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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

CLASS ACTION

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR CLASS CERTIFICATION PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 23(A), 23(B)(3), AND 23(C)(4)

Date: January 22, 2018
Time: 9:00 A.M.
Courtroom: 850
Assigned to: Hon. R. Gary Klausner

Trial Date: Not Yet Set

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I. INTRODUCTION

The U.S. Supreme Court has described class action litigation as "an evolutionary response to the existence of injuries unremedied by the regulatory action of government." *Deposit Guar. Nat'l Bank v. Roper*, 445 U.S. 326, 339 (1980). The present action is based on injuries which resulted from Defendants' failure to exercise ordinary care by complying with medical device regulations. These injuries remain unremedied by regulatory action, and are now properly redressable in tort through class proceedings under either Rule 23(b)(3) or 23(c)(4) of the Federal Rules of Civil Procedure.

The Ninth Circuit has expressly contemplated class certification in the context of personal injuries arising from the use of medical products, even those spanning multiple states. *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1230 (9th Cir. 1996). This action is appropriate for class certification within the parameters illustrated by *Valentino*, as a common pattern of regulatory reporting violations has caused a common type of closed-head injury to all members of the putative class, uniformly without warning, through a common electrical mechanism of harm. Moreover, while the Ninth Circuit in *Valentino* suggested that even a multi-state plaintiff class might be certified in the medical product context, the putative class in the case at bar is limited to a single state, creating an additional layer of commonality through the application of a uniform set of state laws.

II. FACTUAL BACKGROUND

A. Regulatory History of ECT

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). Defendants herein, Mecta Corporation ("Mecta") and Somatics LLC ("Somatics"), are the only two companies that have continued to manufacture and sell ECT devices. PA 123 (Ex. 3) (Emord Decl., ¶ 7).

In 1976, Congress enacted the Medical Device Amendments of 1976 ("MDA"). The MDA specifically amended the Food, Drug and Cosmetic Act (FDCA) "to provide for the safety and effectiveness of medical devices intended for human use." Through the MDA, Congress directed the FDA to classify and regulate medical devices which included by definition ECT devices. Medical devices were thus classified into three groups, from Class I (safest and least stringently regulated) to Class III (most dangerous and most stringently regulated).

On September 4, 1979, the FDA issued an Order directing Defendants to submit premarket approval (PMA) applications for electroconvulsive therapy to the FDA within 30 months, by about May 28, 1982, as these devices were (and continue to be) officially classified as Class III devices due to the substantial risk of injury they present to patients. PA 128-129 (Ex. 3.A) (ECT Citizen Petition at pp. 4-5); 21 C.F.R. § 882.5940. A PMA application would have required submission of robust proof of ECT's safety and effectiveness, including data derived from clinical investigations involving human subjects. *See* 21 C.F.R. § 814.20. Defendants, in violation of the 1982 FDA Order, did not submit a PMA application and simply allowed the deadline to pass. PA 128-129 (Ex. 3.A) (ECT Citizen Petition at p.4-5).

In 1990, Congress passed the Safe Medical Devices Act of 1990 (the "SMDA") which amended the FDCA for the purpose of making "improvements in the regulation of medical devices". Pursuant to the SMDA, the FDA was directed to take action as to those pre-MDA medical devices for which PMA applications had not been submitted despite the FDA Order. This included Defendants' ECT devices. *See* 21 U.S.C. § 360e. Accordingly, in 1995, the FDA published a second Order requiring Defendants to submit all safety and effectiveness data relating to use of their ECT devices, which data was either known to Defendants or which was otherwise available to them. Defendants were ordered to make this submission no later than August 14, 1997. *See* PA 131 (Ex. 3.A) (ECT Citizen Petition at p.7). Defendants again simply ignored this second FDA Order and allowed the

submission deadline to pass without response. PA 131 (Ex. 3.A) (ECT Citizen Petition at p.7).

In a third attempt to regulate ECT devices, in 2009 the FDA essentially renewed its second Order, requiring Defendants to submit the requisite safety and effectiveness data no later than August 7, 2009. PA 131-132 (Ex. 3.A) (ECT Citizen Petition at pp. 7-8). This time, the Defendants did technically provide a response to the FDA Order but their submissions failed to disclose critical details, that were known or at least knowable, about permanent memory loss, traumatic brain injury, and cognitive impairment, as well as information about the myriad adverse events that regularly result from ECT treatments. PA 131-132 (Ex. 3.A) (ECT Citizen Petition at p.7). Defendants, as medical device manufacturers, have had an obligation throughout this regulatory history to investigate and to report reasonably known information about death or serious injury associated with the use of their ECT devices. However, serious adverse events associated with ECT use have been documented, and known or knowable, since at least the 1970's. [1] Studies have shown ECT treatment to cause intracranial bleeding and there has been an active and growing group of ECT survivors who have unified in their opposition to ECT. Despite this, Defendants have never submitted a single adverse event report to the FDA. The FDA maintains a Medical and User Facility Device Experience (MAUDE) database that contains all reported adverse events. To date there are no manufacturer-submitted adverse event reports under "Device, Electroconvulsive Therapy" in the MAUDE system. *See* PA 009-59 (Ex. 1.B) (ECT MAUDE Entries), PA 87(Ex. 2.) (Breggin Decl., ¶ 24); PA 123 (Ex. 3) (Emord Decl., ¶ 7).

Defendants are prohibited from manufacturing, delivering, or introducing ECT devices into interstate commerce because of their failure to comply with the above referenced FDA Orders, and failure to promptly submit adverse event

[1] *See* PA 079, 080, 088 (Ex. 2) (Breggin Decl.. ¶¶ 10, 12, 14, 28); PA 141, 148 (Ex. 3.A) (ECT Citizen Petition at pp. 17, 24); PA 123 (Ex. 3) (Emord Decl, ¶ 7).

reports. Specifically, Defendants were required to promptly submit Adverse Event Reports ("AER's") within 30 days of "becoming aware" of information from any source that reasonably suggests ECT contributed to a death or serious injury. *See* 21 C.F.R. § 803.50. Moreover, the FDCA provides that a Class III device becomes "adulterated" where the FDA issues an Order under FDCA 360e(b) requiring submission of a PMA application and no PMA application is submitted by the deadline. 21 U.S.C. § 351(f). A device becomes "misbranded" where there has been a failure to furnish information required under 21 U.S.C. § 360i, the section of the FDCA requiring submission of adverse event reports by a medical device manufacturer. 21 U.S.C. § 352(t). The FDCA expressly prohibits the manufacture, delivery, or introduction into interstate commerce of adulterated or misbranded devices. 21 U.S.C. § 331.

As such, Defendants have, and have had for decades, a statutory obligation or duty to refrain from manufacturing and/or delivering ECT devices for medical use. *See* 21 U.S.C. §§ 331, 351, 352. The parallel state common law duty of reasonable care requires that they comply with this statutory obligation. This, however, has not deterred Defendants who continue to profit from the sale and use of ECT devices within California and the rest of the United States. One of the two defendants, Mecta, has admitted to regulatory noncompliance and the existence of adverse events resulting from ECT in sworn testimony[2], but continues to manufacture, sell and distribute ECT devices. The other defendant, Somatics, claimed in its 2009 submission to the FDA that "there has been no occurrence of a reported adverse event" resulting from use of its devices. As adverse events occur regularly and are known or knowable, Somatics statement is an admission of regulatory noncompliance.[3]

[2] *See* PA 064-074 (Ex. 1.D) (Nicol Depo., Vol I at 67:14-18, 68:13-25, 84:10-85:1, 98:9-12, 99:19-25, 101:3-6, 109:6-110:4).

[3] PA 075 (Ex. 1.E) (Somatics Submission to FDA at p. 4-5); PA 125, 150, 151, 167 (Ex. 3.A) (ECT Citizen Petition at pp. 1, 26, 27, 43).

B. Non-Compliance Resulted in Harm to the Class

The Plaintiffs are five individuals who received ECT in California, believing it would effectively treat psychological conditions. As a result of unwarned traumatic brain injury resulting from their ECT treatment, they now suffer from lasting cognitive impairment including severe, permanent loss of past memory and chronic short term memory loss, as well as related damages of a type not reported or disclosed by Defendants such as chronic traumatic encephalopathy.

Plaintiffs were led to believe that they would recover cognitively in due time, and that their symptoms of "confusion, nausea, headaches and short-term memory loss" were transient side-effects unrelated to traumatic brain injury. Tragically, this is not the case, as physical brain injury and significant to severe cognitive damages post-ECT exposure have frequently been found to be permanent. *See* PA 79-80 (Ex.2) (Breggin Decl., ¶¶ 10, 11, 12, 13, 14).

Had Defendants complied with their regulatory requirements, the ECT devices at issue would never have been manufactured or delivered for use. *See* 21 U.S.C. § 331. In addition, the knowledge of the true risks of brain injury, chronic traumatic encephalopathy, chronic short-term memory loss, and severe, permanent loss of past memory inherent in ECT administration would have become public knowledge as early as 1982, would have been available to medical providers who have administered ECT to putative class members, and would have reached those medical providers in time to prevent injury to members of the putative class. PA 087 (Ex. 2) (Breggin Decl., ¶ 22, 23); *see Coleman v. Medtronic*, 223 Cal. App. 4th 413, 429-30 (2014). This did not occur, and Plaintiffs as well as the putative class members have been injured as a proximate result.

The Food, Drug and Cosmetic Act and its implementing regulations are designed to limit risk inherent in Class III medical devices. As recipients of treatment administered using Class III medical devices, members of the putative class are those the statute and regulations are meant to protect.

See Coleman v. Medtronic, 223 Cal. App. 4th 413, 433 (2014). Therefore, in satisfaction of their duties of reasonable care to members of the putative class, Defendants had an obligation to comply with the Food, Drug and Cosmetic Act and its implementing regulations.

III. PROPOSED CLASS DEFINITION

The class that the Plaintiffs propose for certification is defined as follows:

1) All individuals in the United States who received ECT treatment in California, and suffered resulting injuries from May 28, 1982 through to the date of judgment, where such treatment was administered by an ECT device manufactured, sold, and/or distributed by either Defendant, Mecta or Somatics, after May 28, 1982.

2) The spouses of the above-referenced patients who have suffered related loss of consortium damages.

The class shall exclude any government agency officials, or judges assigned to hear any aspect of this litigation, as well as their immediate family members.

IV. ARGUMENT

A. Standards for Class Certification

The party moving for class certification must satisfy all requirements of Fed. R. Civ. P. 23(a), as well as at least one of the subdivisions of Rule 23(b). In an action seeking certification under Rule 23(b)(3), even if common issues do not predominate over individual issues such that certification of the entire action is warranted, Rule 23(c)(4) authorizes a district court to certify common issues for class treatment where appropriate. *Valentino v. Carter-Wallace*, 97 F.3d 1227, 1234-35 (9th Cir. 1996). The Ninth Circuit recently clarified that neither "ascertainability" of the class nor "administrative feasibility" of identifying absent class members are prerequisites to class certification under Rule 23. *See Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1124-25 n.4 (9th Cir. 2017).

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B. The Proposed Class Meets the Requirements of Rule 23(a).

1. Class Members Are So Numerous that Joinder of all is Impractical

The putative class of plaintiffs must be so numerous that joinder of all members is impracticable. Fed. R. Civ. P. 23(a)(1). The numerosity requirement has been satisfied where there have been fewer than 200 members. *See, e.g., Gay v. Waiters' & Dairy Lunchmen's Union, Local No. 30*, 549 F.2d 1330, 1332-34 (9th Cir. 1977) (184 class members was sufficient); *Slaven v. BP Am., Inc.*, 190 F.R.D. 649, 654 (C.D. Cal. 2000) (class size of 25 to 30 members was sufficient).

ECT has been in widespread use across California for decades. PA 078 (Ex. 2) (Breggin Decl., ¶ 8). A report by the California Department of Mental Health indicates that over 18,000 people underwent ECT treatment in California in 2001 alone, and the annual number is likely to have increased since that time. Since use of ECT continues until this day, it is reasonable to estimate that there are hundreds of thousands of ECT victims in California since May 28, 1982. *See* PA 078-079 (Ex. 2) (Breggin Decl., ¶ 9). Moreover, since ECT universally causes some degree of brain injury without warning, everyone treated with ECT has a colorable claim against the manufacturers. *See* PA 079-80, 086, 088 (Ex. 2) (Breggin Decl., ¶¶ 11, 12, 14, 20, 27).

Because joinder of tens, perhaps hundreds, of thousands of individuals into a single action would be impracticable, the numerosity requirement is satisfied.

2. There Are Questions of Law and Fact Common to the Class.

Federal Rule 23(a)(2) requires that there be questions of law or fact that are common to the class. A common question must be "of such a nature that it is capable of classwide resolution." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). "[E]ven a single [common] question" will do (*Wal-Mart Stores, Inc. v. Dukes* (2011), 564 U.S. 338, 359), but the answer to that question must have the capacity to "drive the resolution of the litigation." *Id* at 350. This inquiry "depends on the nature of the underlying legal claims that the class members have raised."

Jimenez v. Allstate Ins. Co., 765 F.3d 1161, 1165 (9th Cir. 2014). Therefore, in determining commonality, the Court should examine the nature of the legal claims at issue.

The Food, Drug and Cosmetic Act and its implementing regulations, in addition to requiring submission of Adverse Event Reports (21 C.F.R. § 803.50), provides that a Class III device becomes "adulterated" where the FDA issues an order under subsection (b) of section 360e of the FDCA requiring submission of a premarket approval application by a deadline and no premarket approval application is submitted. 21 U.S.C. § 351(f). The FDCA also provides that a device becomes "misbranded" where there has been a failure to furnish information required under 21 U.S.C. § 360i, the section of the FDCA requiring submission of Adverse Event Reports by a medical device manufacturer. 21 U.S.C. § 352(t). The Act further prohibits the manufacture, delivery, or introduction into interstate commerce of adulterated or misbranded devices. 21 U.S.C. § 331. State common law provides a damages remedy where a manufacturer of a medical product causes injury by violating the Food, Drug and Cosmetic Act or its implementing regulations. *See Riegel v. Medtronic*, 552 U.S. 312, 330 (2008).

Here, all putative class members pursue the same claims (negligence and strict liability) based on the same acts of Food, Drug and Cosmetic Act noncompliance by Defendants. The primary common questions of fact that will drive the resolution of this action include whether the Defendants complied with their regulatory obligations under the FDCA and implementing regulations by reporting the reasonably known adverse events to the FDA,[4] whether those at the vanguard of scientific knowledge would have been able to know of the potential for traumatic brain injury resulting from ECT, whether ECT devices would have been

[4] Both defendants have admitted comprehensively violating these regulatory obligations continuously since 1982, given the continuously-repeating occurrence of reasonably known adverse events resulting from ECT. *See* footnotes 2 and 3, *supra*.

available for use had Defendants refrained from the manufacture and delivery of adulterated and/or misbranded medical devices, and whether Defendants' acted with conscious disregard for the rights and safety of others such that an award of punitive damages is appropriate.

The primary common questions of law that will drive the resolution of this litigation include whether ECT devices are "adulterated" due to a failure to respond to the FDA's first Order, determination of the time at which ECT device became "misbranded" (given a continuous failure to report adverse events to the FDA since 1982), and whether Defendants violated the medical device reporting obligations of the Food, Drug and Cosmetic Act. Although this action is premised upon a breach of duties under state law running parallel to the FDCA's regulatory requirements, Defendants nevertheless raise the affirmative defense of federal preemption, which is resolved through proof common to all class members. These questions constitute the majority of the action, leaving only the extent of individual damages for determination after class treatment. Because the claims of putative class members all share several central common issues that will drive the resolution of the litigation, the "commonality" requirement of Rule 23(a) is met.

3. The Claims of Class Representatives are Typical of Those of the Class.

Federal Rule 23(a)(3) requires that the named Plaintiffs' claims for relief be typical of the claims of all class members. "[R]epresentative claims are 'typical' if they are reasonably co-extensive with those of absent class members; they need not be substantially identical." *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1020 (9th Cir. 1998). The class representative must pursue his or her claims under the same legal or remedial theories as the represented class members. *In re Paxil Litig.*, 212 F.R.D. 539, 549 (C.D. Cal. 2003).

Plaintiffs Marcia Benjamin, Jose Riera, Marcia Benjamin, Michelle Himes, Diane Scurrah, and Deborah Chase each underwent multiple rounds of ECT treatment in California, using ECT devices manufactured by the Defendants.

See PA001 (Ex. 1) (Karen Decl., ¶ 1) PA123 (Ex. 3) (Emord Decl., ¶ 7). ECT caused traumatic brain injury, severe long-term retrograde and anterograde amnesia, and cognitive impairment, among other injuries to each class representative. *See* PA 080 (Ex. 2) (Breggin Decl., ¶ 14); PA 174 (Ex. 4) (M. Benjamin Decl., ¶¶ 1, 2); PA 178 (Ex. 6) (Chase Decl., ¶¶ 1,2); PA 180 (Ex. 7) (Himes Decl., ¶¶ 1, 2); PA 182 (Ex. 8) (Riera Decl. ¶¶ 1,2); PA 184 (Ex. 9) (Scurrah Decl., ¶¶ 1, 2).

All members of the putative class, including class representatives, received ECT without warning of brain injury, and the lack of warning of brain injury resulting from ECT is a direct result of Defendants' regulatory noncompliance. PA 080, 087-088 (Ex. 2) (Breggin Decl., ¶¶ 14, 22-29). The injuries of all the members of the putative class, as well as those of the named Plaintiffs, result from Defendants' inadequate reporting to the FDA and from manufacturing and delivering their adulterated and misbranded ECT devices to medical providers in the United States. *See* PA 123 (Ex. 3) (Emord Decl., ¶¶ 6,7); PA 087 (Ex. 2) (Breggin Decl., ¶ 22). Accordingly, representative claims are reasonably coextensive with those of absent class members, and the claims of the representative plaintiffs are typical of those of the class.

4. The Representative Parties Will Fairly and Adequately Represent the Class.

Federal Rule 23(a)(4) requires that the named Plaintiffs fairly and adequately represent the interests of the class. Representative parties are adequate if: (1) the named plaintiffs and their counsel have no conflicts of interest with other class members, and (2) the named plaintiffs and their counsel will prosecute the action vigorously on behalf of the class. *Hanlon*, 150 F.3d at 1019. Adequate representation is usually presumed in the absence of contrary evidence. *Californians for Disability Rights, Inc. v. California Dept. of Transp.*, 249 F.R.D. 334, 349 (N.D. Cal. 2008).

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Class counsel is adequate, having had significant experience including complex and class litigation, and the named Plaintiffs will vigorously prosecute the class's case. PA 001-004 (Ex. 1) (Karen Decl. , ¶¶ 1-4, 9); PA 005-007 (Ex. 1.A); PA 175 (Ex. 4) (M. Benjamin Decl., ¶ 5); PA 177 (Ex. 5) (D. Benjamin Decl., ¶ 6); PA 179 (Ex. 6) (Chase Decl., ¶ 5); PA 181 (Ex. 7) (Himes Decl., ¶ 5); PA 183 (Ex. 8) (Riera Decl., ¶ 5); PA 185 (Ex. 9) (Scurrah Decl., ¶ 5). Moreover, there is no conflict of interest between Plaintiffs, the putative class, and Plaintiffs' counsel. In light of the presumption of adequacy of counsel, and the lack of conflicts of interest between Plaintiffs and putative class members, lead counsel and named Plaintiffs are adequate.

C. <u>The Proposed Class Satisfies Rule 23(b)(3).</u>

Federal Rule 23(b)(3) is a two-pronged test requiring both predominance and superiority, both of which are satisfied in this context.

1. Common Questions Predominate over Individual Issues

To meet the predominance test, "the proposed classes must be sufficiently cohesive to warrant adjudication by representation. *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 623 (1997). This inquiry turns on close scrutiny of "the relationship between the common and individual issues." *Hanlon*, 150 F.3d at 1022. "[M]ass tort cases arising from a common cause . . . may, depending on the circumstances, satisfy the predominance requirement." *Amchem*, 521 U.S. at 625. Here, all liability issues are amenable to common proof and the classes are therefore cohesive enough to warrant adjudication by representation.

(i) <u>Negligence</u>

The elements of duty, breach of duty, and causation in the negligence claim will be resolved through common proof without inquiring into the individual circumstances of the putative class members. First, the duty owed by Defendants is determined by reference to FDA Orders, the FDCA and implementing regulations, and its requirement, regardless of the individual plaintiff, that manufacturers of

medical devices engage in post-sale reporting to the FDA of information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury. 21 C.F.R. § 803.50.

Second, the issue of Defendants' breach of duty can similarly be resolved through common proof. In determining whether Defendants breached their common law duty to engage in post-sale reporting to the FDA of information reasonably suggesting that ECT may have caused or contributed to a serious injury, examination of the interactions between Defendants and the FDA is sufficient. *See Coleman v. Medtronic*, 223 Cal. App. 4th 413, 432-33 (2014). Additionally, since Defendants' ECT devices are both adulterated and misbranded, breach of duty can be established be proof that Defendants continued to manufacture and deliver their devices despite their failure to report. 21 U.S.C. § 331.

Third, the element of causation is established through common proof under two separate legal theories. First, had Defendants refrained from manufacturing or distributing adulterated and misbranded devices, as was required under 21 U.S.C. § 331, members of the putative class would never have suffered injury. No matter the course of conduct of each individual Plaintiff, the type of device that caused injury to each one would not have been manufactured or delivered, and therefore each putative class member would have avoided injury. Secondly, had Defendants complied with their duty to report adverse events to the FDA, their adverse event reports would have appeared in the MAUDE database, a public database known to and discussed in the psychiatric community. *See* 21 C.F.R. § 20.20(b); PA 123 (Ex. 3) (Emord Decl., ¶¶ 2-7). Properly submitted adverse event reports would have effectively warned the psychiatric and medical professions, including the putative class's healthcare providers who administered ECT, both directly and through discussion among the professional community. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770-71 n. 5 (5th Cir. 2011); PA 123 (Ex. 3) (Emord Decl, ¶¶ 2-7). Since the standard for causation is whether healthcare providers would have

had access to the withheld information in time to prevent injury to patients (*Coleman v. Medtronic* (2014), 223 Cal. App. 4th 431, 429-30), and healthcare providers are obliged to stay apprised of information relating to the safety of devices they use on patients, causation will be shown through common proof. *See* PA 123 (Ex. 3) (Emord Decl., ¶ 5)

On both theories, the issue of causation should be resolved through class proceedings, leaving only the individualized issue of damages remaining, which does not defeat class certification. *Leyva v. Medline Industries Inc.*, 716 F.3d 510, at 514-516 (9th Cir. 2013).

(ii) Strict Liability - Failure to Warn

The elements of strict liability – failure to warn are as follows: (1) the defendant manufactured, distributed or sold the product; (2) the product had potential risks that were known and/or knowable in light of the scientific knowledge that was generally accepted in the scientific community at the time of manufacture, distribution or sale; (3) the risks presented a substantial danger when the product is used or misused in a reasonably foreseeable way; (4) ordinary consumers would not have recognized the potential risks; (5) Defendants failed to adequately warn or instruct of the potential risks; (6) the plaintiff was harmed; and (7) the lack of warning or instruction was a substantial factor in causing harm. *Jian Wu v. Ean Holdings, LLC*, 2014 WL 117338 (N.D. Cal), at *3; California Civil Jury Instructions (CACI) 1205 – Strict Liability – Failure to Warn (2017).

Each of the Strict Liability elements, except for the extent of harm, is subject to common proof: (1) whether Defendant manufactured, distributed or sold ECT devices is resolved through the common proof of Defendants' business activities; (2) the issue of whether ECT devices present risks that were known and/or knowable in light of generally accepted scientific knowledge at the time of manufacture, distribution and sale is resolved through a survey of the available scientific literature; (3) the issue of whether ECT devices cause brain damage when

used in an intended or reasonably foreseeable way will be resolved through the common proof of expert testimony and a survey of the available scientific literature; (4) the issue of whether ordinary consumers (healthcare providers) would have recognized the risk of brain damage inherent in ECT absent a warning is resolved through the common proof of expert testimony relating to the effect that Defendants' failure to report has had on the data available to the psychiatric profession, as well as the representations made by Defendants and opinion leaders in the industry about the safety and efficacy of ECT devices; (5) the issue of whether Defendants failed to adequately warn of the potential risks inherent in ECT is determined by the common proof of Defendants' reporting to the FDA; and (7) the issue of whether Defendants' failure to report was a substantial factor in causing harm to the putative class, is resolved through the common proof of the effect that Defendants' failure to report has had on the information available to the psychiatric profession.

Finally, punitive damages require a showing, by clear and convincing evidence, of "fraud, oppression or malice" by Defendants. Cal. Civ. Code § 3294. Nonintentional torts support punitive damages when the defendant's conduct involves conscious disregard of the rights or safety of others. *Pfeifer v. John Crane, Inc.*, 220 Cal. App. 4th 1270, 1299 (2013). Since punitive damages are determined by reference to Defendants' conduct, and not the individual circumstances of each class member, the propriety of punitive damages will be determined by common proof.

The sixth element, the harm to each class member, is the only element of Plaintiffs' case requiring examination of the individual circumstances of each plaintiff. Everyone in the class has suffered harm, given that ECT invariably damages the brain. PA 080 (Ex. 2) (Breggin Decl., ¶ 14). Therefore, the extent of individual damages would be the only element of Plaintiffs' case-in-chief left to address after class treatment. As is discussed *supra*, such is not grounds for denial

of class certification, *Leyva*, 716 F.3d, at 514-16 (2013), as common questions predominate over individual ones.

2. A Class Action is the Superior Method of Resolving This Dispute.

Rule 23(b)(3) lists four factors relevant in determining superiority.

(i) The class members' interests in individually controlling the prosecution of separate actions do not warrant individual adjudication.

The social stigma associated with mental illness, and the corresponding public attention that would likely follow when bringing an individual suit, weigh against many class members' interests in proceeding individually. *See* PA 086 (Ex. 2) (Breggin Decl., ¶ 19, 20). In addition, class treatment lends credibility and strength in numbers to members of the putative class. Further, putative class members might otherwise suffer a rhetorical disadvantage in individual suits in which the Defendants could frame an individual Plaintiff's injury as a one-off happening, rather than one of thousands of serious identical injuries resulting from a pervasive and continuing regulatory violation. PA 087 (Ex. 2) (Breggin Decl., ¶ 25). These factors magnify the interests of putative class members in proceeding as a class.

Normally, individual class members' entitlement to large damages remedies suggests an interest in individually controlling the prosecution, but even where a significant portion of the class suffered minimal damages, class treatment is sometimes appropriate. For example, this Court in *Haley v. Medtronic*, 169 F.R.D. 643, 656 (C.D. Cal. 1996) expressly indicated that a personal injury class limited to plaintiffs in a single state should be certified in order to address the significant portion of class members who suffered minimal damages, and therefore would not have an incentive to pursue costly individual claims.

Here, on one hand, many members of the putative class received only one round or a few rounds of ECT shock treatment, and may have suffered only minor long-term cognitive impairment. *See* PA 079 (Ex. 2) (Breggin Decl., ¶ 12).

These class members suffered damages insufficient to incentivize costly individual lawsuits, and therefore a geographically limited statewide class action would be appropriate in resolving those claims. On the other hand, many putative class members have died, or have suffered life-changing brain damage and injuries resulting from ECT treatment, warranting more substantial damage remedies. However, the large number of smaller claims which are likely to otherwise go unremedied creates an interest in class treatment which heavily outweighs any class member's interest in individually controlling the prosecution of a separate action. This rationale is particularly compelling in the present case, where all plaintiffs' injuries are traceable to the exact same wrongful conduct, and all were subjected to the exact same mechanism of injury in the form of intracranial electrical trauma. *Haley*, 169 F.R.D. 643, at 656.

(ii) There is no ongoing litigation concerning the controversy by or against class members.

While patients have brought actions against ECT manufacturers for injuries resulting from ECT shock treatment, Plaintiffs' counsel has discovered no ongoing litigation concerning Defendants' regulatory noncompliance.

(iii) Concentration of the litigation of claims of the putative class members in this forum is desirable.

Litigating all of the claims of the putative class members in California is a desirable way of resolving this dispute, since all class members underwent ECT in California and California law applies to all claims.

(iv) This putative class action is manageable.

Courts must consider the manageability of proceeding with class treatment, but there is a "well-settled presumption that courts should not refuse to certify a class merely on the basis of manageability concerns." *Briseno v. ConAgra Foods, Inc.*, *Inc.*, 844 F.3d 1121, 1127-28 (9th Cir. 2017).

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Once common issues are resolved, the extent of damages to each class member can be resolved through individual fact finding. With respect to the extent of injury resulting from brain damage, the putative class can utilize a claims administration process in order to undergo CT scans, electroencephalogram testing, and diagnostic testing with a court-appointed specialist. *See* PA 081 (Ex. 2) (Breggin Decl., ¶ 18). A sampling method such as that approved by the Ninth Circuit in 1996 may be effective in resolving the extent of damages to each putative class member. *See Hilao v. Estate of Marcos*, 103 F.3d 767, 783-84 (9th Cir. 1996). With respect to the extent of other more externally-visible types of injury, such as dental trauma, court-appointed specialists can examine each patient to determine the extent of harm caused. If necessary, damages inflicted upon each individual can be tried in separate actions by separate local juries.

Defendants may highlight *Zinser v. Accufix Research Institute, Inc.*, 253 F.3d 1180 (9th Cir. 2001) in contesting class certification. There, determining the mechanism of injury to each class member required examination of the manufacturing, shipping and handling histories of each individual pacemaker. Here, a closed-head injury was inflicted through electrical trauma to each and every ECT patient at the precise moment each one was administered ECT, regardless of the manufacturing, shipping, or handling histories of each device. PA 080 (Ex. 2) (Breggin Decl., ¶ 14). Therefore, *Zinser* is inapposite.

(v) Other factors weigh in favor of a finding of superiority.

A common question of law that could be determinative in all individual cases supports a finding of superiority. *See, e.g., In Re Agent Orange Products Liability MDL No. 381*, 818 F.2d 145, 166-67 (2d Cir. 1987), *cited with approval in Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1232 (9th Cir. 1996); *Jenkins v. Raymark Indus., Inc.*, 782 F.2d 468, 472-473 (5th Cir. 1986) (certifying the "state of the art" defense for class treatment). Like the government contractor defense did in *Agent Orange*, the common issues of the federal preemption defense and

Defendants' general regulatory noncompliance, along with the other common issues in this action, support a finding of superiority here.

In addition, given the debilitating nature of the injuries at issue in this suit, the higher the claim's value, the more severe the injuries, and the less likely the claimant will be able to expend the cognitive resources necessary to organize and file suit. *See* PA 080 (Ex. 2) (Breggin Decl., ¶ 14). Thus, the only claimants likely to bring suit are ones with smaller claims relative to those of the class. "The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights." *Amchem*, 521 U.S. 591, 617 (1997). *Amchem*'s policy rationale for class treatment therefore applies to the case at bar.

Finally, certification will deter similar longstanding and knowing violations of federal regulatory duties. Deterrence is one of the widely recognized public policy objectives of class actions. *Najarian v. Avis Rent A Car System*, 2007 WL 4682071 (C.D. Cal. 2007). Since 1982, individual actions have been unsuccessful in deterring defendants' continuous refusal to report adverse events and/or warn treating psychiatrists of ECT's potential to cause traumatic brain injury. If a class is not certified, this wrong may never be remedied.

Thus, the tests of predominance and superiority are both met, and Rule 23(b)(3) is satisfied.

D. <u>Issue Certification is Appropriate</u>

In the products liability context, even if the predominance requirement of Rule 23(b)(3) is not met, Rule 23 authorizes the district court in appropriate cases to isolate the common issues under Rule 23(c)(4) and proceed with class treatment of these particular issues." Fed. R. Civ. P. 23(c)(4); *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1233-34 (9th Cir. 1996); Manual for Complex Litigation, Fourth, § 21.24, at 273 n.839.

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Rule 23(c)(4) has proved to be particularly useful in the mass tort context when numerous personal injury cases present significant common questions.[5]

Moreover, this Court addressed the option of issue certification under Rule 23(c)(4) in a putative class action seeking damages for personal injuries resulting from use of a defective medical device. *See Haley*, 169 F.R.D. at 656. The court indicated that issue certification would have been proper in the absence of fraud and misrepresentation claims if the geographic area of the class were limited to a single state. *Id.*

Here, all of the issues pertinent to the Defendants' liability can be resolved through common proof of regulatory noncompliance, as is discussed *supra*. In addition, Plaintiffs assert no fraud or misrepresentation claim requiring proof of individual reliance, and the class is limited to California patients. This action therefore avoids the pitfalls which prevented issue certification in *Haley*. Since liability and punitive damages can be resolved through common proof, this Court should certify those issues for class treatment under Rule 23(c)(4).

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[5] The U.S. Courts of Appeals have utilized this type of multiphasic approach in resolving mass accident, product liability, and/or personal injury disputes on multiple occasions. *See In re Exxon Valdez*, 270 F.3d 1215 (9th Cir. 2001) (describing multiphase class-wide trial of claims arising from the Exxon Valdez oil spill and affirming class-wide compensatory damages award); *Hilao v. Estate of Marcos*, 103 F.3d 767 (9th Cir. 1996) (affirming a three-phase class-wide trial of punitive damages, liability, and compensatory damages of 10,000 member class of victims of alleged atrocities by the Marcos regime); *Wesleyan Coll. v. Kaiser Gypsum Co., Inc.*, 6 F.3d 177, 189 (4th Cir. 1993) (approving partial conditional certification of class of asbestosis victims as to eight common issues); *Cent.; Sanford v. Johns-Manville Sales Corp.*, 923 F.2d 1142, 1145 (5th Cir. 1991) (trying liability and punitive damages before one jury and compensatory damages before another in asbestos litigation); *In re Bendectin Litig.*, 857 F.2d 290 (6th Cir. 1988) (upholding constitutionality of trial to verdict of generic causation issue in aggregate proceedings); *Jenkins v. Raymark Indus.*, Inc., 782 F.2d 468, 473 (5th Cir. 1986) (finding classwide resolution of the common "state of the art" defense superior than "repeating, hundreds of times over. . .the same witnesses, exhibits and issues from trial to trial" in a mass tort case).

E. Class Notice

Here, should this court find that "ascertainibility" and "administrative feasibility" remain as prerequisites to class certification (*See Briseno,* 844 F.3d 1121, at 1124-5), notice can be directed to putative class members through the traditional opt-out method by discovery of all of the healthcare provider-purchasers of ECT devices from Defendants during the class period, followed by subpoena of the identities and mailing addresses of ECT recipients from those hospital-purchasers. HIPAA does not bar such disclosure where a court orders it pursuant to a discovery request and the party seeking discovery makes reasonable effort to secure a qualified protective order. 45 C.F.R. § 164.512(e); *Thomas v. Hickman*, 2007 WL 4302974 (E.D. Cal. 2007); *Hutton v. City of Martinez*, 219 F.R.D. 164, 167 (N.D. Cal 2003). Counsel in this action intends to seek such a protective order.

Alternatively, notice can be directed to the bulk of ECT victims in the state through first-class mail to known class members in addition to strategic publication, internet and media broadcasting, and by contacting the various psychiatric rights' groups throughout California. Either of the aforementioned two methods would be "reasonable effort" toward achieving the "best notice practicable under the circumstances." *See Briseno,* 844 F.3d, at 1128-1129.

V. CONCLUSION

Plaintiffs respectfully request that this Court certify the common issues in this action for class treatment and appoint Plaintiffs' counsel of record as class counsel, both to expeditiously resolve this action and deter any similar longstanding violations of federal public health regulations.

Dated: December 9, 2017

Respectfully submitted,

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