No. 21-55517

S273887

In the

United States Court of Appeals

for the

Ninth Circuit

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN;

Plaintiffs-Appellants,

vs.

SOMATICS, LLC,

Defendant-Respondent.

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

APPELLANTS' EXCERPTS OF RECORD
VOLUME 1 OF 6

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; DEBORAH CHASE; MICHELLE HIMES; DIANNE SCURRAH; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

vs.

MECTA CORPORATION; SOMATICS, LLC,

Defendants.

Case No.: 2:17-CV-06686-RGK-JCx

~~[PROPOSED]~~
FINAL JUDGMENT

This Court, based on its May 14, 2021 Order Re: Defendant's Motion for Summary Judgment [DE 278], and good cause appearing, HEREBY ORDERS, ADJUDGES AND DECREES AS FOLLOWS:

1. Final Judgment is entered against Plaintiffs MICHELLE HIMES, MARCIA BENJAMIN and DANIEL BENJAMIN ("Plaintiffs"), pursuant to the Court's May 14, 2021 Order [DE 278], dismissing Plaintiffs' third and fourth claims with prejudice and granting summary judgment in favor of Defendant, SOMATICS LLC ("Somatics"), with respect to Plaintiffs' remaining claims.

IT IS SO ORDERED, ADJUDGED AND DECREED.

Dated: May 21, 2021

Gary Klausner

Hon. R. Gary Klausner
UNITED STATES DISTRICT COURT

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-cv-06686-RGK-JC	Date	May 14, 2021
Title	***Jose Riera et al v. Mecta Corporation et al***		

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

Proceedings: **(IN CHAMBERS) Order Re: Defendant's Motion for Summary Judgment [DE 231]**

I. INTRODUCTION

On June 15, 2020, Plaintiffs Michelle Himes, Diane Scurrah,[1] Marcia Benjamin ("M. Benjamin"), and Daniel Benjamin ("D. Benjamin") filed the operative Fifth Amended Complaint ("5AC") against Somatics, LLC ("Somatics," or "Defendant). Plaintiffs assert claims that arise from injuries that Himes and M. Benjamin allegedly sustained as a result of electroconvulsive therapy that was administered to them by doctors using devices designed and manufactured by Defendant. D. Benjamin asserts a related claim for the loss of consortium of his wife, M. Benjamin.

Presently before the Court is Defendant's Motion for Summary Judgment. ("Motion") (ECF No. 231). For the reasons that follow, the Court **GRANTS** Defendant's Motion.

II. FACTUAL BACKGROUND

The following facts are undisputed unless otherwise noted:

Electroshock or electroconvulsive therapy ("ECT") is the practice of inducing grand mal motor seizure through application of electricity to the brain. (Pls.' Additional Separate Statement of Uncontroverted Facts ("SUF") ¶ 1, ECF No. 239-1).

[1] The Court subsequently dismissed Scurrah's claims with prejudice pursuant to a stipulated dismissal, (ECF No. 220); she is no longer a party to this suit.

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-cv-06686-RGK-JC	Date	May 14, 2021
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In the 1980s, Richard Abrams, M.D. and Conrad Swartz, M.D., founded Somatics for the purpose of developing their own ECT machine. (*Id.* ¶ 8). Somatics subsequently designed and manufactured an ECT machine called the Thymatron System IV. Himes and M. Benjamin both underwent ECT administered by doctors using Defendant's Thymatron System IV. Himes received ECT from Dr. Raymond Fidaleo ("Dr. Fidaleo"), and M. Benjamin received ECT from Dr. Michael Frankel ("Dr. Frankel). (Pls.' Statement of Genuine Disputes of Material Fact ("SGD") ¶¶ 8, 10–11, ECF No. 239-1).

Somatics has never conducted any clinical trials of its Thymatron System IV device to determine its safety and efficacy. (Pls.' SUF ¶ 12). Over the years, Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death associated with ECT. (*Id.* ¶ 24). Somatics never investigated these complaints, nor did it submit adverse events to the FDA or warn physicians and consumers of these risks. (*Id.* ¶ 25).

A. Plaintiff Himes

Plaintiff Himes has been hospitalized on various occasions for depression and suicidal ideation. (*Id.* ¶ 96). In April 2011, Himes enrolled in an inpatient program at Sharp Mesa Vista Hospital and began treatment with Dr. Fidaleo. (*Id.* ¶ 98). Dr. Fidaleo determined that ECT was appropriate for Himes, and he began discussing this treatment option with her. (*Id.* ¶ 100). Himes asserts that the only warnings she received from Dr. Fidaleo regarding the dangers of ECT concerned the risk of short-term memory loss, and a warning that she may experience confusion due to the administration of anesthesia. (*Id.* ¶¶ 102–03). Defendant asserts that Dr. Fidaleo also warned Himes of a risk of permanent memory loss. (Def.'s Response to Pls.' Additional Separate Statement ¶ 103, ECF No. 242-1). Dr. Fidaleo proceeded to administer 26 ECT treatments to Himes from April 13, 2011, to January 3, 2012. (Pls.' SUF ¶ 107).

Himes alleges that as a result of her ECF treatment, she suffers from severe physiological, psychological, and emotional injuries, including but not limited to permanent brain dysfunction, severe permanent cognitive and memory impairment, lasting short-term memory difficulties, and complete neurological collapse. (5AC ¶¶ 5, 33). Though she received her last ECT treatment on January 3, 2012, Himes did not suspect that her injuries were caused by ECT until 2017, when she began researching the effects of ECT online. (Pls.' SUF ¶¶ 123–25). Before researching ECT, Himes attributed her memory difficulties to various psychiatric medications that she had taken. (*Id.* ¶ 121). Himes then sought legal counsel and filed this action on September 11, 2017.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

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B. Plaintiff M. Benjamin

In March 2011, M. Benjamin visited the emergency room after experiencing dizziness, discomfort, and chest pain. (*Id.* ¶ 52). There, she was diagnosed with severe anxiety and prescribed Xanax. (*Id.* ¶ 53). M. Benjamin then sought treatment with a psychiatrist, Dr. Gudeman, who increased her Xanax dosage and eventually switched her prescription to Klonopin. (*Id.* ¶¶ 54, 55, 60). Klonopin made her feel worse, and the symptoms that she experienced from the drug were so severe that she was not able to walk. (*Id.* ¶ 61). Dr. Gudeman then informed M. Benjamin that, because she had not responded well to previous medications, ECT was her next treatment option. (*Id.* ¶ 62).

In September 2012, Dr. Gudeman referred M. Benjamin to Dr. Frankel at Northridge Hospital for an ECT consult. (*Id.* ¶ 63). When M. Benjamin and her husband, D. Benjamin, met with Dr. Frankel to discuss ECT, Dr. Frankel told them that ECT was a safe, easy, outpatient procedure that took only 20 minutes. (*Id.* ¶ 64). Plaintiffs assert that Dr. Frankel only informed the Benjamins that the side effects of ECT included some confusion right after treatment and short-term memory loss that would be temporary. (*Id.* ¶ 65). Defendant disputes this fact because "Dr. Frankel testified that he also tells his patients that there is a risk of permanent memory loss." (Def.'s Response to Pls.' Additional Separate Statement ¶ 65).

From September 28, 2012 to March 4, 2013, Dr. Frankel administered 20 ECT treatments to M. Benjamin. (Pls.' SUF ¶ 68). During this period, M. Benjamin complained of memory problems, but Dr. Frankel assured her that these were temporary side effects of ECT that were to be expected. In response to her complaints, Dr. Frankel prescribed further ECT sessions. (*Id.* ¶ 69). M. Benjamin alleges that the ECT caused her severe physiological, psychological, and emotional injuries, including but not limited to permanent brain dysfunction, severe permanent cognitive and memory impairment, lasting short-term memory difficulties, complete neurological collapse, and dental trauma. (5AC ¶¶ 5, 28). Had M. Benjamin been adequately warned of the risk of permanent or long-term memory loss, she would not have consented to ECT treatment. (Pls.' SUF ¶ 67).[2] Although her last ECT treatment was on March 4, 2013, and she consulted various doctors in the years that followed, it wasn't until July of 2017 that M. Benjamin was informed by a medical specialist that her neurocognitive injuries and memory issues were due in part to her ECT treatment. (*Id.* ¶¶ 77–93). M. Benjamin and her husband D. Benjamin then filed their lawsuit against Somatics on November 7, 2017.

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[2] Defendant disputes that M. Benjamin was not warned about the risk of long-term and potentially permanent memory loss by Dr. Frankel. (Def.'s Response to Pls.' Additional Separate Statement ¶¶ 65–67).

C. Plaintiff D. Benjamin

Plaintiff D. Benjamin's claim for loss of consortium arises from his allegation that he "suffers a loss of [the] consortium that M. Benjamin offered during the course of their marriage as a result of ECT shock treatment." (5AC ¶ 32). D. Benjamin alleges generally that his "loss of consortium was a direct and proximate result of the Defendant's acts." (*Id.* ¶ 114).

III. JUDICIAL STANDARD

Under Federal Rule of Civil Procedure 56(a), a court may grant summary judgment only where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Facts are "material" only if dispute about them may affect the outcome of the case under applicable substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict for the nonmovant. *Id.*

To prevail on a summary judgment motion, the movant must show that there are no genuine issues of material fact as to matters on which it has the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Such a showing "must establish beyond controversy every essential element" of the movant's claim or affirmative defense. *S. Cal. Gas Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003) (internal quotation marks omitted). On issues where the moving party does not have the burden of proof at trial, the moving party is required only to show that there is an absence of evidence to support the non-moving party's case. *See Celotex*, 477 U.S. at 325. Upon such showing, the court may grant summary judgment "on all or part of the claim." Fed. R. Civ. P. 56(a)–(b).

To defeat a summary judgment motion, the non-moving party may not merely rely on its pleadings or on conclusory statements. *See Celotex*, 477 U.S. at 324. Nor may the non-moving party merely attack or discredit the moving party's evidence. *Nat'l Union Fire Ins. Co. v. Argonaut Ins. Co.*, 701 F.2d 95, 97 (9th Cir. 1983). Rather, the non-moving party must affirmatively present specific evidence sufficient to create a genuine issue of material fact for trial. *See Celotex*, 477 U.S. at 324.

IV. DISCUSSION

Defendant moves for summary judgment as to all five of Plaintiffs' claims. In their Opposition, Plaintiffs state: "in the interest of judicial economy and to streamline the case for trial, [P]laintiffs agree to dismiss the First and Fourth Claims." (Pls.' Opp. to Mot. for Summ. J. at 1, n.1, ECF No. 241). The Court therefore **DISMISSES** with prejudice Plaintiffs' first and fourth claims. Accordingly, three claims remain. Plaintiffs' second and third claims are for negligence and strict liability arising from Somatics' alleged failure to warn of the risks associated with its Thymatron System IV. The fifth claim alleged in

the operative complaint is D. Benjamin's claim for loss of consortium resulting from "Defendant's acts." (5AC ¶ 114).

Defendant moves for summary judgment on two grounds. First, Defendant argues that Plaintiffs' claims are barred by the applicable two-year statute of limitations. Second, Defendant argues that under California's learned intermediary doctrine, Defendant may not be held liable for its failure to warn Plaintiffs of the dangers associated with ECT and the Thymatron System IV. Because the Court determines that Defendant is entitled to summary judgment under the learned intermediary doctrine, the Court does not reach Defendant's statute of limitations argument.

1. *The Learned Intermediary Doctrine*

Under the learned intermediary doctrine, manufacturers of drugs and medical devices owe a duty to warn of the dangers associated with their products to physicians, but not to patients. *See Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187 n.10 (2016); *Carlin v. Superior Ct.*, 13 Cal. 4th 1104, 1116 (1996) ("[I]n the case of prescription drugs, the duty to warn runs to the *physician*, not to the patient."); *Bigler-Engler v. Breg, Inc.*, 7 Cal. App. 5th 276, 319 (2017) ("The learned intermediary doctrine . . . has been extended in California to implantable medical devices in addition to prescription drugs."). A manufacturer discharges this duty to warn by "provid[ing] adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990–91 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004)). The rationale for this doctrine, as outlined by California courts with reference to prescription drugs, is as follows:

> (1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

Bigler-Engler, 7 Cal. App. 5th at 319 (quoting *Fogo v. Cutter Laboratories, Inc.*, 68 Cal. App. 3d 744, 754–755 (1977)).

The learned intermediary doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship[,]" *Webb*, 63 Cal. 4th at 187 n.10, but "does not apply to

medical devices . . . which require the patient to use and apply the medical device themselves." *Bigler-Engler*, 7 Cal. App. 5th at 319. Where the doctrine applies, a plaintiff who asserts claims "based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *See Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017) (quoting *Motus*, 196 F. Supp. 2d at 991). "[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." *Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004).

The Court concludes that the learned intermediary doctrine applies to Plaintiffs' failure to warn claims arising from injuries caused by Defendant's Thymatron System IV.[3] M. Benjamin and Himes received ECT treatment from their respective doctors in a hospital setting. M. Benjamin's ECT was administered by Dr. Frankel at Northridge Hospital from September 28, 2012 to March 4, 2013, and Hime's ECT was administered by Dr. Fidaleo at Sharp Mesa Vista Hospital from April 13, 2011 to January 9, 2012. (Pls.' SGD ¶¶ 8, 10). Because M. Benjamin and Himes were treated with the Thymatron System IV by their doctors in a hospital setting, the learned intermediary doctrine applies. *See Webb*, 63 Cal. 4th at 187 n.10 (The learned intermediary doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship."); *cf. Bigler-Engler*, 7 Cal. App. 5th at 319 (declining to apply the learned intermediary doctrine to a device because it was "the patient who must play an active role in treating herself with the device, including by operating the device herself."); *Dreifort v. DJO Glob. Inc.*, No. 3:18-CV-02393-BTM (KSC), 2019 WL 5578240, at *8 (S.D. Cal. Oct. 28, 2019) (declining to apply the doctrine because the medical device at issue was "intended to be operated by the patient without medical assistance."). Further, application of the doctrine in this context is consistent with the three rationales underlying the doctrine. *See Bigler-Engler*, 7 Cal. App. 5th at 319.

Plaintiffs, relying on *Hill v. Novartis Pharmaceuticals Corp.*, 944 F. Supp. 2d 943, 953–54 (E.D. Cal. 2013), argue that the learned intermediary doctrine is inapplicable because Defendant did not provide any warnings to Plaintiffs' ECT doctors, (Pls. Opp. to Def.'s Mot. for Summ. J. at 16), and the doctrine "applies only if a manufacturer provided adequate warnings to the intermediary." *Hill*, 944 F.

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[3] Though Plaintiff D. Benjamin's claim for loss of consortium is not expressly styled as a claim for failure to warn, he alleges that his injury was "a direct and proximate result of the Defendant's acts." (5AC ¶ 114). Because the only other operative claims in this case are premised on Defendant's alleged failure to warn about the dangers of its Thymatron System IV, the Court concludes that D. Benjamin's claim for loss of consortium is "based on a failure to warn" for purposes of the learned intermediary doctrine.

Supp. 2d at 953. This argument fails. *Hill* draws the rule that the learned intermediary doctrine "applies only if a manufacturer provided adequate warnings to the intermediary" from a California Court of Appeals case that addressed the *sophisticated* intermediary doctrine—not the learned intermediary doctrine. *See Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23, 29 (2010) ("[T]he sophisticated intermediary doctrine, . . . where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary."). Moreover, *Stewart* has since been overturned on that very point. *See Webb*, 63 Cal. 4th at 188. *Hill* and *Stewart* therefore have no bearing on the applicability of the learned intermediary doctrine to the case at bar.

2. *Application*

Because the learned intermediary doctrine applies, to prevail on their claims Plaintiffs must prove (1) that Somatics did not warn Drs. Frankel and Fidaleo of the risks associated with the Thymatron System IV "or the warning was inadequate," and (2) "that the inadequacy or absence of the warning caused" their injuries. *Wendell*, 858 F.3d at 1238 (citation omitted). The Court now considers whether Plaintiffs have presented specific evidence sufficient to create a genuine issue of material fact as to each factor.

As to the first factor, Plaintiffs assert that it is "undisputed that Somatics did not provide any warnings to [P]laintiffs' ECT doctors, much less any adequate warnings concerning brain injury or permanent memory loss." (Pls.' Opp. to Def.'s Mot. for Summ. J. at 16). Defendant does not dispute this assertion in its Reply brief. The Court therefore assumes for purposes of this Order that Defendant did not provide any warnings to Dr. Frankle and Dr. Fidaleo concerning the risk of brain injury or permanent memory loss. Accordingly, Plaintiffs' have satisfied the first factor.

The second factor that Plaintiffs must prove is that the inadequacy or absence of warnings from Defendant to Plaintiffs' ECT doctors caused Plaintiffs' injuries. To satisfy this burden, Plaintiffs must demonstrate that the non-disclosed risks associated with the Thymatron System IV "was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Motus*, 196 F. Supp. 2d at 995–96 (quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 815 (5th Cir. 1992)); *accord Brown v. Johnson & Johnson*, No. 1:17-CV-01285-AWI (EPG), 2019 WL 2577296, at *9 (E.D. Cal. June 24, 2019); *Guillen v. Eli Lilly & Co.*, 394 F. App'x 814, 816 (2d Cir. 2010) (affirming district court's holding that the plaintiff "failed to demonstrate that her treating physicians would have altered their decision to prescribe Zyprexa had a different warning been provided by [the manufacturer]."). Here, Plaintiffs fail to present specific evidence sufficient to create a genuine issue of material fact as to this factor.

UNITED STATES DISTRICT COURT
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Plaintiffs point to no evidence in the record that suggests that a more detailed warning as to the risks associated with the Thymatron System IV would have changed Dr. Frankle's and Dr. Fidaleo's decisions to administer ECT to M. Benjamin and Himes, respectively. Instead, Plaintiffs argue that "had Somatics issued timely warnings of the risks of brain damage and permanent memory loss, [Drs. Frankle and Fidaleo] would have changed their conduct and would have relayed such warnings and risks to their respective patients[,]" including M. Benjamin and Himes. (Pls. Opp. to Def.'s Mot. for Summ. J. at 19). But whether the doctors would have relayed such warnings and risks to Plaintiffs is not the inquiry—the question is whether the risk of which Defendant failed to warn the doctors "was sufficiently high that it would have changed [their] decision[s] to prescribe the product for the plaintiff[s]." *See Motus*, 196 F. Supp. 2d at 995–96, *aff'd*, 358 F.3d 659 (9th Cir. 2004); *Thomas*, 949 F.2d at 815 (5th Cir. 1992); *Guillen*, 394 F. App'x at 816 (2d Cir. 2010). Because Plaintiffs fail to present specific evidence sufficient to create a genuine issue of material fact as to this factor, the Court concludes that Defendant is entitled to summary judgment on Plaintiffs' failure to warn claims and related loss of consortium claim. *See Motus*, 358 F.3d at 661 ("[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.").

V. CONCLUSION

In accordance with the foregoing, the Court **DISMISSES** Plaintiffs' third and fourth claims with prejudice and **GRANTS** Defendant's Motion as to Plaintiffs' remaining claims.

IT IS SO ORDERED.

_____ : _____