UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK (PJW)	Date	September 14, 2018
Title	***Jose Riera and Deborah Chase v. Somatics, LLC***		

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 Defendant:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS) Order Re: Plaintiffs' Motion for Partial Summary Judgment and Defendant's Motion for Summary Judgment (DE 79, 80)**

I. INTRODUCTION

On September 11, 2017, Marcia Benjamin ("M. Benjamin"), Daniel Benjamin ("D. Benjamin"), Jose Riera ("Riera"), Michelle Himes ("Himes"), Diane Scurrah ("Scurrah"), and Deborah Chase ("Chase"), individually and on behalf of all others similarly situated, filed a Complaint against Mecta Corporation ("Mecta") and Somatics, LLC ("Somatics") (collectively, "Defendants"). The six Plaintiffs filed a Third Amended Complaint ("TAC") on April 19, 2018. On June 19, 2018, pursuant to a Motion to Dismiss under Federal Rule of Civil Procedure ("Rule") 12(b)(6), the Court dismissed the claims of M. Benjamin, D. Benjamin, Himes, and Scurrah as barred by the statute of limitations, dismissed all claims against Mecta, and dismissed Riera's and Chase's claims against Somatics with leave to amend.

Plaintiffs Riera and Chase (collectively, "Plaintiffs") filed a Fourth Amended Complaint ("FAC") against Somatics on June 26, 2018. The FAC alleges six causes of action for negligence, product liability, and strict liability.

On July 29, 2018, Plaintiffs filed the instant Motion for Partial Summary Judgment on Presumption of Failure to Exercise Due Care on Elements (1) and (4) of California Evidence Code 699, requesting summary adjudication as to two elements of the negligence per se claims. On July 30, 2018, Defendants filed the instant Motion for Summary Judgment as to all claims. For the following reasons, the Court **DENIES** Plaintiffs' Motion in part, **GRANTS** Plaintiffs' Motion in part, **DENIES** Defendant's Motion in part, and **GRANTS** Defendant's Motion in part.

II. FACTUAL BACKGROUND

Somatics is a developer[1] of an electroconvulsive therapy ("ECT") device called the Thymatron System IV ("Thymatron"), which is used to treat severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief but intense electrical current to the patient's head. Somatics is one of only two U.S. manufacturers of ECT devices. Plaintiffs are patients who received ECT from Somatics' devices and now allege that they suffer ECT-induced concussive brain trauma and ensuing physiological, psychological, and emotional injuries including permanent brain dysfunction and memory loss. Riera was first given ECT at Huntington Hospital between April and May 2016, and Chase received ECT at Kaiser Permanente beginning on April 3, 2015 to Spring of 2016.

Specifically, Riera contends that he cannot recall new information, has forgotten past knowledge and skills, and is unable to remember people, events, daily routines, or to process information. Chase contends that she suffers from permanent memory loss and cannot remember significant life events from her children's childhoods or recognize faces and that she experiences anxiety, embarrassment, and distress as a result.

Before receiving ECT, Riera was hospitalized for expressing suicidal ideations and becoming "nonfunctional." He has a history of alcoholism and mild psychomotor retardation. Prior to her ECT treatments, Chase was also hospitalized for symptoms of severe recurrent depression and has a long history of using medications, having difficulty concentrating, and suffering from memory problems.

Plaintiffs seek recovery for injuries resulting from Somatics' alleged negligence in failing to comply with medical device reporting, adulteration, and misbranding obligations of the Food, Drug and Cosmetic Act ("FDCA") and from Somatics' failure to warn consumers of ECT's risks. The FDCA requires medical device manufacturers to report instances of death or serious injury ("adverse events") caused by their devices and to maintain internal controls sufficient to investigate, evaluate, and report potential adverse event complaints.

In relevant part, Plaintiffs allege that Somatics' failure to comply with the FDCA and give adequate warnings caused Plaintiffs to suffer brain injuries from ECT. Had they or their psychiatrists known the risks of "craniocerebral trauma," Plaintiffs would either not have been given or not have agreed to the treatment. (Pl.s' Compl. ¶ 87.) In the alternative, Plaintiffs argue that the Thymatron

[1] Although the parties disagree about whether Somatics manufactures its devices on its own, Somatics acknowledges that Elektrika, Inc. ("Elektrika") fabricates the Thymatron device, which is then sent to Somatics for the final steps in the repackaging process. Mirkovich Decl. ¶ 21 (ECF No. 81-1).

product would not have been sold to their respective hospitals in the first place. Huntington Hospital purchased a Thymatron in 2006 and Kaiser bought one in 2011.

A. Adverse Event Reports and Complaints

Somatics does not dispute that it has never reported an adverse event to the FDA. However, Somatics maintains that it has investigated complaints regarding potential adverse events but has not yet received a complaint sufficiently serious or credible to report. (Mirkovich Decl. ¶¶ 7–9, ECF No. 81-1.) Plaintiffs, on the other hand, contend that Somatics had notice of adverse events and failed to report them in violation of the FDCA.

Specifically, Somatics did not report adverse events from the publicly-accessible Manufacturer and User Facility Device Experience ("MAUDE") database. Somatics maintains that it monitors the database and has not received information necessitating a report. (Mirkovich Decl. ¶¶ 8–10, Ex. B, ECF No. 81-3.)

1. 1995 Order

An FDA Order in 1995 required Somatics to submit information related to the safety and efficacy of its ECT device by August 1997. Although Plaintiffs contend that Somatics did not respond to this Order based on the absence of a record of a response, *see* Karen Decl. Ex. G (ECF No. 79-12), Somatics presents evidence that they did respond to the Order, *see* Abrams Decl. ¶ 3 (ECF 81-4). Regardless, the FDA did not contact Somatics seeking further information. (*Id.* ¶ 6.)

2. 2009 Public Docket

In 2009, the FDA opened a public docket to collect comments on the classification of ECT devices.[2] *See* 74 Fed. Reg. 46607 (Sep. 10, 2009). By 2010, the docket had yielded over 3,000 comments about ECT containing reports of death, brain damage, and memory loss. The FDA issued an Executive Summary of the complaints in 2011. Somatics reviewed the comments but contends that it did not have sufficient information to investigate further or file a report. (Mirkovich Decl. ¶¶ 15–18, ECF No. 81-1.)

[2] The FDA classifies the Thymatron as a "Class III" device. At the time of the 2009 docket, the FDA was considering reclassifying it from a Class III to a Class II device but did not ultimately choose to do so. *See* 80 Fed. Reg. 81226 (Dec. 29, 2015).

The parties disagree about whether the complaints in the public docket were severe enough to require adverse event reports. (*Compare* Makowski Decl. ¶ 14, ECF No. 81-5, *with* Mirkovich Decl. ¶¶ 14–17, ECF No. 81-1.) Somatics believes that the complaints were politically motivated "anti-ECT propaganda aimed at defeating the FDA's recommendation to declassify ECT devices" and thus unreliable. (Mirkovich Decl. ¶ 14, ECF No. 81-1.) Plaintiffs, on the other hand, argue that Somatics had sufficient information to investigate and that the complaints were reportable. (*See* Arrowsmith Decl. ¶¶ 6–13. ECF No. 79-3.) Somatics admits that it did not investigate any of the complaints.

B. 2012 and 2016 Facility Inspections

In 2012, the FDA inspected the Somatics facility and observed that Somatics' written Medical Device Reporting ("MDR") procedures were inadequate with respect to the timely and effective identification and evaluation of adverse events. At the end of the inspection, the FDA official issued Somatics an FDA Form 483 with a list of "objectionable observations."[3] (Makowski Decl., Ex. B, 0012. ECF No. 81-7.)

An FDA inspector returned in 2016 for a facility inspection and determined that "the firm had made corrections" and no further action was required. (Makowski Decl., Ex. C 0039, ECF No. 81-8.) However, the inspector flagged a patient skin burn complaint that was caused by a Thymatron in 2013 that Somatics should have documented and submitted as an MDR. Although Somatics had responded to the complaint in a letter to the FDA, the event constituted a serious injury and thus required an official report. (Makowski Decl., Ex. C 0043, ECF No. 81-8.) Notably, however, the inspector "did not include this deviation on the FDA-483 since the FDA had been made aware of this event" through Somatics' letter and did not need more information on the specific skin burn. *Id.*

Somatics has not received a regulatory sanction from the FDA. At the end of the 2016 inspection, the FDA inspector warned Somatics that if it did not take corrective action to address objectionable observations, the "FDA *can* take such actions as issuance of Warning Letter or seizure of product." (Makowski Decl., Ex. C 0049, ECF No. 81-8 (emphasis added).) It has not yet chosen to do so. Plaintiffs only offer evidence that a manufacturer who fails to report adverse events "*should* be found in violation of its reporting and investigatory responsibilities" under the FDCA. (Arrowsmith Decl., ¶ 14, ECF No. 79-3.)

[3] The FDA Form 483 lists objectionable observations and indicates that the produce or manufacturer may be in violation of the FDCA. *See* U.S. Food and Drug Administration, *Inspections, Compliance, Enforcement, and Criminal Investigations: Inspection Observations*, https://www fda.gov/iceci/inspections/ucm250720.htm (last accessed September 4, 2018).

III. JUDICIAL STANDARD

Pursuant to Federal Rule of Civil Procedure 56(a), a court may grant summary judgment 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). Rule 56(a) also provides for summary judgment on "part of each claim or defense." *Id.* To prevail on a summary judgment motion, the moving party must show that there are no triable issues of material fact as to matters upon which it has the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

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

The materiality of a fact is determined by whether it might influence the outcome of the case based on the contours of the underlying substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over such facts amount to genuine issues if a reasonable jury could resolve them in favor of the nonmoving party. *Id.*

IV. DISCUSSION

C. Plaintiffs' Motion for Summary Judgment

Plaintiffs move for summary adjudication on two elements of their negligence per se claims on the following issues: (1) Somatics failed to maintain an internal system for evaluation, investigation, and reporting of adverse events as required by 21 C.F.R. § 820.198; (2) Somatics misbranded its "Thymatron" device in violation of 21 U.S.C. § 352(t) and 21 U.S.C. § 352(o); (3) Somatics breached its duty of care under California law by failing to comply with 21 C.F.R. § 820.198; (4) Somatics breached its duty of care by misbranding its devices under 21 U.S.C. § 352(t) and 21 U.S.C. § 352(o); and (5) Somatics breached its duty of care by introducing its misbranded "Thymatron" device in violation of 21 U.S.C. § 331.

California Evidence Code § 669 establishes a presumption that a party failed to exercise due care if: (1) he "violated a statute, ordinance, or regulation of a public entity"; (2) the "violation proximately caused death or injury to the person or property"; (3) the "death or injury resulted from an occurrence of the nature which the statute, ordinance, or regulation was designed to prevent"; and (4) the "person suffering the death or the injury to his person was one of the class of persons for whose protection the

statute, ordinance, or regulation was adopted." Cal. Evid. Code § 669(a). With reference to the five issues above, Plaintiffs seek summary adjudication on elements (1) and (4).

1. Element One – Violation of a Statute, Ordinance, or Regulation of a Public Entity

The first issue is whether Somatics violated a statute, ordinance, or regulation of a public entity and as such breached its duty of care. Both parties agree that the Somatics is subject to the provisions of the FDCA applicable to medical devices. Relevant here are the Medical Device Reporting ("MDR") regulations in Title 21 of the Code of Federal Regulations, authorized by the FDCA.

a. California Duty of Care

Plaintiffs maintain that Somatics' alleged violations of the FDCA constitute a breach of the standard of care in California because the FDCA establishes the applicable standard for medical device manufacturers. *See* Cal. Evid. Code § 669. California's duty of care under California Evidence Code 669 parallels the FDA regulations. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *DiRosa v. Showa Denko K.K.*, 44 Cal. App. 4th 799, 808 (Cal. Ct. App. 1996) ("the FDCA has been adopted as the standard of care in a negligence action"). Therefore, if Somatics violated the FDCA as alleged, then Somatics also breached the standard of care in California under element (1) of California Evidence Code 669. Cal. Evid. Code § 669(a).

b. Internal Procedures of 21 C.F.R. § 820.198 and 21 C.F.R. §§ 803.17(a)–(b)

Plaintiffs first argue that Somatics violated the FDCA regulations on maintaining internal procedures to record, investigate, and evaluate medical device reports. Manufacturers are required to maintain complaint files and establish written, standardized procedures for "receiving, reviewing, and evaluating complaints" to determine "whether the complaint represents an event which is required to be reported to FDA." 21 C.F.R. § 820.198(a)–(b); 21 C.F.R. § 803.17. In addition, manufacturers must evaluate all complaints to determine whether further investigation is warranted, and if not, the manufacturer "shall maintain a record that includes the reason no investigation was made" as well as the manufacturer's responses. *Id.* at § 820.198(b); 21 C.F.R. § 803.18.

The parties disagree as to whether Somatics has ever maintained an internal system for the investigation, evaluation, and reporting of adverse events. Somatics insists that it had a system prior to 2012 and simply improved its written system after the 2012 inspection, *see* Mirkovich Decl. ¶¶ 3–6 (ECF No. 81-1) ("At all times during my employment, Somatics has maintained an internal procedure for evaluating, investigation, and reporting adverse events to the FDA."), while Plaintiffs maintain that Somatics has never had an internal system, Karen Decl. Ex. A 0036 (ECF No. 79-6). Between the first

FDA inspection in 2012 and the second in 2016, Somatics hired the consulting firm Emergo to help update its procedures. (Mirkovich Decl. ¶ 4, ECF No. 81-1.) Those changes have been adopted by Somatics and are still in effect today. (*Id.*; *see also* Mirkovich Decl., Ex. A, ECF No. 81-1.)

Plaintiffs rely largely on the 2012 FDA investigation of the Somatics facility in which the inspector noted that Somatics' written internal procedures were inadequate. However, as discussed in the 2016 inspection report, Somatics implemented the requested changes and now has a detailed procedure in place. Somatics also presented evidence that before 2012 they had internal systems for evaluating and logging complaints; these were just not as detailed as the inspector in 2012 preferred.

More importantly, the observational objections in 2012 do not conclusively show a violation of the FDCA provisions above. The FDA issued no Warning Letters or regulatory sanctions, and while the absence of an official sanction is not dispositive on whether Somatics was in violation of the law, there is a genuine issue as to material fact about whether Somatics' procedures rose to the level of a violation of 21 CFR § 820.198 or 21 CFR §§ 803.17(a)-(b).

c. Reporting Requirements under 21 C.F.R. § 803.50 and 21 C.F.R. § 803.20

Plaintiffs also allege that Somatics breached its reporting requirements under 21 C.F.R. §§ 803.20–803.50. In general, manufacturers must file a report within thirty days of receiving information, from any source, that "reasonably suggests that a device that [they] market . . . [m]ay have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). Information "reasonably suggests" that an adverse event has occurred when it includes "professional, scientific, or medical facts, observations, or opinions that would cause [a manufacturer] to come to a reasonable conclusion that the device has caused or may have caused or contributed to an MDR reportable event." 21 C.F.R. § 803.20(c). Serious injuries are those that are life threatening, result in permanent impairment of a body function or structure, or necessitate medical intervention to preclude irreversible damage to a body structure, excluding "trivial impairment or damage." 21 C.F.R. § 803.3(w).

After receiving a complaint, the manufacturer is "responsible for conducting an investigation of each event and evaluating the cause of the event" to report it as needed. 21 C.F.R. § 803.50(b)(3). Adverse events do not have to be reported when the manufacturer reasonably concludes that the device did not cause the death or serious injury, that it was not the manufacturer of the device in question, or that the information is erroneous. 21 C.F.R. § 803.22(b). However, even if the manufacturer determines that an adverse event was not reportable, it must retain documentation of the complaint, the information on which the finding of non-reportability is based, and an explanation of the conclusion that it was not reportable. 21 C.F.R. § 820.198; 21 C.F.R. § 803.18.

Somatics has never filed an adverse event report with the FDA. However, there is genuine disagreement about whether there have been adverse events to report, and thus whether Somatics has violated its reporting requirements. Plaintiffs cite five pieces of evidence to prove that Somatics violated its reporting requirements. The Court will address each in turn.

1. 2013 Skin Burn

Somatics did not report the skin burn discussed in the 2016 FDA Inspection, but Somatics and Plaintiffs offer conflicting evidence about whether this burn qualified as a reportable adverse event. This disagreement does not need to be resolved, however, because this evidence is not material.

Even if the evidence indisputably proved that the skin burn was a reportable event, and Somatics violated the law by failing to report, Plaintiffs present no evidence indicating that this violation proximately caused their injuries as required under the second element of California Evidence Code 669. Cal. Evid. Code § 669(a)(2). Plaintiffs do not allege that they suffer from skin burns or that had they known about incidences of skin burns prior to receiving ECT treatment, they would not have agreed to undergo this treatment. (*See* Pl.s' Compl. ¶ 87.) Instead, they specifically allege that had Somatics reported or warned of adverse events of "craniocerebral trauma" and permanent memory loss, they would have been less likely to agree to ECT. As a result, Somatics' alleged failure to report the skin burn is immaterial and cannot form the basis of granting summary judgment on this issue.

2. 3,000 Docket Reports

The second piece of evidence that Plaintiffs cite is the 2011 FDA Summary of the 3,000 complaints of ECT-related injuries, including death, memory loss, and brain damage. Somatics believed the comments were unreliable and that they did not have enough information to investigate. Plaintiffs, however, offer evidence that the events were reportable and thus Somatics is in violation of the FDCA. The FDA inspector in 2012 and 2016 made no mention of these complaints, despite discussing the skin burn above. As such, there is a genuine dispute as to material fact about whether Somatics was in breach of its obligation to report these events.

3. 1995 FDA Order and Response

Similarly, Plaintiffs cite the 1995 FDA Order and the apparent lack of a response as evidence that Somatics violated reporting requirements, but Somatics has presented sufficient evidence to raise a genuine dispute as to whether they responded.

4. MAUDE Database Reports

There is a genuine dispute as to whether Somatics reviews and reports adverse events discovered through the MAUDE database, and a such this Court cannot find that Somatics has violated its statutory duties on this ground.

d. Misbranding under 21 USC §§ 352(o), 352(t), § 331(a), § 360(i), and § 360(t)

Plaintiffs also allege that the violations listed above caused the Thymatron devices to be "misbranded" and introduced into interstate commerce in violation of 21 U.S.C. § 331(a). A device is misbranded if there has been "a failure or refusal to give required notification or to furnish required material information" under the FDCA. 21 U.S.C. § 352(t). Because there is a genuine dispute as to material fact about whether Somatics was in violation of the regulations above, this Court cannot find that the Thymatron device was misbranded on this ground.

A device is also misbranded if it was "manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered" with the FDA. 21 U.S.C. § 352(o); 21 U.S.C. § 360(i); 21 C.F.R. § 807.20(a). However, prior to October 1, 2012, contract manufacturers were not required to register with the FDA if they manufactured the device according to another's specifications and did not distribute the device to consumers directly. 21 C.F.R. § 807.20(a)(2) (2012), *amended by* 21 C.F.R. § 807.20 (2018). Now, they must register. 21 C.F.R. § 807.20(a)(2).

The parties dispute whether Elektrika is a contract manufacturer that must register within the meaning of 21 C.F.R. § 807.20(a). If Elektrika manufacturers the final product that Somatics distributes, it is now required to register with the FDA. If it failed to do so, the Thymatron device is likely misbranded. However, the law that requires Elektrika to register was enacted in 2012, which is one year after the Thymatron device was sold to Plaintiff Chase's treating hospital and six years after the other Thymatron was sold to Plaintiff Riera's treating hospital. Prior to 2012, Somatics did not need to register Elektrika. Therefore, the timeline makes it impossible for Plaintiffs to show that the failure to register Elektrika after 2012 proximately caused their injuries, and as such the alleged misbranding of Elektrika is immaterial.

e. Conclusion

Based on the evidence above, there is a genuine dispute about whether Somatics violated its requirements for internal procedures under 21 CFR § 820.198 and 21 CFR §§ 803.17(a)-(b), reporting under 21 CFR § 803.50 and 21 CFR § 803.20, or misbranding under 21 USC §§ 352(o), 352(t), §

331(a), § 360(i), and § 360(t). A reasonable juror could conclude that Somatics did not violate a statute, ordinance, or regulation of a public entity. Cal. Evid. Code § 669(a).

As a result, the Court must **DENY** summary judgment on the first element of California Evidence Code § 669(a).

2. Element Four – The Class of Persons for Whose Protection the Statutes, Ordinances, or Regulations were Adopted

The FDCA's medical device reporting regulations provide a mechanism by which the FDA and device manufacturers can identify and monitor adverse events to "detect and correct problems in a timely manner." Medical Device Reporting for Manufacturers Guidance for Industry and Food and Drug Administration Staff, 2016 WL 6903478, at *6 (Nov. 8, 2016) ("Guidelines"). Moreover, the Guidelines assist the FDA to "protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use." 21 C.F.R. § 803.1(a).

Plaintiffs request summary judgment on the issue of whether Plaintiffs are among the class of persons for whose protection the regulations at issue here were adopted, satisfying the fourth element of negligence per se under California Evidence Code § 669. Cal. Evid. Code §669 (the "person suffering the death or the injury to his person was one of the class of persons for whose protection the statute, ordinance, or regulation was adopted.") Plaintiffs are patients who received ECT from their treating doctors using Somatics' Thymatron devices. Somatics does not offer evidence to the contrary. Therefore, Plaintiffs are among the class protected by the FDCA regulations.

Accordingly, this Court **GRANTS** summary judgment on element four of California Evidence Code § 669(a).

D. Defendant's Motion for Summary Judgment

Somatics moves for summary judgment on all six of Plaintiffs' claims. The Court will examine each claim in turn.

1. Claim 1: Negligence – Adulteration and Misbranding

Plaintiffs' first claim is for negligence and negligence per se based on the misbranding and adulteration of the Thymatron. To prevail on the negligence claim, Plaintiffs must show: (1) a legal duty to use due care; (2) a breach of that duty; and (3) the breach proximately and legally caused the resulting injury to Plaintiff. *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 433 (Cal. Ct. App. 2014). When applicable, the FDCA "has been adopted as the standard of care in a negligence action." *DiRosa v.*

Showa Denko K.K., 44 Cal. App. 4th 799, 808 (Cal. Ct. App. 1996). This claim is premised on Somatics' alleged violations of the FDCA.

To prevail on the negligence per se claim, Plaintiff must show that Somatics (1) violated the statute or regulation; (2) which proximately caused Plaintiffs' injuries; (3) from an occurrence of the nature which the statute or regulation was designed to prevent; and (4) Plaintiffs were of the class of persons for whose protection the statute or regulation was enacted. Cal. Evid. Code § 669(a). Plaintiffs have met the burden of showing the fourth element.

As discussed above, there is a genuine dispute as to material fact regarding whether the Thymatron device was misbranded in violation of the FDCA. Therefore, summary judgment is not appropriate with respect to whether Somatics breached its duty.

With respect to causation, Plaintiffs allege that had the devices not been misbranded, they would not have been sold to Plaintiffs' respective treating hospitals, and therefore Plaintiffs would not have received ECT. However, Plaintiffs do not provide evidence to support this contention. There is a genuine dispute as to whether the devices were misbranded, but assuming they were, it is still not clear how Plaintiffs would prove that but for the misbranding, the Thymatron devices would not have been sold into the stream of commerce. For example, even if the adverse events that Plaintiff describes from the 2009 Public Docket had been reported separately by Somatics to the FDA, there is nothing to suggest that the FDA would have taken the Thymatron device off the market – especially since the FDA knew about the complaints in the Docket and took no action. Moreover, there is no evidence that the information would have gotten to Plaintiffs' hospitals prior to purchasing their respective Thymatron devices. Therefore, Plaintiffs have not presented evidence sufficient to create a genuine issue of fact on this issue.

Because Plaintiffs failed to meet their burden to create a factual contention on causation, summary judgment is appropriate in favor of Somatics on this claim.

2. Claim 2: Negligence – Failure to Investigate, Evaluate, and Report

Plaintiffs' second claim is for negligence and negligence per se based on Somatics' failure to investigate, evaluate, and report adverse events. The elements Plaintiffs must prove are the same as claim one. Once again, there is a genuine dispute as to whether Somatics breached its statutory duty to investigate, evaluate, and report adverse events, and whether there is causation.

The question of causation in negligence or products liability cases is often "peculiarly for the jury." *Campbell v. General Motors Corp.*, 32 Cal. 3d 112, 120 (Cal. 1982) (citations omitted).

Moreover, Plaintiffs have the burden of establishing causation. *Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 968 (Cal. 1997).

To show causation, Plaintiffs contend that had Somatics reported adverse events, the doctors would have warned Plaintiffs of the dangers of brain trauma, memory loss, and cognitive defects, and Plaintiffs would not have agreed to receive ECT. Plaintiffs present evidence from two doctors stating that had they known that there was a risk of permanent memory loss or brain damage, they would have warned Plaintiffs. (*See* Depo. of Navin Adatia, ECF No. 84-4; Depo. of Viguen Movsesian, ECF No. 84-4.) Plaintiffs further allege that had a single adverse event been reported to the FDA, it would have reached Plaintiffs' doctors, and the doctors would have either passed the warnings along to Plaintiffs, who would have declined treatment, or they would not have recommended that Plaintiffs get ECT in the first place. Somatics contends that the chain of causation is tenuous; there is no evidence that the FDA would have made the adverse reports public, or that Plaintiffs or their doctors would have received the information, or that Plaintiffs would have declined ECT had they known. (*See* Arrowsmith Decl. ¶ 15, ECF No. 84-17.) As such, there is a genuine issue of fact on this element.

Additionally, there is a genuine dispute as to whether ECT caused Plaintiffs' injuries at all. Somatics presents evidence that Plaintiffs cannot establish that their cognitive impairment and memory loss were caused by ECT, given Plaintiffs' prior experiences of memory issues, chronic depression, Chase's past medication use, and Riera's past alcohol use. Moreover, Somatics' expert argues that "there is no empirical way to test whether the ECT administered to [Plaintiffs] had any adverse effect on them specifically." (Kellner Decl. ¶¶ 29–32, ECF No. 80-2.) On the other hand, Plaintiffs present evidence that "to a reasonable scientific certainty," Plaintiffs have suffered structural brain damage "consistent with the patterns found in the literature on ECT." (Perillo Decl. ¶ 16, ECF No. 84-23.) Plaintiffs' expert "completely disagree[s]" with Somatics' expert regarding the issue of causation, and as such, there is a genuine dispute as to material fact on the question of whether the ECT device caused Plaintiffs' injury.

Accordingly, the Court denies summary judgment on this claim.

3. Claim 3: Negligence – Failure to Warn

Plaintiffs' third claim for negligence is based on the failure to warn. To prevail on this claim, Plaintiffs must show that (1) Somatics sold the product; (2) Somatics knew or reasonably should have known that it was dangerous; (3) Somatics knew or should have known that users would not have realized the danger; (4) Somatics failed to adequately warn of the danger or instruct users on the safe use; (5) a reasonable manufacturer would have warned of this danger; (6) Plaintiffs were harmed; and (7) Somatics' failure to warn was a substantial factor in causing Plaintiffs' harm. *Motus v. Pfizer, Inc.*,

196 F. Supp. 2d 984, 990–91 (C.D. Cal. Dec. 20, 2001); *Putensen v. Clay Adams, Inc.*, 12 Cal. App. 3d 1062, 1076–77 (Cal. Ct. App. 1970).

The parties present conflicting evidence about whether Somatics knew or should have known of the risk of brain damage and whether the existing warnings for memory loss and brain damage were adequate. Somatics presents evidence that while amnesia is a well-known and scientifically acknowledged risk of ECT, brain damage is not. (*See* Kellner Decl. ¶¶ 12, 14, 17, ECF No. 80-2; Benkner Decl., Ex. A, SOM 281-83, ECF No. 105-2.) Plaintiffs' experts, however, argue that scientific literature suggests that brain trauma from ECT causes both cognitive defects and memory loss in patients, and therefore that all are well-known. (*See* Dolan Decl. ¶ 62, ECF No. 84-19; Castleman Decl. ¶ 18, ECF No. 84-12; Perillo Decl. ¶¶ 15–17, ECF No. 84-23.) Therefore, there is a genuine dispute as to whether the risk of brain damage is well-known or scientifically-accepted. If brain damage is a known risk of ECT, Somatics would have a duty to warn, and Plaintiffs would then need to show that Somatics' warnings were inadequate.

Somatics' Thymatron device comes with both a Patient Information Pamphlet and an Operator's Manual. The Operator's Manual is given to the facilities that administer ECT, and it provides instructions and warnings and directs the operators to follow the American Psychiatric Association's Task Force Report ("Task Force Report"). This Task Force Report summarizes current scientific knowledge regarding the proper use and risks of ECT.

Somatics presents evidence that the Task Force Report is the most thorough and authoritative report on ECT and indicates the widely-known risks of ECT, including cognitive side effects. The Report indicates that amnesia may sometimes result from ECT, and that although it is usually short-term, in rare circumstances it lasts longer. (*See* Kellner Decl. ¶ 11, ECF No. 80-2.) Moreover, the Report indicates that "[a] small minority of patients treated with ECT later report devastating cognitive consequences," although it goes on to say that these reports are rare and that "[m]ultiple factors likely contribute." (*Id; see also* Kellner Decl., Ex. F, 70–71, ECF No. 80-8. The Patient Information Pamphlet indicates that the main side effects of ECT include confusion and short-term memory loss that "occasionally continues in a mild form for a period of months, or longer." (Kellner Decl., Ex. D, SOM 06095, ECF No. 80-6. When asked if ECT causes brain damage, the pamphlet says that "[t]he available evidence speaks against this possibility" and the animal studies "have shown no evidence of brain damage." *Id.* Finally, the pamphlet indicates that ECT does not cause permanent memory loss "in most people." *Id.* Somatics argues that for the well-known risk of permanent memory loss, their warnings were adequate, and that because the risk of brain damage is not scientifically established, no warning was necessary.

Plaintiffs, however, present evidence that these warnings were inadequate and that the Task Force Report is unreliable. (*See* Dolan Decl. ¶ 62, ECF No. 84-19; Castleman Decl. ¶¶ 15–18, ECF No. 84-12.) Riera and Chase both declare that they would not have gotten ECT had they known the risk of permanent memory loss or brain damage. (Riera Decl. ¶ 3, PA 182–83, ECF No. 26-2; Chase Decl. ¶ 4, PA 179, ECF No. 26-2.) Whether the warnings were adequate and whether Plaintiffs would have agreed to receive ECT had the warnings been more detailed is a question of fact about which there is a genuine dispute.

Accordingly, summary judgment on this claim is not appropriate.

4. Claim 4: Strict Products Liability – Failure to Warn Because of Failure to Investigate, Evaluate, and Report

Plaintiffs' fourth claim is for strict products liability based on the failure to warn through the investigation, evaluation, and reporting of adverse events. Plaintiffs allege that had Somatics filed the adverse event reports as required by the FDCA, Plaintiffs or their doctors would have seen the reports and been effectively warned against receiving ECT.

To prevail, Plaintiffs must prove that (1) Somatics manufactured the product; (2) the Thymatron had known or knowable risks in light of generally-accepted scientific and medical knowledge; (3) the potential risks presented a substantial danger when the Thymatron is used in a reasonably foreseeable way; (4) that ordinary consumers would not recognize; (5) Somatics failed to adequately warn of this risk; (6) Plaintiffs were harmed; and (7) the lack of warnings was a substantial factor in causing Plaintiffs' harm. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 995–96 (Cal. 1991). The adequacy of warnings is generally a question of fact for the jury. *Jackson v. Deft, Inc.*, 223 Cal. App. 3d 1305, 1320 (Cal. 1990).

As discussed above, there is a genuine dispute as to whether there is a known and substantial risk of brain injury about which Somatics failed to adequately warn consumers. Moreover, there is a genuine dispute about whether Somatics failed to investigate, evaluate, or report adverse events, or whether this failure caused Plaintiffs' injuries. Therefore, summary judgment cannot be granted on this claim.

5. Claim 5: Strict Products Liability – Adulteration and Misbranding

Plaintiffs also allege that because Somatics failed to comply with the regulatory duties described above, a misbranded product was introduced on the market, which eventually caused Plaintiffs' injuries. Had the product not been misbranded, it may not have been sold to Plaintiffs' treating hospitals and Plaintiffs would not have been given ECT.

To prevail, Plaintiffs must show that they were harmed by the product that contained a manufacturing defect. *Johnson v. United States Steel Corp.*, 240 Cal. App. 4th 22, 30 (Cal. Ct. App. 2015). Here, Plaintiffs argue that the Thymatron is misbranded under the FDCA, and thus defective. But for Somatics' introduction of a defective medical device into interstate commerce, the Plaintiffs would never have been injured by ECT. More specifically, Plaintiffs contend that regulatory compliance would have forced Somatics to address "epistemological difficulties" in the research on the risks of ECT, and this has caused a "paucity of evidence" on whether brain damage is caused by ECT. (Arrowsmith Decl. ¶¶ 7–13, ECF No. 79-3.) Plaintiffs present no evidence to support this chain of causation. Accordingly, as discussed with respect to claim one above, Plaintiffs have not met their burden to affirmatively present specific admissible evidence sufficient to create a genuine issue of material fact for trial. Summary judgment is granted for Somatics on this claim.

6. Claim 6: Strict Products Liability – Failure to Warn Doctors Directly

Finally, Plaintiff's sixth claim is for strict products liability based on the failure to warn doctors directly. The elements of this claim are the same as the fourth claim, above. The warning at issue in this claim would have been given to Plaintiffs' physicians. *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (Cal. Ct. App. 1999).

As discussed above, the parties present conflicting evidence about whether there is a known or substantial risk of brain injury and permanent memory loss, whether ordinary consumers would be aware of these risks, whether the warnings were adequate, and whether this failure to warn caused Plaintiffs' injuries.

Somatics contends that Plaintiffs cannot show that the doctors would have read the public docket reports, but the Court assumes that the doctors would have performed their legal duties and passed along warnings about which they were aware. *See* Welf. & Inst. Code § 5326.2. Moreover, Plaintiffs present evidence that had doctors known of the risk of permanent memory loss or brain damage, they would have told their patients. Therefore, there is a genuine dispute of fact on this issue, and summary judgment is not appropriate.

Accordingly, summary judgment is not appropriate on this claim.

V. EVIDENTIARY OBJECTIONS

To the extent the parties have objected to any of the evidence relied upon by the Court, those objections are overruled for purposes of this Order.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK (PJW)	Date	September 14, 2018
Title	***Jose Riera and Deborah Chase v. Somatics, LLC***		

VI. CONCLUSION

For the foregoing reasons, this Court:

DENIES Plaintiff's Motion for Partial Summary Judgment as to Presumption of Failure to Exercise Due Care on Element (1) of the California Evidence Code 669; and

GRANTS Plaintiff's Motion for Partial Summary Judgment as to Presumption of Failure to Exercise Due Care on Element (4) of California Evidence Code 669;

GRANTS Defendant's Motion for Summary Judgment as to Claims One and Five; and

DENIES Defendant's Motion for Summary Judgment as to Claims Two, Three, Four, and Six.

IT IS SO ORDERED.

_____ : _____

Initials of Preparer _____