No. 18-_____

In the

United States Court of Appeals

for the

Ninth Circuit

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

Plaintiffs-Petitioners,

vs.

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

Defendants-Respondents.

Appeal from an Order of the United State District Court for the Central District of California, Case No. 2:17-cv-06686-RGK-PJW

PLAINTIFFS' RULE 23(F) PETITION FOR PERMISSION TO APPEAL ORDER DENYING MOTION FOR CLASS CERTIFICATION

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INTRODUCTION

The purpose of class treatment is "vindication of rights of groups of people who individually would be without effective strength to bring their opponents into court at all." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 617 (1997). Certification of this class would vindicate the rights of a group that, for decades, has been without effective strength to ever meaningfully challenge its opponents in court.

Defendants have been the only two "Electroconvulsive Therapy" ("ECT") device manufacturers since 1985. Defendants did not report thousands of serious adverse event allegations to the FDA, have kept improper financial ties with influential organizations and opinion leaders within the field of psychiatry in the interest of suppressing the information about the dangers of ECT devices, and have not been held accountable for the serious injuries they have caused. For almost 4 decades, Defendants have taken advantage of a market shrouded in deliberate ignorance by selling and profiting from their adulterated and misbranded devices. This conduct is prohibited by 21 U.S.C. § 331 and treats as a farce the FDA's postmarket reporting obligations (21 C.F.R. § 803.50), regulations designed to prevent the type of injury at issue in this case.

Pursuant to Fed. R. Civ. P. 23(f), this Court has the jurisdiction to review the order denying class certification. Plaintiff-Petitioners respectfully request this timely permission to appeal the order of the United States District Court, Central District of California, denying Plaintiff-Petitioners' Motion for Class Certification.

ISSUES PRESENTED

1. Does the need for individualized mini-trials after a class trial foreclose a finding of manageability under Fed. R. Civ. P. 23(b)(3)?
2. Does severity of some claimants' injuries foreclose a finding that individuals have a greater interest in proceeding as a class than individually under Fed. R. Civ. P. 23(b)(3)?
3. Do the significant common issues and individual issues in a putative class action need to fit into respective categories of "liability" and "damages" for partial certification under Rule 23(c)(4) to "materially advance the disposition of the litigation?"
4. Is it the *number* of common issues or their *significance*, relative to the individual issues in a putative class action, that renders partial certification under Rule 23(c)(4) proper?
5. Did the District Court properly weigh the common issues in this action, in relation to the individual issues, in determining whether Rule 23(c)(4) partial certification would materially advance the disposition of the litigation?

STATEMENT OF FACTS

The practice of inducing grand mal seizures in patients through application of electricity to cranium, in the field of psychiatry, is referred to as "Electroconvulsive Therapy" or "ECT". *See* 21 C.F.R. § 882.5940. It is often called "shock treatment". The prevailing rationale for ECT treatment is that it "corrects

biochemical imbalances" but there is no sound scientific proof for this claim. Patients receive assurance prior to treatment that the practice presents no real risk of injuring the brain. The truth is that ECT, still widely prescribed, presents an unavoidable risk of electrical injury to the brain. Defendants have played a deliberate part in keeping that truth concealed from the public, causing countless unwarned concussive brain injuries.

The FDA has attempted to regulate the use of ECT devices since 1979. Defendants, the only two ECT device manufacturers, have been in violation of FDA regulations throughout this history without consequence. See Dkt. 26-1 (Cert.Mtn. 1:27-28); Dkt. 26-2 (Emord ¶7). Defendants have never submitted a required PMA application despite its Class III status, **have ignored an FDA order requiring submission of all adverse safety information, have submitted misinformation in response to a second identical FDA order, and have never kept a system in place for the timely investigation, evaluation, and reporting of adverse event allegations to the FDA**. See Dkt. 26.1 (Cert.Mtn. p. 2-4). Further, Defendants are gaming the regulatory system by, on one hand, continuing to market their devices as "substantially equivalent" to predicate devices while, on the other, now claiming different intended uses and differing technological characteristics. See Dkt. 37 (Oppo. 7:8-18); Dkt. 37-2 (Weiner ¶¶6, 14). **Neither Defendant, between the genesis of the FDA's postmarket reporting obligation in the early 1980's and the filing of this suit, evaluated, properly investigated, or reported to the FDA**

any of the thousands of serious allegations of injury resulting from ECT of which they were aware. See Dkt. 38 (Reply 2:10-18); Dkt. 38-1 (Emord ¶2). This is unsurprising, as Defendants still represent ECT devices to be safe. See Dkt. 37-1 (Coffey ¶5, 12); Dkt. 37-2 (Weiner ¶11).

All ECT devices are **misbranded**, and have been since the advent of the Food, Drug and Cosmetic Act's post market reporting requirements, for failing to attempt to comply with said requirements. *See* 21 U.S.C. §§ 352(t), 360i.

All ECT devices are also **adulterated** according to Defendants' contentions, because they obtained market clearance on grounds of 510(k) "substantial equivalence" to predicate ECT devices, but they are marketed for a different intended use than the predicate devices and Defendants claim that the devices present new questions of safety and effectiveness as a resulting of differing technical characteristics. Dkt. 37 (Oppo. 7:8-18); Dkt. 37-2 (Weiner ¶ 6, 14). *See also* 21 U.S.C. § 351(f); 21 U.S.C. § 360e(a)(2).

The Plaintiffs are five individuals who received ECT in California, believing it would effectively treat psychological conditions by "correcting a biochemical imbalance" as relayed by their psychiatrists. ECT caused them unwarned traumatic brain injury and ensuing lasting cognitive impairment including severe, permanent loss of past memory and chronic short term memory loss. See Dkt. 39 (SAC).

By Order entered on March 19, 2018, the District Court denied Class Certification under Rule 23(b)(3) ruling that class treatment is not the superior

method of adjudicating this action. The District Court focused on only two of the four factors used to determine superiority: the manageability of a class action in this context, and, to a lesser extent, the presumed interest of the putative class members in controlling their own litigation. *See* Dkt. 50 (Order). Finally, the District Court declined to certify particular issues for class treatment under Fed. R. Civ. P. 23(c)(4), based on the District Court's conclusion that issues relating to Defendants' liability "involve more individual questions than common ones." See Dkt 50. (Order).

The District Court abused its discretion and committed manifest reversible error in that it: (1) applied the wrong standard in evaluating the propriety of partial certification under Rule 23(c)(4); and (2) did not conduct a "rigorous analysis" in applying Rule 23 to the facts of this case. *See Cox v. Aero Automatic Sprinkler Company*, 2015 WL 3658031, at *1 (N.D. Cal. 2015), citing *Comcast Corp. v. Behrend*, 133 S.Ct. 1426, 1432 (2013).

REASONS FOR GRANTING THIS PETITION

Here, permission to appeal should be granted because this case presents "unsettled and fundamental issue[s] of law" worthy of this Court's clarification, because the District Court's ruling denying class certification and/or issue certification was a "manifestly erroneous" abuse of discretion, and, perhaps most importantly, because a lack of class adjudication would sound the "death knell" for

the putative class's chance of ensuring warning of traumatic brain injury to future recipients of ECT shock treatment. *See Chamberlan v. Ford Motor Co*., 402 F.3d 952, 959 (9th Cir. 2005).

I. THE CERTIFICATION ORDER AT BAR TURNS ON NOVEL AND/OR UNSETTLED QUESTIONS OF LAW.

The certification decision here turns on multiple novel and unsettled issues of law regarding class certification.

A. The law is unsettled regarding when District Courts should partially certify classes under Rule 23(c)(4).

Courts have advanced varied views on whether (and how) class treatment and/or issue certification should be applied to mass tort actions. *See, e.g.*, *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227 (9th Cir. 1996) (approving in some circumstances); *Jenkins v. Raymark Indus.*, 782 F.2d 468 (5th Cir. 1986) (certifying a class for common issues, leaving individualized issues for mini-trials). *But see Castano v. Am. Tobacco Co.*, 84 F.3d 734 (5th Cir. 1996); *In re Am Med. Sys. Inc.*, 75 F.3d 1069 (6th Cir. 1996); *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293 (7th Cir. 1995).

"Neither the Ninth Circuit nor the Supreme Court has established when certification of an issue class is appropriate." *Saavedra v. Eli Lilly & Co.*, 2014 WL 7338930, at *10 (C.D. Cal. 2014). Courts say that issue certification should be used to "materially advance the disposition of the litigation" but no consistent standard has emerged beyond that. *See* MANUAL FOR COMPLEX LITIGATION, FOURTH § 22.75.

This case presents a valuable opportunity to provide clarity and definition to the terms "appropriate" and/or "material" for purposes of Fed. R. Civ. P. 23(c)(4), giving much-needed guidance to lower courts in their application of the Rule.

1. It is unsettled whether common and individual issues must fit squarely into respective categories of "liability" and "damages" under Rule 23(c)(4).

Courts often refer to Rule 23(c)(4) issue classes as "liability-only" classes. *See Rahman v. Mott's LLP*, 693 Fed. Appx. 578, 579 (9th Cir. 2017). The District Court denied issue certification, in part, because "causation, and by extension, liability" present "more individual issues" than common ones. See Dkt. 50 (Order p.4). The District Court's ruling raises the novel question of whether the common and individual issues must fit squarely into the respective categories of liability and damages in order for issue certification to be proper, despite the absence of such a requirement from the text of Rule 23. *See Briseno v. ConAgra Foods*, 844 F.3d 1121, 1125 (9th Cir. 2017).

2. The District Court's ruling raises questions as to whether the *number* or the *relative significance* of common issues is the relevant inquiry for issue certification.

The same reasoning applies to the District Court's consideration of the *number* of individual issues in relation to common ones. The case at bar presents at least three (3) outcome-determinative common issues: 1) regulatory noncompliance (which encompasses the whole of Defendants' actionable conduct);

2) generic causation of gross structural brain pathology resulting from ECT (the precise injury at issue in this action); and 3) preemption. These issues, in addition to many other common issues,[1] present the opportunity to better clarify the "appropriate" interplay between the *number* of common issues and the relative legal *significance* of those issues in the context of issue certification. *See* Fed. R. Civ. P. 23(c)(4).

3. It is unclear how the Seventh Amendment reexamination clause applies to partial certification under Rule 23(c)(4) and subsequent mini-trials.

Circuit courts are split on whether the Seventh Amendment's reexamination clause is violated by asking different juries to decide separate elements of a single claim. *See* U.S. CONST. Am. 7; *compare Robinson v. Metro-North Commuter R.R. Co.*, 267 F.3d 147 (2d Cir. 2001) ("Trying a bifurcated claim before separate juries does not run afoul of the Seventh Amendment: as long as a single factual issue is not "tried by different, successive juries") *with In re Rhone Poulenc*, 51 F.3d at 1303 (first jury impaneled to hear them must hear all juriable issues). *See also* MANUAL FOR COMPLEX LITIGATION (FOURTH), § 21.25 n. 841.

This action presents an opportunity to clarify the circuit split on Seventh

[1] These include, *inter alia*, (1) the propriety of punitive damages, (2) issues relating to the burden of under *Haft v. Lone Palm Hotel*, 3 Cal. 3d 756 (1970), (3) what the state of AER's in the MAUDE database would have been, had defendants complied with the FDCA, (4) equitable estoppel and fraudulent concealment for statute of limitations purposes, and (5) the scope of "foreseeable misuse" for strict liability purposes.

Amendment reexamination in the context of damages mini-trials after a class trial.

B. No court has addressed the novel question of whether an issue class may be certified for the issue of adulteration and/or misbranding of a product or other FDCA noncompliance.

In 2012, this Court granted *en banc* review of a District Court decision finding the particular type of state law failure-to-report claim at issue in this action preempted. *See Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013)

This case presents the same failure-to-report claim as *Stengel*, and the same question of causation in the context of a failure to report adverse events. *See id*, at 1234-35 (Watson, J, concurring). The alternate theory of causation here, based on adulteration and/or misbranding, in which injury is caused through illegally introducing the dangerous adulterated and/or misbranded device into interstate commerce in the first instance, rather than through a failure to report adverse events to the FDA, presents *Stengel*'s causation issue in further detail. *See* 21 U.S.C. § 331.

Adulteration and/or misbranding of an FDA-regulated product is a significant legal concept, giving rise to various types of liability where established. *See, e.g.*, 21 U.S.C. §§ 331(a)-(b), 333; *United States ex. rel Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 897 (9th Cir. 2017) (False Claims Act liability); *United States v. Dotterweich*, 320 U.S. 277 (1943) (criminal prosecution), *Coleman v. Medtronic, Inc.*,223 Cal.App. 4th 413, 434 (2014) (civil liability under California law).

If the adulteration and/or misbranding of a product is an issue appropriate for

Rule 23(c)(4) treatment, this method is an expeditious way to address injury caused by a manufacturer's continuous violation of federal food, drug, cosmetic, and medical device regulations.

II. THE DISTRICT COURT'S DENIAL OF CLASS CERTIFICATION WAS MANIFESTLY ERRONEOUS.

The District Court's conclusion that partial certification would not materially advance the disposition of the litigation was manifestly erroneous, as it is not based on application of established law, constituting an abuse of discretion.

A. The District Court's ruling on superiority committed manifest errors of law and fact.

In its superiority analysis, the District Court's determination was based almost exclusively on one of the four superiority factors: the perceived lack of manageability of class treatment in this litigation—to the exclusion of the remaining superiority factors. Dkt. 50 (Order pp. 2-3), *quoting* Fed. R. Civ. P. 23(b)(3).

1. The District Court's Decision Runs Contrary to Law Governing Manageability.

"Rule 23(b)(3) calls for a comparative assessment of costs and benefits of class adjudication, including the availability of 'other methods' for resolving controversy". *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121 (9th Cir. 2017).

The District Court's decision to rest its ruling on lack of manageability, without a comparative assessment of management alternatives, runs contrary to *Briseno*. The District Court concluded that:

> "a class action would not be manageable because the Court would have to conduct mini-trials to resolve individual issues of causation including which ECT device was used on each claimant; the experience, knowledge and method of administration of ECT treatment of each claimant's treating physician; the specific injury experienced by each claimant; and whether the treatment, in fact, caused the injury. Moreover, affirmative defenses may apply depending on each claimant's factual scenario."

Dkt. 50 (Order p.3). These conclusions, summarily stated, are not a "comparative assessment" as contemplated by *Briseno* and are not a "rigorous analysis" of the underlying facts as required by Rule 23. *See Cox v. Aero Automatic Sprinkler Company*, 2015 WL 3658031, at *1 (N.D. Cal. 2015), *citing Comcast Corp. v. Behrend*, 133 S.Ct 1426, 1432 (2013).

First, the possibility of having to conduct mini-trials to resolve issues not addressed by class treatment does not render a class unmanageable. *See Briseno v. ConAgra Foods, Inc*., 844 F.3d 1121, 1128 (9th Cir. 2017), *citing with approval In re Visa Check/Master Money Antitrust Litig*., 280 F.3d 124, 141 (2nd Cir. 2001) (approving bifurcation of issues within the action to be tried by different juries).

Second, there was no assessment whatsoever of the specific tools that could be invoked to lessen any perceived cost or burden or difficulty in managing class treatment. This is true even though Plaintiffs raised several such tools for consideration in their Motion for Class Certification. Dkt. 26-1 (Cert.Mtn. 7:1-12).

2. <u>The District Court overemphasizes and misidentified the individual issues that may exist.</u>

The specific individual issues identified by the District Court were either

legally irrelevant or overemphasized, and do not confound case management to the extent that would justify denial of class certification. The District Court enumerated the specific "individual issues of causation" that it determined weighed against class treatment to be: (1) determination of the specific ECT device used on each putative plaintiff; (2) the experience, knowledge and method of administration of ECT treatment of each treating physician; (3) the specific injury experienced by each plaintiff; and (4) whether the treatment, in fact, caused the injury. Dkt. 50 (Order p. 3). The District Court also noted that "affirmative defenses may apply depending on each claimant's specific factual scenario." See Dkt. 50 (Order p.3). These conclusions are drawn without reference to their legal relevance, are inaccurate, and constitute an abuse of judicial discretion.

First, as taken in turn, identifying the particular ECT device that was used on each putative plaintiff is not relevant to liability. ECT devices are defined in the FDA's regulations without reference to any specific manufacturer, and any ECT device on the market since 1976 must be "substantially equivalent" to the pre-1976 devices, and to each other. *See* Dkt. 38-4. Every device must have the same intended use – the inducement of a grand mal seizure through application of electricity to the cranium (21 C.F.R. § 882.5940) and must not differ in technological characteristics in a way that affects safety or effectiveness. ECT devices as defined in 21 C.F.R. § 882.5940 are fungible, especially in terms of the unwarned adverse safety risks they present.

Moreover, this is a case in which cross-manufacturer liability should be invoked under California law. Plaintiffs introduced evidence and made arguments to that effect, but the District Court did not address the evidence or arguments. *See* Dkt. 38 (Reply at pp. 3-4).

Second, no individual inquiry into the administering of ECT treatment is legally relevant for partial certification. Plaintiffs' claim that all ECT devices deliver electrical current to the cranium that is sufficient to induce a grand mal seizure and that, by its very design, causes craniocerebral trauma. See Dkt. 39 (Second Amended Complaint, ¶¶2-3). The physician's knowledge, experience or method of delivery does not come into play as the grand mal seizure is both the intent and mechanism of injury. *See* Dkt. 38 (Reply at pp. 5-6).

Defendants' failure to comply with regulatory mandates and failure to report adverse events mean that *all* ECT patients were injured in a qualitatively uniform fashion and that *no* patients received proper warning about the craniocerebral trauma resulting from ECT treatment. *See* Dkt. 26-2, PA 086, 088 (Breggin at ¶¶ 20, 27)

Moreover, no physician has discretion to withhold warning of craniocerebral trauma resulting from ECT. *See Cobbs v. Grant*, 8 Cal.3d 229, 244 (1972). Conveyance of a warning to patients of information relating to such an unavoidable adverse safety risk would have been legally required, had Defendants reported the information to the FDA. *Id.*

Third, regardless of the specific injury or extent of injury suffered by each plaintiff, every putative class member suffered craniocerebral trauma. Dkt. 38-3 (Dolan at ¶ 8). To the extent that the damages among individuals differ, this is not a reason to deny class certification. *See, e.g. Leyva v. Medline Indus. Inc.,* 716 F.3d 1161, 1164 (9th Cir. 2013).

Fourth, the extent of injury suffered by any individual patient, or the notion that perhaps some patients somehow escaped injury, is not a sufficient reason to deny class certification. *Jimenez v. Allstate Ins. Co.,* 765 F.3d 1161, 1164 (9th Cir. 2014); *Kamakahi v. American Society for Reproductive Medicine*, 305 F.R.D. 164, 187-88 (N.D. Cal. 2015).

Finally, individualized affirmative defenses do not defeat class certification, especially not the statute of limitations defense in the context of a uniform omission or equitable estoppel, as is applicable here. *See* 2 NEWBERG ON CLASS ACTIONS § 4:57 n.2 ("The doctrine of fraudulent concealment . . . often applies to most or all class members."). Moreover, the defense of voluntary assumption of the risk is not available in cases featuring violation of a safety statute or regulation designed to protect a class of persons unable to ensure their own safety for reasons of bargaining inequality or lack of knowledge. *Ford v. Gouin,* 3 Cal. 4th 339, 355-356 (1992).

3. <u>The District Court concluded that putative class members have a strong interest in proceeding individually without addressing Plaintiffs' evidence or arguments to the contrary.</u>

Plaintiffs showed that the putative class members have a strong interest in proceeding as a class. Dkt. 38-2 (Schwartzkopff at ¶8)*;* Dkt. 26 (Cert. Mtn. at pp. 15-16, 18). Without certification it is highly improbable that injured ECT patients will have the ability or financing to bring individual lawsuits. Given the four (4) decades of continuous regulatory noncompliance, the astoundingly large number of ECT treatments still administered each year, and the absence of individual litigation pursued to vindicate the rights of patients injured by ECT devices, there are clear signs that class treatment is necessary and in the interests of justice, and that failure to certify this class would be a "death knell" to the putative plaintiffs.

Despite this, the District Court concludes in the abstract that, "[g]iven the severity of the injury alleged, putative class members would have a strong interest in individually controlling their own separate actions and potential recovery." *See* Dkt. 50 (Order p. 3). There is no alleged or factual support for this conclusion. It is argued that all putative class members sustained injury resulting from an induced grand mal seizure. The extent of the injuries, however, will vary by plaintiff and is subject to proof. While some may have extensive damages, many more will likely be injured to a degree that they are not able to find an attorney or pursue redress.

Moreover, as the district court acknowledged, mini-trials for each plaintiff would be conducted after a class trial anyway. This would allow claimants the opportunity to exercise control of their damage claim determinations.

4. The District Court improperly relied on *Zinser v. Accufix* and ignored a clear distinguishing factor.

The District Court cited to *Zinser v. Accufix Research Inst., Inc.,* 253 F.3d 1180, 1192 (9th Cir. 2001) for the proposition that class certification should be denied for lack of superiority where the complexities of class outweigh the benefits.

In *Zinser,* the end of pacemaker lead would break out of the casing after implant causing injury, and the shipping, handling, and manufacturing of each pacemaker affected the manner in which the lead tip would protrude from the casing. Here, each plaintiff received an electric shock to the cranium regardless of the shipping, handling, or manufacturing of the device at issue. *Zinser* is distinguishable on this basis, and Plaintiffs argued to that effect in their Motion. *See* Dkt. 26-1 (Cert.Mtn. 17:13-20).

B. The District Court did not properly evaluate whether issue certification under Rule 23(c)(4) would materially advance the disposition of the litigation.

1. The District Court applied the wrong standard in determining the propriety of issue certification.

Fed. R. Civ. P. 23(c)(4) authorizes class treatment for common issues, even absent predominance. *See Valentino v. Carter-Wallace, Inc*., 97 F.3d 1227, 1234 (9th Cir. 1996). Here, Plaintiffs sought issue certification of the significant common issues. The District court declined to partially certify this class because "causation – and by extension – liability, involve more individual questions than common ones." Dkt. 50 (Order p. 3). This conclusion is manifestly erroneous.

To determine whether issue certification is appropriate, the relevant inquiry is whether resolution of common issues would *materially advance the disposition of the litigation*. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) §22.75; *See also Kamakahi*, 305 F.R.D. at 193, *citing Valentino v. Carter-Wallace, Inc*., 97 F.3d 1227, 1229 (1996).

Instead of engaging in this evaluation, the District Court focused only on whether common issues would neatly fall into the category of "liability" as opposed to "damages", and on the number of individual issues that might remain despite issue certification. This approach by the District Court was manifestly erroneous.

First, there is no requirement in Fed. R. Civ. P. 23(c)(4) that common issues fit neatly into categories of "liability", and that individual issues fit neatly into the category of "damages." *See* Fed. R. Civ. P. 23(c)(4). It is improper to insert new requirements that are unmentioned in the Rule. *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1125-26 (9th Cir. 2017).

Second, even one significant common liability-related issue can suffice. *See Wright et al.*, FED PRAC & PROC. § 1790. District Courts have found that the common issue of whether a defendant violated a particular law is appropriate for partial certification even absent certainty of injury to every class member. *See, e.g.*, *Kamakahi v. Am. Soc'y for Reprod. Med*., 305 F.R.D. 164, 188 (N.D. Cal. 2015).

2. <u>The District Court greatly understated the significance of the common issues.</u>

The District Court concluded that there are "very discrete portions of each individual case" that can "theoretically be handled as a class" but that issue certification would be impractical and the time saved would be "insignificant." Dkt. 50 (Order p.4). This is manifestly erroneous. The significant common issues include, *inter alia:* (1) Defendants' regulatory noncompliance - the entire course of Defendants' conduct giving rise to liability for resulting injury; (2) generic causation of craniocerebral trauma resulting from ECT - the undisclosed risk at issue in this action; and (3) federal preemption.

Should Defendants prevail on any one of these three outcome-determinative issues, the litigation is over. These issues are fundamental, will take up the vast majority of time in each trial, will clarify individual issues in mini-trials, and will be hard-fought. In terms of litigation costs, Defendants and the judicial system would benefit profoundly from not having to repeatedly adjudicate these common issues in hundreds, if not thousands of individual lawsuits. *See Butler v. Sears, Roebuck & Co*., 727 F.3d 796, 799 (7th Cir. 2013); *Jenkins v. Raymark Industries, Inc*., 782 F.2d 468, 473 (5th Cir. 1986).

Finally, after a class trial, the scope of individual issues left for resolution in mini-trials would be drastically reduced. On an adulteration or misbranding theory, the only issue remaining in the case-in-chief would be the extent of injury resulting from electrical brain trauma. On a failure-to-report theory, the only issues remaining in the case-in-chief would be whether adverse event information,

had Defendants timely reported them, would have reached individual psychiatrists in time to prevent injury, and the extent of injury sustained. This would greatly facilitate case management. *See id* (noting that such a bifurcated approach would obviate the need for days of the same exhibits and witnesses from trial to trial).

3. The District Court erroneously analogized this case to *In re N. Dist. of Cal. Dalkon Shield IUD Prod. Liab. Litig.* and ignored clear distinguishing factors.

The District Court analogized this case to *In re N. Dist. of Cal., Dalkon Shield IUD Prod. Liab Litig.*, 693 F.2d 847 (9th Cir. 1982). Dkt. 50 (Order p.4). This case, however, is distinguishable. In *Dalkon Shield*, the plaintiffs presented theories of negligence, strict liability, breach of warranty, conspiracy, and fraud. ECT devices are not implants. Importantly, plaintiffs in *Dalkon Shield* did not assert any claims based on defendant's failure-to-report to the FDA. The claim was premised on, among other claims, a traditional failure to warn individual physicians and/or patients. *Id*. This essential difference in the claims asserted drives the analysis, creating material distinguishing factors between this action and *Dalkon Shield*, which were glossed over or ignored by the District Court.

Here, Plaintiffs have asserted negligence and strict liability, based only on failure to report adverse events to the FDA and adulteration/misbranding. *See Coleman v. Medtronic, Inc.*, 223 Cal.App.4th 413 (9th Cir. 2014). Plaintiffs have not asserted any claims requiring proof of "reliance" or *any* particular warranty made to individual plaintiffs. The relevant inquiry for purposes of partial certification is

not individually focused on the Plaintiffs, but rather on the conduct of the Defendants in failing to report through the mandated *singular, centralized governmental adverse event reporting scheme*. That adverse event information would have been displayed in the FDA's adverse event database, which by design, is to effectively warn the medical profession of the relevant adverse risks. This scheme, common to every putative class member, is exactly what Defendants have avoided for nearly 40 years.

In that sense, the relationship between the government and the ECT manufacturers (which establishes duty and breach of duty for each and every putative class member's claim) is more analogous to the situation in *In re Agent Orange Product Liability Litigation* than it is to the highly individualized relationships between manufacturer and physician/patient presented by *Dalkon Shield*. *Dalkon Shield*, 693 F.2d 847, 853 (9th Cir. 1982) , *citing In re Agent Orange Product Liability Litigation,* 506 F.Supp 762 (E.D.N.Y. 1980).

III. CONCLUSION

For all the foregoing reasons, including Defendants' unambiguous disregard for the FDA's regulatory scheme and the potential to vindicate this historically scorned class of plaintiffs, this Rule 23(f) petition for permission to appeal should be granted by this Court.

Respectfully submitted,

DATED: April 2, 2018

By: *<u>/s/ David M. Karen</u>*

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PROOF OF SERVICE

Case Name: **Jose Riera, et al. v. Mecta Corporation, et al.**
Case Number: **Ninth Circuit Case Number 18-_____**
U.S. District Court Case No. 2:17-CV-06686-RGK-PJW

I, the undersigned hereby declare, as follows:

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

On April 2, 2018, I served the foregoing document described as: **PLAINTIFFS' RULE 23(F) PETITION FOR PERMISSION TO APPEAL ORDER DENYING MOTION FOR CLASS CERTIFICATION** on all interested parties in this action by place a true copy thereof enclosed in sealed envelopes addressed as follows:

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__x__ **BY E-MAIL OR ELECTRONIC TRANSMISSION:** On April 2, 2018, I caused the documents to be sent to the persons at the e-mail addresses listed above. I did not receive, within a reasonable period of time after the transmission, any electronic message or other indication that the transmission was unsuccessful.

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I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the law of the United States of America that the above is true and correct. Executed on April 2, 2018, at Thousand Oaks, California.

/s/ Elvira Abdon
Elvira Abdon, Declarant

No. 18-_____

In the

United States Court of Appeals

for the

Ninth Circuit

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

Plaintiffs-Petitioners,

vs.

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

Defendants-Respondents.

Appeal from an Order of the United State District Court for the Central District of California, Case No. 2:17-cv-06686-RGK-PJW

ORDER SUBJECT TO APPEAL

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK-PJW	Date	March 19, 2018
Title	***RIERA ET. AL. v. MECTA CO. ET. AL.***		

Present: The Honorable	R. GARY KLAUSNER, UNITED STATES DISTRICT JUDGE	
Sharon L. Williams (Not Present)	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendant:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS)** Order Re: Plaintiffs' Motion for Class Certification

I. INTRODUCTION

On November 7, 2017, Marcia Benjamin, Daniel Benjamin, Jose Riera, Michelle Himes, Diane Scurrah, and Deborah Chase (collectively "Plaintiffs"), individually and on behalf of all others similarly situated, filed a First Amended Complaint ("FAC") against Mecta Corporation and Somatics LLC (collectively "Defendants") alleging (1) negligence/negligence per se; (2) strict product liability—marketing and information defect—failure to warn; and (3) loss of consortium.

On December 10, 2017, Plaintiffs filed the current Motion for Class Certification, continued by stipulation to March 12, 2018.

On March 6, 2018, Plaintiffs filed a Second Amended Complaint ("SAC") to include the spousal loss of consortium subclass in the proposed class definition, as Plaintiffs do in their Motion for Class Certification. In the FAC, Plaintiffs had inadvertently included such spouses in the same class as those who received ECT treatment.

For the following reasons, the Court **DENIES** Plaintiffs' Motion.

II. FACTUAL BACKGROUND

Plaintiffs allege the following in the SAC:

Defendants are the only U.S. manufacturers of electroconvulsive therapy ("ECT") devices. ECT devices are used for treating patients with severe psychiatric disturbances by applying a brief intense electrical current to the patient's head to induce a major motor seizure. Defendants failed to comply with statutory obligations to report or address information about the safety and effectiveness of the device. As a result, ECT devices have never satisfied premarket approval standards required of such medical devices. Moreover, Defendants' failure to warn the FDA of the devices' risks left the public, including medical providers and members of the putative class, without information about its dangers.

Plaintiffs are six California citizens who seek to represent a proposed class of:

1) All individuals in the United States who received ECT shock treatment in California after May 28, 1982, administered by an ECT shock device that was manufactured, sold and/or distributed by Defendants after May 28, 1982, and who suffered an injury as a result thereof, with the exception of [government entities, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members].
2) All spouses of such individuals that have suffered related loss of consortium damages.

Plaintiffs allege that they and members of the putative class are suffering from concussive brain trauma and varying degrees of ensuing physiological, psychological and emotional trauma including skin burns, permanent brain damage, severe permanent cognitive and memory impairment, broken teeth, prolonged seizures, myocardial infarction, ruptured bowels, acute and/or chronic organic brain syndrome, complete neurological collapse, and sometimes death, secondary to ECT shock treatment.

III. JUDICIAL STANDARD

For the Court to grant class certification, the plaintiff must establish that the following elements have been established pursuant to Federal Rule of Civil Procedure ("Rule") 23(a): (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation. Fed. R. Civ. P. 23(a); *see Hanlon et. al. v. Chrysler Co. et. al.*, 150 F.3d 1011, 1019 (9th Cir. 1998). Plaintiff must also satisfy one of the requirements under Rule 23(b). *Wang v. Chinese Daily News, Inc.*, 623 F.3d 743, 753 (9th Cir. 2010).

IV. DISCUSSION

Plaintiffs argue that their proposed class satisfies the requirements of Rules 23(a) and 23(b)(3). They also argue that even if common issues do not predominate as required by Rule 23(b)(3), the Court should certify certain issues for class treatment under Rule 23(c)(4). For the following reasons, the Court finds Plaintiffs' class does not satisfy Rule 23(b)(3), and issue certification is not appropriate. [1]

A. Plaintiffs Have Not Satisfied the Requirements of Rule 23(b)

Plaintiffs seek class certification under Rule 23(b)(3), which provides that a class may be certified if "the court finds that questions of law and fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods." Fed. R. Civ. P. 23(b)(3).

In assessing superiority, courts can consider "(A) the class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by or against class members: (C) the desirability or

[1] Because the Court finds the Class falls short of satisfying Rule 23(b), it need not consider whether it satisfies Rule 23(a).

undesirability of concentrating the litigation of the claims in the particular forum; and (D) the likely difficulties in managing a class action." *See id.*

Here, those factors weigh against class action treatment. *See Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1192 (9th Cir.), *opinion amended on denial of reh'g*, 273 F.3d 1266 (9th Cir. 2001) (holding that "when the complexities of class action treatment outweigh the benefits of considering common issues in one trial, class action treatment is not the 'superior' method of adjudication").

First, a class action would not be manageable because the Court would have to conduct mini-trials to resolve individual issues of causation including which ECT device was used on each claimant; the experience, knowledge and method of administration of ECT treatment of each claimant's treating physician; the specific injury experienced by each claimant; and whether the treatment, in fact, caused the injury. Moreover, affirmative defenses may apply depending on each claimant's specific factual scenario.[2] *See* Fed. R. Civ. P. 23(b)(3)(D).

It is true that 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.*, 844 F.3d 1121, 1127-28 (9th Cir. 2017). Rather, courts should "balance the benefits of class adjudication against its costs." *Id.* at 1128. In *Briseno*, which involved a putative class action against a cooking oils manufacturer, the Ninth Circuit held that administrative feasibility was not required for certification. *Id.* at 1126. However, the court reasoned that in cases like *Briseno* involving inexpensive consumer goods, there is "no realistic alternative to class treatment." *Id.* at 1128.

Here, manageability is not the only 23(b)(3) factor that militates against class action treatment. Unlike *Briseno*, this case does not involve inexpensive consumer goods but rather damages for harm by 'shock treatment' to the brain. Given the severity of injury alleged, putative class members would have a strong interest in individually controlling their own separate actions and potential recovery. *See* Fed. R. Civ. P. 23(b)(3)(A).

Considering the significant incentive putative class members would have to file individual lawsuits and the myriad individual issues that would render this case unmanageable as a class action, class treatment is not superior to other methods of resolving the dispute. *See* Fed. R. Civ. P. 23(b)(3). As such, the action cannot be certified for class treatment. *See* Fed. R. Civ. P. 23(a)-(b).

B. Issue Certification Under Rule 23(c)(4) Is Inappropriate

Plaintiffs additionally argue that even if common issues do not predominate over individual ones, certain issues should be certified for class treatment under Rule 23(c)(4). The Court disagrees.

[2] The presence of these individual issues is also relevant to the predominance requirement. The Court is not persuaded that common issues predominate over the many individual issues in this action. However, because the Court finds the putative class action does not satisfy superiority, the Court need not formally assess predominance, as Rule 23(b)(3) requires both.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

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Rule 23(c)(4) states that "[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues." Fed. R. Civ. P. 23(c)(4). The Ninth Circuit has interpreted this rule as authorizing the district court to isolate the common issues and proceed with class treatment of those particular issues even if common questions do not predominate such that class certification of the entire action is warranted. *See Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1234 (9th Cir. 1996).

Here, Plaintiffs argue that all issues pertinent to Defendant's liability can be resolved through common proof of regulatory noncompliance. As such, they move the Court to certify the issues of liability and punitive damages for class treatment under Rule 23(c)(4). As discussed above, however, causation—and by extension, liability—involve more individual questions than common ones.

While there may be very discrete portions of each individual case that could theoretically be handled as a class, the Court finds this impractical. In *In re N. Dist. of Cal., Dalkon Shield IUD Prod. Liab. Litig.*, 693 F.2d 847 (9th Cir. 1982), *as amended* (July 15, 1982), the court assessed superiority. *Id.* at 856. In so doing, the court considered how severing and litigating certain portions of liability would affect the action. *Id.* However, the court rejected issue certification, reasoning that "[t]he few issues that might be tried on a class basis in this case, balanced against issues that must be tried individually, indicate that the time saved by a class action may be relatively insignificant." *Id.* "A few verdicts followed by settlements might be equally efficacious." *Id.* Here, given the number of individual issues, issue certification is similarly inappropriate. *See* Fed. R. Civ. P. 23(c)(4).

V. CONCLUSION

For the foregoing reasons, the Court **DENIES** Plaintiff's Motion for Class Certification.

IT IS SO ORDERED.

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Initials of Preparer _____