintiffs

Plaintiffs propose that the parties timing for disclosures under FED. R. CIV. P. 26(a)(2) as they relate to the issues related to alleged injuries and damages be August 2, 2018.

Defendants

The Defendants propose that the named Plaintiff's timing for disclsoures under FED. R. CIV. P. 26(a)(2) as they relate to the named Plaintiffs' alleged injuries and damages be July 2, 2018. The Defendants propose that Mecta and Somatics' timing for disclosures under FED. R. CIV. P. 26(a)(2) as they relate to the named Plaintiffs' alleged injuries and damages be August 2, 2018.

8. Discovery Plan

Initial Disclosures were made as required by January 15, 2018.

Plaintiffs and Defendants disagree on the extent of Plaintiffs' burden of proof in satisfying the requirements of Rule 23(a) and 23(b) and therefore disagree on the timing of discovery needed.

The parties stipulate that all discovery may be produced electronically and transmitted via email.

The parties anticipate agreeing upon a proposed confidentiality order. The parties do not request any changes to the limitations on discovery that are in the Federal Rules of Civil Procedure.

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Plaintiffs

Plaintiffs contend they have submitted all evidence necessary to show that Rule 23(a) and 23(b)(3)'s requirements of numerosity, typicality, commonality, adequacy, predominance and superiority are satisfied. Plaintiffs contend they have submitted such evidence in support of their Motion for Class Certification, including expert testimony confirming that ECT devices, as legally defined, inherently cause injury when used on patients as intended. No discovery into the individual medical histories of each plaintiff or specific injuries of other putative class members is needed in determining numerosity, commonality, typicality, adequacy, predominance, or superiority, and therefore such discovery is unnecessary prior to class certification. Those medical histories will become relevant when each individual plaintiff's mini-trial approaches.

To the extent there is a dispute about common issues such as whether ECT always causes brain injury, whether evidence that a plaintiff used a particular ECT device is necessary in order to hold that device's manufacturer liable, whether tolling doctrines will toll the statute of limitations on a common basis, or whether a proper warning was given to the learned intermediary (the FDA), those common issues are properly addressed in a class trial after class certification. Issues particular to each plaintiff can then be appropriately addressed in mini-trials after common issues are adjudicated in a class trial.

Thus, when a class is certified, discovery into common issues such as regulatory noncompliance, propriety of punitive damages, general causation, and preemption should take place prior to the class trial. Before the class trial, Plaintiffs will need to conduct discovery into Defendants' compliance with FDA regulations and communications with the FDA, the state of knowledge of adverse events resulting from ECT, and the state of the available medical literature surrounding ECT in order to determine general causation at the class trial. Plaintiffs will, after class certification and before the class trial:

(a) Depose key employees of each Defendant, including directors and those responsible for evaluating and reporting MDR reportable events,

(b) Obtain written discovery from named Defendants,

(c) Subpoena from Defendants all adverse event reports submitted by Defendants and adverse event complaints submitted to defendants,

(d) Perform discovery on and depose the named Defendants' experts regarding general causation of brain injury resulting from ECT,

(e) Subpoena records from the FDA relating to FDA inspections of Defendants' facilities, Defendants' responses to the three FDA orders, and adverse event reports submitted to the FDA, and

(f) Depose relevant employees within the FDA to lay foundation for documents described in (e).

Discovery into each individual plaintiff's medical histories and injuries should take place in relation to the time of that plaintiff's mini-trial in order to determine the individual issues of extent of compensatory damages and assumption of risk.

Defendants

Because this case was brought as a class action, Defendants contend Plaintiffs are required to prove the elements of FED. R. CIV. P. 23(a) and 23(b)(3). Namely, that Plaintiffs will be required to prove numerosity, commonality, typicality, adequacy, that questions of law or fact common to the class predominate over questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

For these reasons, Defendants need to perform discovery as to these elements required for class certification. Namely, Defendants will need to obtain all relevant information pertaining to the named Plaintiffs' medical histories and alleged injuries. Defendants will further need to perform discovery to determine

whether the named Plaintiffs' received ECT from Defendants' ECT devices. Finally, Defendants will further need to perform discovery on whether the named Plaintiffs' claims are barred by the statute of limitations, the learned intermediary defense, and the informed consent doctrine. These issues wholly predominate over questions common to the putative class (i.e., whether Defendants complied with FDA regulations).

To perform such discovery, Defendants need to:

(1) obtain written discovery from the named Plaintiffs;

(2) depose the named Plaintiffs;

(3) subpoena all of the named Plaintiffs' medical records and bills;

(4) depose all of the named Plaintiffs' healthcare providers;

(5) perform discovery on and depose the named Plaintiffs' experts regarding their alleged injuries and damages; and

(6) engage in discovery to determine whether there are other patients who received ECT via Defendants' ECT devices in California after May 28, 1982 and were injured.

After this discovery has occurred and the Court has ruled on the named Plaintiffs' Motion for Class Certification, Defendants are amendable to performing discovery on Plaintiffs' allegations as they relate to Defendants' alleged violations of FDA regulations.

Because the putative class and allegations against Defendants date back to May 1982, there is a distinct possibility that evidence may not have been preserved.

The parties stipulate that all discovery will be produced electronically and transmitted via email.

The parties have agreed to the following proposed confidentiality order, which is attached hereto as "Exhibit A". The parties do not request any changes to the limitations on discovery that are in the Federal Rules of Civil Procedure.

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