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' OPENING BRIEF

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INTRODUCTION

Everyone has an *absolute right* to refuse treatment based on their own determination of the risks and benefits of a medical intervention. And yet, the district court ignored this basic principle of personal sovereignty by holding that the *only* factual consideration that matters in assessing whether a failure to warn caused a treatment to occur (resulting in injury) is the doctor's opinion—what the patient would have done with a proper warning is, according to the district court, not only insufficient as a matter of law, but *irrelevant*. This disregard of personal sovereignty finds no support in the law, the practice of medicine, or common sense. When plaintiffs testified they would have refused electroshock treatment had the risk of permanent memory loss and brain damage been disclosed, it created a triable issue of fact as to whether the failure to warn caused the electroshock treatment to occur. And, that triable issue of fact exists even if the treating doctor, despite knowing the risks, would still have recommended the procedure. A competent adult patient can always say no—indeed, many likely would when faced with the prospect of permanent memory loss and brain damage. By disregarding this testimony, the district court improperly granted summary judgment on the

issue of causation. Plaintiffs have a right to a jury deciding this factual, triable, issue. Summary judgment should be reversed, and the case remanded for trial.

JURISDICTIONAL STATEMENT

This products liability and putative class action was initiated on September 11, 2017, in the United States District Court for the Central District of California. The district court possessed subject-matter jurisdiction under 28 U.S.C. §1332(d), because, at the time of filing, the amount in controversy exceeded the sum of $5,000,000.00, there were at least 100 putative class members, and the parties were minimally diverse, to the extent required by the Class Action Fairness Act. While the district court subsequently denied Rule 23 class certification, this did *not* divest the district court of jurisdiction. *United Steel, Paper & Forestry, Rubber, Mfg., Energy, Allied Indus. & Serv. Workers Int'l Union, AFL-CIO, CLC v. Shell Oil Co.*, 602 F.3d 1087, 1092 (9th Cir. 2010) ("a district court's subsequent denial of Rule 23 class certification does not divest the court of jurisdiction.").

On May 14, 2021, the district court granted defendant-respondent Somatics, LLC's ("Somatics") Motion for Summary Judgment and dismissed plaintiff-appellants Michelle Himes, Marcia Benjamin, and

Daniel Benjamin's claims with prejudice. 1-ER-3-10. On May 18, 2021, appellants filed a timely notice of appeal (6-ER-1217–1218) and, on May 21, 2021, the district court formally entered final judgment (1-ER-2). Accordingly, this Court has appellate jurisdiction under 28 U.S.C. §1291 and Federal Rule Civil Procedure Rule 54(b) because the district court entered final judgment on May 21, 2021.

To the extent plaintiffs' notice of appeal (6-ER-1217–1218) filed on May 18, 2021 (within 30-days of the district court's order granting defendant-respondent's Motion for Summary Judgment and dismissing all of plaintiff-appellants' claims with prejudice, but prior to formal entry of judgement) is deemed premature, under the applicable rules and precedent, a premature notice of appeal relates forward and is treated as if timely filed on the date of and after the formal entry of judgment. FED. R. APP. P. 4(a)(2); *FirsTier Mortg. Co. v. Inv'rs Mortg. Ins. Co.*, 498 U.S. 269, 275 (1991); *Radio Television Espanola S.A. v. New World Entm't, Ltd.*, 183 F.3d 922, 932, n.12 (9th Cir. 1999).

ISSUES PRESENTED

1. Did the district court err, as a matter of law, in applying the learned intermediary doctrine even after concluding the defendant device

manufacturer failed to provide adequate warnings to plaintiffs' doctors?

2. Assuming the learned intermediary doctrine applies, did the district court err by disregarding testimony from both plaintiffs that they would have refused electroshock therapy had the risk of permanent memory loss and brain damage been disclosed when it decided there was no triable issue of fact concerning whether the defendant's failure to warn caused plaintiffs' injuries?

3. Did the district court err in presuming that plaintiffs' doctors would have prescribed *and administered* electroshock therapy to plaintiffs, illegally and without their consent, notwithstanding that presumption finding no support in the record?

4. Did the district court err in impermissibly and in violation of California Supreme Court precedent conclude that the purported and unfounded intervening acts of the doctors (which the district court impermissibly presumed in disregard of the law and evidence) absolve Somatics of liability for its undisputed failure to warn?

STATEMENT OF THE CASE

I. Procedural History

This products liability and putative class action was initiated on

September 11, 2017, by plaintiffs, Jose Riera ("Riera"), Deborah Chase ("Chase"), Michell Himes ("Himes"), and Diane Scurrah ("Scurrah") on behalf of themselves and other class members against the sole manufacturers of ECT, Mecta Corporation ("Mecta") and Somatics, LLC ("Somatics"). 5-ER-1191-1214. Plaintiffs alleged they and similarly situated class members suffered various physiological, psychological, and emotional trauma, including brain damage and *permanent* cognitive impairment and memory loss as a result of undergoing shock treatment, and further alleged that defendants' devices were misbranded as a result of defendants' failure to comply with applicable federal law governing medical devices. 5-ER-1210-1213.

On November 7, 2017, a First Amended Complaint was filed, which added appellants Marcia Benjamin ("Benjamin") and Daniel Benjamin as plaintiffs. 5-ER-1162-1190. Like the other plaintiffs, Benjamin alleged she underwent shock treatment and, as a result, sustained severe injuries, including brain damage and *permanent* memory loss. 5-ER-1170. Her husband, Daniel Benjamin, alleged loss of consortium. *Id*. On December 10, 2017, plaintiffs filed a motion to certify the class action, which was denied on March 19, 2018. 6-ER-1221, 1224.

On May 10, 2018, defendants jointly filed motions to dismiss plaintiffs' claims on statute of limitations and causation grounds. 6-ER-1224. On June 19, 2018, the district court issued its Order on the motions to dismiss. 5-ER-1153-61. As to the statute of limitations motion, the district court granted defendants' motion and held that the claims of Benjamin, Himes, and Scurrah were all time barred and thus granted the motion *with prejudice* and without leave to amend. *Id*. As to the causation motion, the district court granted the motion as to co-defendant Mecta (as discovery revealed that Mecta did not manufacture the devices used in the named plaintiffs' procedures) but allowed plaintiffs Riera and Chase (whose claims were not alleged to have been time-barred), to amend the complaint to specifically identify Somatics as the manufacturer of the ECT device to which they were exposed. *Id*.

On July 30, 2018, Somatics filed a motion for summary judgment seeking to dismiss all of Chase and Riera's claims primarily on causation grounds, including arguing that plaintiffs' claims were barred by the learned/sophisticated intermediary doctrine. 6-ER-1227. Chase and Riera opposed the motion. *Id*.

On September 14, 2018, the Court issued an Order granting in part

and denying in part Somatics' summary judgment motion. 5-ER-1137–1152. The court *denied* the motion as to the negligence and strict liability failure to warn and failure to report causes of action. *Id*. As to the learned intermediary causation defense Somatics had raised, the court held there was a genuine dispute of fact as to the issue of causation because plaintiffs presented "evidence that had doctors known of the risk of permanent memory loss they would have told their patients" (5-ER-1151) and that, "Riera and Chase both declare that they would not have gotten ECT had they known the risk of permanent memory loss or brain damage[.]" 5-ER-1150.

The district court subsequently denied Somatics' challenges to plaintiffs' experts (6-ER-1235) and trial was scheduled to begin on October 2, 2018, but on the eve of trial, Chase and Riera settled with Somatics. 6-ER-1235. In light of the settlement, on October 1, 2018, the district court entered an order dismissing the action. *Id*.

Thereafter, on October 30, 2018, Scurrah, Himes, and Benjamin – whose claims the district court had previously dismissed on statute of limitations grounds – filed a notice of appeal. 6-ER-1235. This Court reversed the district court's dismissal and remanded the matter. 5-ER-

1134-36.

On remand, the district court ordered Scurrah, Himes, and Benjamin to file an amended complaint, which plaintiffs did on June 15, 2020. 6-ER-1236 (Order); 5-ER-1103-1131 (Fifth Amended Complaint). Plaintiffs' causes of action included negligence (adulteration/misbranding); negligence (failure to warn); strict liability (failure to warn); strict liability (adulteration/misbranding) and loss of consortium. 5-ER-1125-31. On March 15, 2021, Scurrah dismissed her claims. 6-ER-1241.

On March 31, 2021, Somatics filed a motion for summary judgment on the remaining plaintiffs', Himes' and Benjamin's, claims. Specifically, Somatics argued that (a) all of plaintiffs' claims were time barred; (b) all of plaintiffs' claims were barred by the learned intermediary doctrine; and (c) plaintiffs could not establish causation for their misbranding and adulteration claims (i.e., the First and Fourth Causes of Action). 5-ER-953-975.

Himes and Benjamin opposed Somatics' summary judgment motion and argued their Second (Negligence), Third (Strict Liability Failure to Warn) and Fifth (Loss of Consortium) Causes of Action were timely filed and were not barred by the learned intermediary doctrine. 2-ER-160-186.

Somatics, thereafter, filed a reply (2-ER-16-25) and responded to plaintiffs' separate statement by largely agreeing with plaintiffs' statement of facts (2-ER-28-74).

On May 14, 2021, the district court, without oral argument, granted Somatics' summary judgment motion exclusively as to causation (learned intermediary doctrine). 1-ER-3-10. This appeal followed. 6-ER-1217–1218.

After the filing of the Notice of Appeal, Somatics sought recovery of its expert costs totaling $70,480.50, which plaintiffs opposed. 6-ER-1248. On August 9, 2021, the district court denied Somatics' motion and, in its Order denying expert costs, the court held: "Defendant overstates the strength of its position on summary judgment. Plaintiffs presented colorable arguments, and both parties had case law to support their position." 2-ER-15.

II. Factual Summary

A. Electroshock Therapy ("ECT") Involves Running a Substantial Amount of Electricity through a Human Brain to Induce a Grand Mal Seizure

Electroshock or electroconvulsive therapy ("ECT") is the practice of inducing a grand mal seizure through application of electricity to the brain. 2-ER-29; 3-ER-443. In the late 1930's, after observing slaughterhouses

apply electricity to pigs to render them "manageable" for slaughter, Ugo Cerletti and Lucino Bini, two scientists at the University of Rome, thought electricity could be used to treat schizophrenia.[1] 2-ER-29; 4-ER-669-70. Cerletti and Bini began to test the theory by initially applying electricity to dogs, where the majority of the dogs died. 2-ER-29-30; 4-ER-669-70. Nonetheless, the scientists progressed to experimenting on humans. 2-ER-30; 4-ER-670. In April 1938, Cerletti and Bini applied ECT to the first human patient, a 40-year-old man found wandering the Rome train station and speaking gibberish. 2-ER-30; 4-ER-670. They applied 70 volts of electricity to his temple and, while deliberating whether they should apply a second higher voltage, the patient pleaded "*Non una seconda! Mortifera*!" ("not again it will kill me!"). 2-ER-30; 4-ER-670. Notwithstanding the man's pleas, Cerletti applied a second and higher voltage (110 volts) of electricity. 4-ER-670. Thereafter, the patient was administered

[1] The intentional creation of seizures was based on the then mistaken belief that people with epilepsy did not suffer from schizophrenia. 4-ER-668. However, as medical experts and researchers have pointed out, "in spite of seven decades of clinical use of ECT for people with schizophrenia, there still is a lack of strong and adequate evidence regarding its effectiveness..." 5-ER-915. Likewise, to date, no mechanism of action by which ECT purportedly treats depression has been identified or proven. 3-ER-445.

approximately a dozen more sessions of ECT but was subsequently lost to follow-up. 2-ER-31; 4-ER-670-71. In May 1938, Cerletti presented his experiment at the Medical Academy of Rome and, shortly thereafter, in the early 1940s, ECT began to gain acceptance for the treatment of schizophrenia (and eventually other psychiatric ailments). 2-ER-31; 4-ER-670-71.

Nearly a century later, ECT continues to be administered in the United States. To avoid patients violently jolting, jarring, and convulsing during the procedure, patients are now placed under anesthesia and administered muscle relaxants. 3-ER-443-46. But, as outlined herein, while the use of anesthesia and muscle relaxants masks overt convulsions—like those shown in films such as *One Flew Over the Cuckoo's Nest*—the permanent side-effects of running electricity through the human brain remain the same, and in some cases, are exacerbated. 3-ER-444-46.

As plaintiffs' electrical engineering expert has explained, and Somatics has not disputed, the Somatics Thymatron IV ECT machine at issue in this case administers electric current to a patient's head that is approximately *one hundred* times what tasers use, roughly *one-fifth* as much current as the electric chair and applies voltage that is more than a *hundred*

times what is required to damage brain cells. 2-ER-47; 3-ER-473.

B. Somatics Failed to Comply with FDA Regulations, Failed to Issue *Any* Timely Warnings to Plaintiffs' Medical Providers and Has Now Admitted (via Tardily Issued Warnings) That ECT Can Cause Brain Injury and Permanent Memory Loss

In the 1980s, Richard Abrams and Conrad Swartz formed Somatics for the purpose of selling their own ECT machines for profit. 2-ER-31; 3-ER-370. Normally, medical devices require advance FDA approval, however, Somatics ***never*** obtained FDA approval to market its ECT machine. 2-ER-32; 3-ER-438. Rather, relying on a statutory loophole that allows a medical device manufacturer to simply claim its device is equivalent to a device that was on the market prior to 1976, Somatics obtained *clearance* from the FDA to sell its "Thymatron" ECT device in 1984. 2-ER-32; 4-ER-677. The distinction between *approval* and *clearance* is critical—an FDA *approved* device is tested by human clinical trials to demonstrate safety and efficacy and the FDA usually spends 1,200 hours reviewing an application prior to approving a medical device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996); 2-ER-33-34. On the other hand, devices

that obtain *clearance*, are usually cleared within a mere 20 hours. *Id*.[2] Remarkably, the FDA has *never* approved *any* ECT device, and no ECT device manufacturer has ever conducted any clinical trials to prove they are safe and effective. Rather, safety and efficacy has been presumed because, well, ECT has been done for so long. In that regard, Somatics has *never* conducted any human clinical trials to determine if its Thymatron ECT device is safe and effective. 2-ER-32-33; 3-ER-372; 3-ER-429. When asked why Somatics has never conducted any studies or tests to analyze the long-term side effects associated with ECT, Somatics' founder and president, Dr. Abrams testified: "that's not our business." 3-ER-371.

Notwithstanding this not being their business, Somatics promoted its ECT device as "The most advanced ECT device technically and operationally, *with demonstrated superior safety and clinical effectiveness.*" 2-ER-35-36; 3-ER-427-429; 4-ER-680 (emphasis added). Indeed, contrary to

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[2] In issuing the clearance letter to Somatics for its ECT machine, the FDA emphasized to Somatics that the FDA had *not* approved the device and that any representations by Somatics that its ECT device was FDA approved would be misleading and would constitute misbranding under federal law. 2-ER-34-35; 4-ER-675, 677. Notwithstanding the FDA's admonitions, Somatics proceeded to *falsely* promote its device on its promotional literature and website as having received FDA "Approval," which constitutes misbranding. 2-ER-35-36; 4-ER-628, 680.

Somatics' claims of safety and efficacy, medical research reveals that ECT is of questionable efficacy and is associated with serious risks, including permanent memory loss. *See* 4-ER-878 ("There is no evidence that ECT is effective for its target demographic…or its target diagnostic group…"); 4-ER-910 (a large-scale prospective study of cognitive outcomes in 2007 found that months after ECT, autobiographical memory of patients were significantly worse and that 12% of ECT patients were deemed to have suffered "marked and persistent retrograde amnesia"). Eventually, Somatics had to remove its false claims of safety and efficacy from its promotional material and the FDA now requires manufacturers to warn that: "The long-term safety and effectiveness of ECT treatment *has not been demonstrated*." 21 C.F.R. § 882.5940; 2-ER-36.

In addition to never having performed any safety and efficacy studies on its ECT devices, a January 2012 FDA inspection revealed that, during the relevant time period, Somatics did not have appropriate procedures in place to identify, evaluate, and warn about adverse events in violation of applicable FDA regulations. 2-ER-36-37; 4-ER-692 (2012 FDA Report (Observations 3 & 4)); *see also* 21 C.F.R. §§ 803.17, 803.18, 803.50 & 820.198; 21 U.S.C. §§ 331 & 352(t). Indeed, between 1984 and 2017, Somatics *never*

submitted a single adverse event report to the FDA. 2-ER-37; 4-ER-634; *see also* 4-ER-698-699. As the district court determined, even though Somatics became aware, or should have been aware, of *hundreds* of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death, Somatics never took any meaningful measures to investigate these complaints, submit adverse event reports to the FDA or warn physicians and consumers of these risks. 1-ER-4; 2-ER-14; *see also* 2-ER-37; 4-ER-634; 4-ER-698-699; 4-ER-714-715. Again, safety and efficacy are simply not their business. *See e.g.*, 3-ER-371.

The manuals Somatics prepared for its ECT device and distributed to the two hospitals where plaintiffs received their respective ECT treatments, ***did not contain any warnings***. 3-ER-509-564 (manual given to Sharp Hospital - no warnings of any kind), 3-ER-565-624 (manual given to Northridge Hospital - no warnings concerning brain damage or permanent memory loss); *see also* 3-ER-387-403. In its ruling, the district court acknowledged that Somatics had not provided any warnings to plaintiffs' respective physicians concerning the risk of brain injury or permanent memory loss. 1-ER-9.

Long before plaintiffs' ECT procedures, which began in 2011 for

Himes and 2012 for Benjamin, Somatics and its owners were aware, or should have been aware, that ECT shock therapy could cause serious injuries, including permanent memory loss and brain damage to patients. 2-ER-39-45; *see also* ER 3-ER-444-452; 3-ER-456- 462; 3-ER-475; 4-ER-663-664; 4-ER-714-715; 4-ER-910; 5-ER-912; 5-ER-1137; 5-ER-1149 (prior Order). [3] Tellingly, one of the Somatics owners, Dr. Abrams, published a book in 2002 wherein he quoted an ECT expert who had written "virtually all patients experience some degree of persistent and, likely permanent retrograded amnesia" and that "increasing evidence has accumulated that some degree of persistent memory loss [with ECT] is common." 2-ER-40; 4-ER-663-664. In the article Dr. Abrams quoted, the author further stated that "[i]t has also become clear that for rare patients the retrograde amnesia due to ECT can be profound, with the memory loss extending back years prior to receipt of treatment." 2-ER-40-41; 4-ER-856. In this same article,

[3] As one of plaintiffs' experts, Dr. Peter Breggin, opined, the trauma suffered by the brain as a result of ECT is similar in its clinical effects to traumatic physical injury to the head and brain, though "ECT seems to produce an especially drastic impact upon personal memories of one's experiences in life, such as family celebrations, holidays, work accomplishments and educational experiences. For this reason, the harm caused by ECT is particularly destructive to personal identity." 3-ER-451.

the author goes on to conclude that there is a need to "update what is communicated in the consent process and to monitor cognitive outcomes." 2-ER-42; 4-ER-862. Notwithstanding, in response to these findings and opinions, Dr. Abrams self-servingly concluded there is no evidence to support the risk of cognitive deficits. 2-ER-42; 4-ER-664.

In the manuals and labeling Somatics provided with its ECT machine, Somatics never provided *any* warnings concerning the risks of permanent memory loss or brain damage. 1-ER-9; 3-ER-387-403; 3-ER-509-564 (manual given to Sharp Hospital), 3-ER-565-625 (manual given to Northridge Hospital). In 2006, in response to a fear of potential lawsuits because its ECT manual (i.e., the device label) did not contain any warnings (including any warnings concerning permanent memory loss), the two Somatics owners (Abrams and Swartz) contemplated adding warnings concerning permanent memory loss. 2-ER-44-45; 4-ER-874-876. However, as outlined in internal communications, the Somatics owners expressed concern that adding a warning about permanent memory loss would cause Somatics to lose customers (i.e., "alienate psychiatrists"). 2-ER-44-45; 4-ER-874. The two ultimately decided *not* to add a warning and instead merely added a disclaimer, which one of the Somatics owners contemporaneously

admitted "is not a warning." 2-ER-44-45; 4-ER-874. Even this disclaimer (which Somatics admitted was not a warning), was never timely given to the physicians or hospitals where Himes and Benjamin received their ECT. 2-ER-45-46.

In 2009, the FDA announced it was opening a docket and inquiry to further look into the safety and efficacy of ECT given the devices had never received FDA approval. *See* 74 Fed. Reg. 46607-01. By 2010, the FDA's public docket had received more than 3,000 notifications of ECT induced injury and, according to the FDA: "The most common type of adverse event reported in the public docket was ***memory adverse event*** (529 reports). This was followed by other ***cognitive complaints*** (413 reports), ***brain damage*** (298 reports) and ***death*** (103 reports)." 2-ER-46; 4-ER-714. While Somatics admitted that, as of 2010, it was aware of these adverse events, Somatics, in violation of 21 C.F.R. § 803.50(b)(3), took no steps to investigate the reports or issue warnings concerning these risks to plaintiffs' medical providers. 2-ER-47; 4-ER-643-44.

It was not until sometime in late 2018, *after* Somatics settled the claims of Chase and Riera in this action and *after* the FDA concluded that Somatics needed to provide instructions and warnings concerning

permanent cognitive injuries (*see* 21 C.F.R. § 882.5940), that Somatics began to implement warnings on its website and in its new user manuals, which stated: "ECT may result in anterograde or retrograde amnesia" (4-ER-652) and "in rare cases, patients may experience permanent memory loss or permanent brain damage." (4-ER-653); see also 2-ER-48; 3-ER-410-420; 4-ER-652-53; 4-ER-658-59. Unfortunately, these warnings, which could and should have been issued decades earlier, came too late for plaintiffs Himes and Benjamin, who are but two of the many victims of Somatics' negligence and failure warn.

C. Had Somatics Warned about Brain Damage and Permanent Memory Loss, Himes' Doctor Would Have Altered His Conduct and Relayed Those Warnings to Himes; and Had Himes Been So Warned, She Would Have Refused ECT

Himes was 25 years old when she was initially administered ECT in April 2011 to attempt to treat her depression. 5-ER-949, 1000-1001. The ECT was prescribed and administered by her doctor, Raymond Fidaleo, M.D. at Sharp Mesa Vista Medical Center ("Sharp Hospital") in San Diego, California. 3-ER-331-32. On April 13, 2011, prior to her first ECT session, Himes executed a "consent" form that was provided to her by Dr. Fidaleo. As Dr. Fidaleo admitted, the consent from did not warn Himes that ECT

could cause permanent memory loss, brain damage, or negatively impact a patient's ability to formulate new memories. 3-ER-342-43, 502.[4]

Dr. Fidaleo never warned Himes of the risk of permanent memory loss and brain damage because Somatics had not provided any such warning to Dr. Fidaleo or Sharp Hospital, either in the manual that accompanied its Thymatron IV ECT device[5] or through any other available

[4] As to cognitive risks, Dr. Fidaleo and the consent documents only informed Himes that the side effects of ECT included some confusion right after treatment and *short-term* memory loss. 3-ER-311-13, 42-43.

[5] During the relevant time period, the manual Somatics supplied to Dr. Fidaleo and Sharp Hospital was the October 2001 (Sixth Edition) Manual for the Somatics Thymatron System IV ECT device since that is the approximate time period Sharp Hospital purchased the ECT device that was used during all of Himes' ECT procedures (which occurred between April 2011 and January 2012). *See* 3-ER-386-93, 509-564. While Dr. Fidaleo does not specifically recall reading the manual, he testified that it is available to him, that his nurse technician who does all of the ECT procedures with him at the hospital read the Somatics ECT manual, that his nurse technician had received training from Somatics personnel on the Thymatron ECT device, and that his nurse technician, in turn, trained him based upon information he had obtained from these Somatics sources. 3-ER-333-35. Somatics has admitted that the manual given to Sharp Hospital did not contain *any* warnings (and likewise did not contain any warnings of permanent memory loss or brain damage). *See* 3-ER-386-93, 509-564.

means, such as "Dear Doctor" letters or labeling updates.[6] Dr. Fidaleo testified that the risk of brain injury is a serious risk and if he knew that a drug or device has the potential to cause brain injury, he "would be reluctant to use it …." 3-ER-337. Dr. Fidaleo testified that "had Somatics provided [him] warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories" he would have relayed those warnings to his patients and such warnings "would be in the informed consent" form. 3-ER-344-45. Himes, in turn, testified that, had she been warned of these risks by Dr. Fidaleo, she would not have consented to ECT (and thus would not have been injured by that ECT). 5-ER-949.

Between April 2011 and January 2012, Himes received a total of 26

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[6] Dr. Fidaleo testified that one of the means by which medical device companies inform him about risks associated with their devices is through "Dear Doctor" letters, which he relies upon in his practice. 3-ER-336. During the relevant time period, Somatics never sent any Dear Doctor letters to Dr. Fidaleo or to Sharp Hospital about the risk of brain damage or permanent memory loss. *See, id.* It was not until *after* Somatics settled the claims of Chase and Riera in this case (October 2018) that Somatics allegedly sent updated warnings via a letter to select doctors concerning the risk of brain damage and permanent memory loss with ECT (4-ER-657-59); and in December 2018, the FDA ordered Somatics to issue enhanced warnings in its Thymatron IV Manual concerning the risk of permanent memory loss associated with its ECT device. 21 C.F.R. § 882.5940.

separate ECT shock treatments at Sharp Hospital utilizing Somatics' Thymatron IV ECT device. 5-ER-949, 1000-1001. In connection with each of these 26 ECT sessions, Himes had to be placed under anesthesia and had electricity administered to her brain. 3-ER-334; *see also* 3-ER 446. As a result of her multiple exposures to ECT, Himes sustained serious cognitive and memory issues, including having long "blacked out" periods of her past, having trouble formulating long term memories, and struggling with reading, retaining basic information, and formulating words. 2-ER-271-74; 5-ER-950.

D. Had Somatics Warned about Brain Damage and Permanent Memory Loss, Benjamin's Doctor Would Have Altered His Conduct and Relayed Those Warnings to Benjamin; and Had Benjamin Been So Warned, She Would Have Refused ECT

Benjamin, an architect who owned her own firm, was 52 years old when she was initially administered ECT in September 2012 to attempt to treat her anxiety and purported depression. 5-ER-942-43, 1040. The ECT was prescribed and administered by her doctor, Michael Frankel, M.D. at Northridge Hospital. *Id.* On September 28, 2012, prior to her initial ECT session, Benjamin executed a "consent" form that was provided to her by Dr. Frankel. 3-ER-490-91. As Dr. Frankel admitted, the consent from did

not warn Benjamin that ECT could cause permanent memory loss or brain damage. 3-ER-364.[7]

Dr. Frankel never warned Benjamin of the risk of permanent memory loss and brain damage because Somatics had not provided any such warning to Dr. Frankel, either in the manual that accompanied its Thymatron IV ECT device (which he had read and on which he relied), or through any other available means.[8] Dr. Frankel testified that, if Somatics had informed him that ECT could be linked to permanent memory loss or permanent brain damage, that is information he would "definitely advise

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[7] As to cognitive risks, Dr. Frankel only informed Benjamin that the side effects of ECT included some confusion right after treatment and *short-term* memory loss. 2-ER-293-94, 3-ER-317-18. He never discussed the risk of brain damage or *permanent* memory loss with the Benjamins. 5-ER-944-45.

[8] The manual supplied to Dr. Frankel and Northridge Hospital by Somatics was the September 20, 2000 (Fifth Edition) Manual for the Somatics Thymatron IV ECT Device since Northridge Hospital purchased its Somatics ECT device in approximately 2001 and that was the device used during all of Benjamins' ECT procedures (which occurred between April 2012 and March 2013). *See* 3-ER-400-403, 565-610. Dr. Frankel testified he read and relied upon the Somatics manual. 3-ER-350-351, 362. This manual, on which Dr. Frankel relied, did not contain *any* warnings about permanent memory loss or brain damage. *See* 3-ER-400-403, 565-610. The district court, not surprisingly, concluded that Somatics had failed to provide adequate warnings concerning the risk of permanent memory loss and brain damage to Dr. Frankel. 1-ER-9.

patients" of during the consent process. 3-ER-364. Benjamin, in turn, testified that, had she been warned by Dr. Frankel that ECT could cause permanent memory loss or brain damage, she would not have consented to the ECT (and thus would not have been injured by ECT). 2-ER-293-94; 5-ER-945.

Between September 2012 and March 2013, Benjamin received a total of 20 separate ECT shock treatments from Dr. Frankel utilizing Somatics' Thymatron ECT Machine. 5-ER-943; 5-ER-1030-31. As a result of her multiple exposures to ECT, Benjamin sustained serious cognitive and memory issues, including forgetting events, cognitive slowness, difficulty formulating her thoughts, and difficulty with reading and writing. 2-ER-298-99; 5-ER-925-40. Her injuries were so severe, she was unable to maintain her architectural firm. 2-ER-284; 5-ER-926. In 2017, Benjamin treated with a neuropsychologist, Dennis Robinson, Ph.D., who performed a neuropsychological examination which revealed severe impairment involving her sensory and cerebral areas and deficits in her ability to organize her memory and learning, with one of the etiologies of her injuries being electroshock therapy. 2-ER-293-94; 5-ER-926-40, 945.

III. Ruling Presented for Review

Although the district court concluded Somatics failed to issue adequate warnings concerning permanent memory loss and brain damage to plaintiffs' doctors, the court still dismissed plaintiffs' claims on causation grounds concluding that, even if the doctors had been warned, they still would have "prescribe[d]" and "administer[ed]" ECT to plaintiffs. 1-ER-9-10. However, the doctors testified that, had they been warned by Somatics, they would have relayed those risks to plaintiffs and plaintiffs have testified that they, in turn, would not have consented to ECT – and thus would never have been administered ECT and would not have been exposed to and sustained the harms of ECT. 2-ER-293-94; 3-ER-344-45, 363-64; 5-ER-945, 949. Under applicable precedent, this is more than sufficient to create a triable issue of fact as to the issue of causation.

SUMMARY OF ARGUMENT

The district court erred in concluding that plaintiffs failed to establish causation pursuant to the learned intermediary doctrine. *First*, under established precedent, Somatics cannot invoke the learned intermediary doctrine as a defense because Somatics *did not* provide adequate warnings to plaintiffs' doctors and the doctors did not independently know that ECT

could cause brain damage or permanent memory loss.

Second, even if the learned intermediary doctrine were to apply, the district court erred in concluding the doctrine barred causation. Specifically, the district court erroneously held that, even if Somatics had provided the doctors with adequate warnings, the doctors would still have prescribed and administered ECT. However, there is no evidence to support this factual proclamation. Indeed, the evidence is to the contrary. Had Somatics provided adequate warnings to the doctors, the doctors would have altered their conduct by relaying those warnings to the plaintiffs, and plaintiffs (after learning of the risks of brain damage and permanent memory loss) would have refused ECT. 2-ER-293-94; 3-ER-344-45, 363-64; 5-ER-945, 949. This undisputed evidence establishes a clean chain of causation— had Somatics warned, plaintiffs would not have been administered ECT and would not have been injured by that ECT.

To accept the district court's conclusion that the doctors still would have administered ECT, one would need to assume and infer that, in violation of civil and criminal laws, the doctors would have repeatedly administered *non-consensual* ECT to patients who refused to consent; an inference that finds no support in any testimony or evidence. So, instead of

drawing all reasonable inferences in *favor* of plaintiffs—as the district court must—the district court drew unreasonable inferences *against* plaintiffs.

Finally, given the district court itself determined Somatics failed to issue any warnings, under California Supreme Court precedent, the intervening acts of the doctors would not absolve Somatics of liability.

STANDARD OF REVIEW

This Court reviews a grant of summary judgment *de novo*. *Clicks Billiards, Inc. v. Sixshooters, Inc.*, 251 F.3d 1252, 1257 (9th Cir.2001). In adjudicating a summary judgment motion, this Court views the evidence "as a whole" and "in the light most favorable to the party opposing the motion," to "determine whether there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law." *Pavoni v. Chrysler Grp., LLC*, 789 F.3d 1095, 1098 (9th Cir. 2015). The Supreme Court has held that, "in ruling on a motion for summary judgment, 'the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.'" *Tolan v. Cotton*, 572 U.S. 650, 651 (2014) (*quoting Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)). "[W]hat is required to defeat summary judgment is simply evidence such that a reasonable juror drawing all inferences in favor of the

[plaintiff] could return a verdict in the [plaintiff's] favor." *Zetwick v. Cty. of Yolo*, 850 F.3d 436, 441 (9th Cir. 2017) (*quoting Reza v. Pearce*, 806 F.3d 497, 505 (9th Cir. 2015)).

Issues of causation, under California law, ordinarily present *a factual question for the jury* and are thus not proper fodder for summary judgment. *Vickers v. United States*, 228 F.3d 944, 953 (9th Cir. 2000); *Campbell v. General Motors Corp*., 32 Cal. 3d 112, 120 (1982) (The question of causation in negligence or products liability cases is often "peculiarly for the jury."); *Vasquez v. Residential Invs., Inc*., 118 Cal. App. 4th 269, 288 (2004) ("causation in fact generally is a question of fact for the jury.")

ARGUMENT

In adjudicating Somatics' motion for summary judgment as to causation, the district court *correctly* concluded that "Defendant did not provide any warnings to Dr. Frankel and Dr. Fidaleo concerning the risk of brain injury or permanent memory loss." 1-ER-9. However, after concluding Somatics had failed to comply with its duties under California law to provide adequate warnings concerning its ECT device, the district court proceeded to dismiss plaintiffs' failure to warn claims by misconstruing and misapplying the learned intermediary doctrine.

Specifically, even though plaintiffs established that, had Somatics adequately warned their doctors about permanent memory loss and brain damage risks, their doctors would have passed on those warnings to plaintiffs and plaintiffs (after being advised of these risks), in turn, would *not* have consented to the ECT procedures (and thus would have avoided the injuries caused by ECT), the district court, nonetheless, held that this was not sufficient under the learned intermediary doctrine to establish causation. 1-ER-9-10; 2-ER-293-94; 3-ER-344-45, 363-64; 5-ER-945, 949. Instead, the district court erroneously held that the *only* path for plaintiffs to establish causation was to show that the doctors would not have "prescribed" ECT. 1-ER-9-10. The district court's ruling conflicts with California law, conflicts with decisions from district courts in this circuit and even conflicts with the district court's prior ruling in this very case. 5-ER-1148. The district court's ruling is flawed in *two* overarching respects.

First, under Supreme Court precedent, Somatics is permitted to rely upon the learned intermediary defense *only* if it demonstrates that it provided adequate warnings to the plaintiffs' doctors. Here, the district court correctly concluded that Somatics had failed to provide adequate warnings to plaintiffs' doctors, thus Somatics was not permitted to rely

upon the learned intermediary doctrine.

Second, even if the learned intermediary doctrine were to apply, plaintiffs established causation by demonstrating that, had an adequate warning been provided by Somatics to their doctors, the doctors' conduct in securing consent would have changed in that they would have relayed those warnings to plaintiffs, and plaintiffs in turn testified that, had they been so warned by their doctors through the consent process, they would have declined the administration of ECT and thus would not have been injured by ECT. 2-ER-293-94; 3-ER-344-45, 363-64; 5-ER-945, 949. This is more than sufficient to establish that Somatics' lack of warning was a cause of plaintiffs being administered ECT (and injured by ECT).

I. Somatics Cannot Assert the Learned Intermediary Defense Because It Failed to Provide Adequate Warnings to those Intermediaries, Rendering them "Un-Learned"

Under established California law, manufacturers have a duty to warn consumers about the hazards inherent in their products. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1003 (1991). The purpose of warnings is to inform consumers about a product's hazards and faults, so they can refrain from using the product altogether or evade the danger by careful use. *Id*. In California, manufacturers are strictly liable for injuries

caused by their failure to warn of dangers that were known or reasonably knowable at the time they manufactured and distributed their product. *Id.*; *see also Carlin v. Superior Court*, 13 Cal. 4th 1104, 1108 (1996). The Supreme Court has made it clear that "[w]hatever may be reasonable from the point of view of the manufacturer, the user of the product must be given the option either to refrain from using the product at all or to use it in such a way as to minimize the degree of danger." *Anderson*, 53 Cal.3d at 1003; *see also Carlin*, 3 Cal.4th at 1109. In *Anderson*, the Supreme Court relied in part upon the Ninth Circuit's decision in *Davis v. Wyeth Laboratories, Inc*. 399 F.2d 121, 129-130 (9th Cir. 1968), which described the manufacturer's need to warn because doing so provides "*true choice*" to consumers and patients. *Anderson*, 53 Cal. 3d at 1003 (*quoting Davis*, 399 F.2d at 129).

In the context of medical products that require a prescription, California has adopted what has often been referred to as the "learned intermediary" doctrine. It provides that, *if* a manufacturer provides adequate warnings to a patient's doctor, then there is no need to warn the patient directly. *Carlin*, 13 Cal. 4th at 1116; *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 994 (1971) ("the manufacturer of an ethical drug discharges its duty of warning if it

adequately warns the doctor..."); *Love v. Wolf*, 226 Cal. App. 2d 378, 395 (1964) (same).

A. Under Supreme Court Precedent, the Learned Intermediary Defense Applies *Only* "If Adequate Warning of Potential Dangers of a Drug Has Been Given to Doctors"

The California Court of Appeal in *Love* articulated the learned intermediary doctrine as follows:

> One who supplies a product directly *or through a third person* for another to use, *is subject to liability to those whom the supplier should expect to use the product with the consent of the other* for bodily harm caused by the use of the product in the manner for which and by a person for whose use it is supplied…This is the law in California. In the case of a drug it has been held there is a duty to exercise reasonable care to warn of potential dangers from use even though the percentage of users who will be injured is not large. ***But if*** adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.

Love, 226 Cal. App. 2d at 395 (cleaned up, emphasis added). Subsequently, the Supreme Court in *Stevens*, relying upon *Love*, adopted the learned intermediary doctrine and held:

> In the case of medical prescriptions, '***if*** adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.'

Stevens, 9 Cal. 3d at 65 (*quoting Love*, 226 Cal.App.2d at 395). Thus, the

learned intermediary is an *exception* to the duty, imposed on any seller of a good, to warn *consumers* directly of known or knowable risks, provided those risks were sufficiently disclosed to the learned intermediary. Indeed, by using the word "*if*" both the Court of Appeal and Supreme Court specifically and intentionally limited the learned intermediary defense (i.e., to avoid a duty to warn patients directly) to those instances where the manufacturer provided "adequate warnings" to the patients' doctors. And, this makes sense. The purpose of the doctrine is not to eliminate a manufacturer's duty to warn; it is to ensure consumers make informed decisions in conjunction with their physician. This principal was echoed and reiterated by the Supreme Court in *Brown*, which held:

> [A] patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties. The manufacturer cannot be held liable ***if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient*** or if the patient relies on inaccurate information from others regarding side effects of the drug

Brown v. Superior Ct., 44 Cal. 3d 1049, 1061–62 (1988) (emphasis added). The drug manufacturer's duty to warn is ultimately for the benefit of the patient, but the manufacturer discharges that duty by providing the warnings to a patient's doctor who, in turn, relays those warnings to the

patient so as to allow the patient to make an informed choice if she wants to expose herself to the risks. *Id*.; *see also Carmichael*, 17 Cal. App. 3d at 994. All of these cases, *Love*, *Carmichael, Stevens,* and *Brown* provide that a pharmaceutical and device manufacturer can only invoke the learned intermediary doctrine "***if*** adequate warning of potential dangers of a drug has been given to doctors." *Stevens*, 9 Cal. 3d at 65 (emphasis added); *Love*, 226 Cal.App.2d at 395; *see also Brown*, 44 Cal. 3d at 1062, n.9 ("It is well established that a manufacturer fulfills its duty to warn ***if*** it provides adequate warning to the physician.") (emphasis added). And, *if* adequate warnings were not given to anyone, the defense is unavailable; any intermediary is, by definition, no longer "learned."

This point was explained cleanly in *Hill v. Novartis Pharms. Corp*., 944 F. Supp. 2d 943 (E.D. Cal. 2013) ("*Hill II*"):

> [T]he doctrine, 'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.' Consequently, where a manufacturer provides inadequate warnings, or no warning at all, it 'cannot rely upon the intermediary, even if learned, to pass on or give warnings.' While Novartis appears to suggest that a drug manufacturer's duty to warn of risks associated with its prescription drugs runs only to a prescribing physician regardless of the adequacy of the warnings, Novartis has provided no authority—and the Court's research reveals no authority—to support such a proposition.

Hill II, 944 F. Supp. 2d at 953–54 (internal citations and brackets omitted) (*quoting Stewart v. Union Carbide Corp.*, 190 Cal.App.4th 23, 29 (2010)).

Here, it is *undisputed* that Somatics did not provide *any* warnings to plaintiffs' ECT doctors, much less adequate warnings, concerning brain injury or permanent memory loss. 1-ER-9; 3-ER-387-93, 400-403, 509-610; 4-ER-612-625. Thus, under California Supreme Court precedent, Somatics cannot invoke the learned intermediary defense. Any other rule would pervert the entire purpose of the learned intermediary doctrine, effectively shielding medical device and pharmaceutical makers from liability even when they clearly did not warn of a known or knowable risk. Summary judgment based on the learned intermediary doctrine should have been denied. *Stevens*, 9 Cal. 3d at 65; *Love*, 226 Cal. App. 2d at 395.

Remarkably, even though plaintiffs' cited *Love*, *Stevens* and *Hill II*, the district court's order fails to make any mention of the Supreme Court's binding *Stevens* decision (or the Court of Appeal's decision in *Love*) and instead focuses exclusively on *Hill II*. And, although the district court's disregard of binding California Supreme Court precedent (i.e., *Stevens*), is itself, reversable error, *see, e.g.*, *In re Kirkland*, 915 F.2d 1236, 1238 (9th Cir. 1990), the district court's discussion of *Hill II* was deeply flawed.

First, the district court attempted to distinguish *Hill II* by explaining that the *Hill II* court applied law regarding the "sophisticated intermediary doctrine – not the learned intermediary doctrine." 1-ER-8-9 (citing *Stewart*, 190 Cal. App. 4th 29). But, that is simply not true. *Hill II* drew its reasoning not only from *Stewart*, which focused on the sophisticated intermediary doctrine, but also from the Court of Appeal decision in *Love*—a case that squarely addressed the learned intermediary doctrine and was specifically endorsed and quoted by the Supreme Court in *Stevens*. *See Hill II*, 944 F. Supp. 2d at 953 (citing *Stewart* and *Love*). Thus, doctrinally, the district court was plain wrong in concluding that the *only* source of reasoning for *Hill II* is *Stewart*.

Second, even if the *Hill II* court drew from caselaw about the sophisticated intermediary doctrine, it is unclear why that renders its analysis incorrect. The two doctrines are clearly "related." *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187, n.10 (2016). And, they both involve the concept that, for certain industries, a manufacturer can discharge its duties to warn the ultimate user (or patient) by warning an intermediary and both have their origins in Section 388 of the Restatement (Second) of Torts. *Webb*, 63 Cal. 4th at 185 & n.10; *see also Bryant v. Tech. Rsch.* Co., 654 F.2d

1337, 1347 (9th Cir. 1981). Thus, the fact that *Stewart* may have dealt with the sophisticated intermediary defense as opposed to the learned intermediary defense is no reason for the district court to have outright disregarded its reasoning.

Lastly, the district court disregarded *Stewart* (and thus *Hill II*), on the grounds that *Stewart's* conclusion that "the sophisticated intermediary doctrine…where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary" (*Stewart*, 190 Cal. App. 4th at 29) was purportedly overturned by the Supreme Court in *Webb*. However, again, that is simply not true.

Webb involved an asbestos case wherein the Supreme Court formally recognized the sophisticated intermediary defense and noted it was "related" to the learned intermediary defense. *Webb*, 63 Cal. 4th at 187 & n.10. The plaintiff in *Webb* had been diagnosed with mesothelioma and sued the company that had brokered the sale of raw asbestos to which he had been exposed. The jury returned a verdict in favor of the plaintiff. The trial court granted judgment notwithstanding the verdict because the defendant, as a broker of raw asbestos, had no duty to warn the end user and that it also did not have a duty to warn the immediate purchaser of the

raw asbestos, because the purchaser was a sophisticated manufacturer who purportedly was already aware of the risk of asbestos. The Supreme Court reversed the trial court's ruling. In *Webb*, the Supreme Court formally adopted the sophisticated intermediary defense and held that, under the doctrine, the bulk supplier may discharge its duties to warn by: (1) either (a) warning the immediate purchaser; or (b) selling to a sophisticated purchaser that the supplier knows is already aware or should be aware of the specific dangers of the product; and (2) the supplier reasonably relies on the immediate purchaser to convey the warnings to downstream users who will use/encounter the product. *Webb*, 63 Cal. 4th at 187. The court further held that, because the sophisticated intermediary doctrine is an affirmative defense, "the supplier bears the burden of proving that it adequately warned the intermediary, or knew the intermediary was aware or should have been aware of the specific hazard, and reasonably relied on the intermediary to transmit warnings." *Id*.

Webb thus held that, "[u]nder the sophisticated intermediary doctrine's first prong, generally the supplier must have provided adequate warnings to the intermediary about the particular hazard[,]" however the court recognized a "narrow exception" and noted that "[i]n some cases the

buyer's sophistication can be a substitute for actual warnings, but this limited exception only applies if the buyer was so knowledgeable about the material supplied that it knew or should have known about the particular danger." *Webb*, 63 Cal. 4th at 188. Based on this narrow exception, the Supreme Court disapproved of the language in *Stewart* that had blanketly held "that [the sophisticated intermediary] doctrine, where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary." The Supreme Court disapproval of *Stewart* was limited to the extent *Stewart* had not recognized the "narrow exception" noted above. *Webb*, 63 Cal. 4th at 188.[9] However, here, Somatics has not argued (nor has it established) that Drs. Fidaleo and Frankel were already aware of the risk of permanent memory loss and brain injury associated with the Somatics ECT machine. To the contrary, the testimony of the two doctors establishes they were not aware of these risks, and had they been so warned by

[9] Indeed, in *Webb*, after formally adopting the sophisticated intermediary defense, the Supreme Court went on to hold that the defendant could not seek shelter behind the defense because the defendant had not warned the intermediary and defendant did not alternatively establish that the intermediary (which notably was "the oldest and largest manufacturer of asbestos containing products" and "aware of the risks of asbestos in general") knew about the risks associated with defendant's asbestos product. *Webb*, 63 Cal. 4th at 192–93.

Somatics, they would have altered their conduct by relaying those risks to their patients. 3-ER-337, 344-45, 363-64.

Thus, given that it is undisputed that Somatics did not issue any warnings of brain injury and permanent memory loss to Drs. Fidaleo and Frankel (1-ER-9; 3-ER-387-93, 400-403, 509-610; 4-ER-612-625), and given that Somatics has not argued nor has it established that these two doctors were independently aware of these risks (indeed the evidence established that the doctors were not aware of these risks), then pursuant to *Love*, *Stevens*, *Brown*, *Stewart*, *Hill* and *Webb*, Somatics is *not* permitted to seek shelter behind the learned intermediary defense.[10] The district court thus erred in dismissing plaintiffs' case under the learned intermediary doctrine

[10] This conclusion has also been reached by other district courts applying California law. *See A.S. v. Pfizer, Inc.*, No. 1:13-CV-00524-LJO, 2013 WL 2384320, at *6 (E.D. Cal. May 30, 2013) ("Where the warning fails to provide the doctor with known or knowable information which militates against use of the drug by certain patients, the learned intermediary doctrine does not preclude imposition of liability."); *Martin v. Merck & Co.*, No. S-05-750 LKK/PAN, 2005 WL 1984483, at *4 (E.D. Cal. Aug. 15, 2005) (same); *see also Salyards ex rel. Salyards v. Metso Mins. Tamper OY*, No. 1:04 CV 05798 OWW LJ, 2005 WL 3021959, at *9 (E.D. Cal. Nov. 10, 2005) (denying summary judgment because "here, the warning in the instruction manual is inferred to be inadequate under summary judgment rules. It is impossible (and improper) for the court to speculate what steps Mr. Warden might have taken to improve safety if a different set of warnings had been included in the manual.").

when the evidence revealed (and the district court itself concluded) that Somatics had not issued warnings to the intermediaries.

B. Under California Supreme Court Precedent, a Manufacturer's Liability for Failing to Provide Adequate Warnings is Not Absolved by a Doctor's Intervening Conduct

It is undisputed that this case is governed by California law and this Court is bound by the decisions of the California Supreme Court. *In re Kirkland*, 915 F.2d at 1238. While the California Supreme Court has recognized the learned intermediary doctrine since at least 1973 (*Stevens*), in the intervening 48 years, *not a single* published California Appellate or Supreme Court case has ever dismissed a pharmaceutical or medical device products liability case on the theory the district court adopted in this case (i.e., that the learned intermediary bars causation even when the manufacturer failed to provide adequate warnings to the plaintiff's doctor). The district court's order does not cite any state cases on this point (*see* 1-ER-7-9), Somatics' motion did not cite any state cases on this point, and plaintiffs' independent research has likewise not revealed a single published California state court decision that has found causation lacking on the grounds of the learned intermediary doctrine under these circumstances. *See e.g.*, *Hill II*, 944 F. Supp. 2d at 953–54 (noting the lack of

California law supporting the drug manufacturer's arguments). The dearth of published state law authority on this point is telling. *Stevens* confirms that the California Supreme Court would *not* endorse the district court's opinion, i.e., that even though the drug manufacturer breaches its common law duties and fails to give adequate warnings to the doctor, the intervening conduct of the doctor allows the manufacturer to escape liability.

Stevens was a wrongful death case wherein it was alleged that the decedent had died as a result of an antibiotic she had been prescribed. *Stevens*, 9 Cal. 3d at 56. The decedent's family sued the prescribing doctor and the drug manufacturer and prevailed against both defendants at trial. *Id*. at 59. On appeal, the drug manufacturer argued that it had issued adequate warnings to the doctor and that the doctor was already aware of the risk of fatality associated with the antibiotic. *Id*. at 67. The Supreme Court held that any warning the manufacturer may have issued in its label, was watered down by its overpromotion. The high court found that the overpromotion led to the warnings being "nullified," i.e., as if the manufacturer had never warned. *Stevens*, 9 Cal. 3d at 67. Alternatively, *and germane to this case*, the Supreme Court went on to hold

that "even assuming for the sake of argument that the jury accepted [the doctor's] testimony that he was cognizant of the dangers of the drug, nevertheless his negligence was not, as a matter of law, an intervening cause which exonerated [the drug manufacturer]." *Stevens*, 9 Cal. 3d at 69. The Supreme Court went on to hold that, under California law, the intervening acts of a third person (i.e., the doctor) do not absolve the liability of the original negligent actor (i.e., the negligent drug manufacturer). *Stevens*, 9 Cal. 3d at 69 ("Parke, Davis cannot be relieved of liability because of the intervening act of Dr. Beland in prescribing the drug while cognizant of its dangers. If there is room for reasonable men to differ as to whether the intervening act was reasonably foreseeable, then the question is properly left to the jury.") (*citing McEvoy v. Am. Pool Corp.*, 32 Cal. 2d 295, 299 (1948)). This language from the Supreme Court in *Stevens* is an indication that California law would not allow the intervening conduct of doctors to allow Somatics (which failed to provide warnings) from escaping liability. At a minimum, this is an issue that should be resolved by the trier of fact. *Stevens*, 9 Cal. 3d at 69; *see also T.H. v. Novartis Pharms. Corp.*, 4 Cal. 5th 145, 184 (2017) ("we have never allowed a defendant to excuse its own negligence as a matter of law simply by

asserting that someone else should have picked up the slack and discharged the duty at issue…Nor have we permitted a negligent actor to evade liability simply because another party may also be liable for a similar tort."); *Stewart v. Cox*, 55 Cal. 2d 857, 864 (1961) ("The fact that a third person does not perform his duty to protect the plaintiff from harm, either because he makes no effort or through his negligence does not succeed, is not a superseding cause."); *see also Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 968–69 (1997) ("California has definitively adopted the substantial factor test of the Restatement Second of Torts for cause-in-fact determinations. Under that standard, a cause in fact is something that is a substantial factor in bringing about the injury. The substantial factor standard generally produces the same results as does the 'but for' rule of causation which states that a defendant's conduct is a cause of the injury if the injury would not have occurred 'but for' that conduct.") (internal citations omitted).[11]

[11] The law from other jurisdictions is in accord. *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972) ("Correspondingly, having put a dangerous drug on the market without adequate warning defendant cannot be heard to say that the physician might have disregarded a proper one."); *Hamilton v. Hardy*, 37 Colo. App. 375, 387 (1976) ("Consequently, we

II. Even If the Learned Intermediary Defense Were Applicable, Plaintiffs Established That Somatics' Failure to Warn their Doctors Was a Cause of Their Injuries

Even though Somatics had not issued adequate warnings to Drs. Fidaleo and Frankel, the district court, relying upon the learned intermediary doctrine, concluded that plaintiffs failed to establish causation. 1-ER-9-10. As outlined *supra*, given that Somatics failed to issue any warnings to plaintiffs' doctors, the Court erred in applying the learned intermediary doctrine to conclude that causation was lacking. *See Stevens*, 9 Cal. 3d at 65, 69; *Love*, 226 Cal.App.2d at 395 and *Hill II*, 944 F. Supp. 2d at 953–54. Moreover, even assuming the learned intermediary doctrine would apply in these circumstances, in dismissing the plaintiffs' claims, the

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hold that where an ethical (i.e., prescription) drug manufacturer puts a drug on the market without adequate warning, the prescribing doctor's conduct may not insulate the manufacturer from liability where the inadequacy of the warning may have contributed to plaintiff's injury. What the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case.") (*overruled on other grounds by State Bd. of Med. Examiners v. McCroskey*, 880 P.2d 1188 (Colo. 1994)); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) ("The sole issue was whether appellant negligently failed to make reasonable efforts to warn appellee's doctors. *If appellant did so fail, it is liable regardless of anything the doctors may or may not have done*. If it did not so fail, then it is not liable for appellee's injury. The issue was to be resolved by the jury, and we see no error in the court's instruction.") (emphasis added).

district court misconstrued the doctrine and plaintiffs' causation burden. Specifically, the district court erroneously held that, under California law, the only way plaintiffs can prove causation is to demonstrate that, had their doctors been properly warned, they would not have prescribed ECT. 1-ER-9-10. While that is certainly one path to establishing causation, it is not the sole path under California law. Rather, under California law (and the law of most jurisdictions), plaintiffs *can* also establish that a lack of warning was a cause of their injuries by demonstrating that, had their doctors been adequately warned by Somatics, the doctors *would have relayed the stronger warnings to plaintiffs* and plaintiffs relying upon the stronger warnings would not have consented to the procedure, which is exactly what plaintiffs in this case established. 2-ER-293-94; 3-ER-344-45, 363-64; 5-ER-945, 949; *see also Georges v. Novartis Pharms. Corp.*, 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013); *Stanley v. Novartis Pharm. Corp.*, 11 F.Supp.3d 987, 1003 (C.D. Cal. 2014). The district court's refusal to accept this causation path, which is consistent with California law, and indeed consistent with the district court's prior ruling in this very case (5-ER-1151), constitutes reversible error.

A. Plaintiffs Are Not Required to Show That, Had Somatics Warned, Their Doctors Would Not Have "Prescribed" ECT; Rather, Plaintiffs Can Establish Causation by Showing that, Had Somatics Warned, Their Doctors Would Have Relayed Those Warnings, and Armed with the Warnings, Plaintiffs Would Have Refused ECT

In *Motus II*, this Court, relying upon a Second Circuit decision applying California law, held that: "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.*, 358 F.3d 659, 661 (9th Cir. 2004) ("*Motus II*") (*citing Plummer v. Lederle Labs., Div. of Am. Cyanamid Co.*, 819 F.2d 349, 358-59 (2d Cir.1987)) (emphasis added). Notably in *Motus II*, this Court did not require that plaintiffs prove that their physician would not have prescribed the drug, rather, this Court recognized that causation can be established by broader means—i.e., demonstrating that "the conduct" of the physician would have been "altered" had stronger warnings been provided. *Motus II*, 358 F.3d at 661. Certainly, if a physician changes his consent document or relays stronger warnings to the patient in light of enhanced warnings, that constitutes "altered" conduct. Indeed, even the Second Circuit's *Plummer* decision on which *Motus II* is grounded, held that causation was

lacking because the doctor testified that he knew of the risks of the vaccine and still decided *not to warn* the patient, thus it was the doctor's refusal to relay the warning to the patient that led to the Second Circuit not finding causation. *Plummer*, 819 F.2d at 358-59.

Accordingly, *Motus II* and its foundation (*Plummer*), make clear that the focus is on whether the doctor would have *relayed the stronger warnings about the drug's risk to the patient* – and, here (unlike the doctor in *Plummer*), both Drs. Fidaleo and Frankel testified that, had Somatics issued timely warnings of the risks of brain damage and permanent memory loss, they would have altered their conduct and would have relayed such warnings and risks to their respective patients, including to Himes and Benjamin. 3-ER-344-45, 363-64. *In addition*, both Himes and Benjamin have attested that, had they received warnings concerning brain damage or permanent memory loss from their doctor concerning ECT, they would *not* have consented to its administration. 2-ER-293-94; 5-ER-945, 949. Under *Motus II, Plummer* and other subsequent federal cases applying California law, this is more than sufficient to establish causation. *Georges*, 988 F. Supp. 2d at 1158; *Stanley*, 11 F.Supp.3d at 1003; *Hill v. Novartis Pharms. Corp.*, No. 1:06-CV-00939-AWI, 2012 WL 6004161, at *4 (E.D. Cal. Nov. 30, 2012) ("*Hill*

I"); see also *Riera v. Somatics, LLC*, 2:17-CV-06686-RGK, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018)(5-ER-1151).

Georges, Stanley, Hill and *Riera* are instructive. In *Georges*, the district court affirmed a jury verdict and held a plaintiff had met her burden of causation since she testified that, even if the doctor would have prescribed the medications, had she received the enhanced warnings (which the manufacturer had failed to provide), her use of the drug would have differed with adequate warnings, and the court held that "[t]his alone is sufficient for a jury to find that Plaintiff's use of the Treatment Drugs would have changed with adequate warning." *Georges*, 988 F. Supp. 2d at 1158.

In *Stanley*, plaintiff alleged the cancer medication she was prescribed caused osteonecrosis of the jaw ("ONJ") and sued the manufacturer of the cancer medication for failing to warn of this risk. The drug manufacturer moved for summary judgment on the grounds that plaintiff's oncologist testified he still would have prescribed the cancer medication even if he had been warned of the risk of ONJ. The district court denied summary judgment and held:

Defendant argues that summary judgment is appropriate on all

> Plaintiff's remaining claims because Plaintiff's oncologists stated that they still would have prescribed [the drugs] if they had been aware of the risk of ONJ at the time they started prescribing the drugs. *While the evidence supports that Dr. Molina and Dr. Nakamura would have prescribed [the drugs] even if they knew about the potential association between these drugs and ONJ, changes to treatment and prescription procedures creates a triable question of fact on specific causation*…Here, Dr. Molina and Dr. Nakamura both testified that they would have a different conversation with their patients regarding the risks and benefits in taking bisphosphonates.

Stanley, 11 F. Supp. 3d at 1003 (emphasis added). The court thus held that the fact the doctors would have relayed stronger warnings to their patients was sufficient to defeat summary judgment. *Id*. Notably, this Court subsequently *favorably* quoted *Stanley* on this very point. *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1239 (9th Cir. 2017) (quoting *Stanley* that "[c]hanges to treatment and prescription procedures created a triable question of fact on specific causation.").

Hill I, like *Stanley*, involved a plaintiff who had sustained ONJ after taking the drug manufacturer's cancer drug. As Somatics did here, the defendant in *Hill* sought summary judgment on the grounds that the plaintiff's doctor would still have prescribed the drug even if he had received enhanced warnings concerning the risk of ONJ. The district court denied summary judgment because the evidence revealed that, had the

doctor been warned, he would have relayed those warnings to the plaintiff and the plaintiff testified that, had she been so warned, she would not have consented to the use of the drug. *Hill*, 2012 WL 6004161, at *4.

Even the district court below, in previously denying Somatics' summary judgment as to plaintiffs Chase and Riera in this case, held summary judgment on such causation grounds was not appropriate because those plaintiffs had presented evidence that, had their doctors been adequately warned, they would have relayed those warnings to plaintiffs. *Riera*, 2018 WL 6242154, at *11 ("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.") (5-ER-1151).

In sum, *Motus II*, *Wendell*, *Georges, Stanley, Hill* and *Riera* confirm that, under California law, when plaintiffs have established that their doctors would have altered their conduct and relayed stronger warnings to plaintiffs (i.e., had the device manufacturer provided adequate warnings to their doctors), and after receiving the warnings, plaintiff's refuse to consent to the use of the device, then plaintiffs have established that the

manufacturer's lack of warnings to their physicians was a cause of their device-induced injuries. The law in other jurisdictions is in accord. *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006) (Texas law) (reversing the district court's grant of summary judgment on the plaintiff's failure to warn claims where the treating physician testified that, had additional risk information about the drug been disclosed to him, he would have discussed those risks with the plaintiff, and in turn, the plaintiff testified that she would not have taken the drug had she known of such risks); *Payne v. Novartis Pharms. Corp.*, 767 F.3d 526, 531–32 (6th Cir. 2014) (Tennessee law) (same); *Toole v. McClintock*, 999 F.2d 1430, 1433 (11th Cir. 1993) (Alabama law); *Fields v. Eli Lilly & Co.*, 116 F. Supp. 3d 1295, 1308 (M.D. Ala. 2015) (Alabama) ("Mrs. Fields can demonstrate factual causation by proving that had Lilly given Dr. Durden a stronger warning about the association between the ingestion of Prozac® during pregnancy and an increased risk of birth defects, Dr. Durden would have informed Mrs. Fields of the risk and his warning would have resulted in a different outcome for Mrs. Fields in that she would not have taken Prozac®…*Toole* is contrary, therefore, to Lilly's argument that the sole method by which to measure a warning's effect on the physician is through evidence that the prescribing physician would not

have prescribed the drug had the warnings been adequate"); *Simon v. Wyeth Pharms.*, Inc., 989 A.2d 356, 375 (2009) (Pennsylvania); *Mongeon v. Ethicon, Inc.*, 456 F. Supp. 3d 298, 301-03 (D. Mass. 2020) (Massachusetts); *Gilliland v. Novartis Pharms. Corp.*, 34 F. Supp. 3d 960, 972 (S.D. Iowa 2014) (Iowa) (denying summary judgment as to the plaintiff's failure to warn claims and holding "[t]he learned intermediary doctrine certainly does not allow health care professionals to substitute their judgment for that of their patients. Nor does it obviate the need to consider whether the plaintiff-patient's decision concerning her recommended course of treatment would have been different, assuming that the warning at issue had been more adequate.").

B. The District Court Misconstrued *Motus I* and Failed to Appreciate That *Motus I* (a Wrongful Death Case) was Factually Distinguishable

In erroneously concluding that plaintiffs had the burden of establishing that, had Somatics issued adequate warnings, their doctors would not have "prescribed" ECT, the district court relied in a large part upon language contained in the district court's *Motus I* decision. *See* 1-ER-9-10 (*quoting Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal. 2001)) ("*Motus I*"). The district court erred to the extent it read *Motus I* to stand

for the proposition that the *sole* path to establishing causation in such cases is to demonstrate that the doctor/intermediary would not have "prescribed" the drug, device, or procedure. *First*, as previously stated, in *Motus II,* the Ninth Circuit clarified that the appropriate standard is not exclusively whether the doctor would not have prescribed the drug or procedure, but rather, whether stronger warnings would have "*altered the conduct* of the prescribing physician." *Motus II*, 358 F.3rd at 661 (*quoting Plummer*, 819 F.2d at 358) (emphasis added). The fact that, in the face of stronger warnings, Drs. Fidaleo and Frankel testified they would have altered the consent forms discussions with plaintiffs and would have relayed the warnings to plaintiffs demonstrates that "the conduct" of the doctors would have been "altered" had they been warned. 3-ER-337, 344-45, 363-64. And, this altered conduct (i.e, relaying of warnings about brain damage and permanent memory loss by the doctors to the plaintiffs) would have led to Himes and Benjamin refusing to consent to ECT and thus averting the ECT-induced injuries. 2-ER-293-94; 5-ER-945, 949. Thus, the district court's cramped reading of *Motus I* (i.e., focusing exclusively on prescription) cannot be reconciled with *Motus II* (which broadly inquired whether a physician's conduct would have been altered) and *Plummer*

(which focused on whether the doctor would have relayed the enhanced warnings to patients). Likewise, the district court's reading of *Motus II* cannot be reconciled with the myriad of other district courts in California which have held the focus is on whether the stronger warnings would have been relayed to the plaintiffs by the doctors. *Georges*, 988 F. Supp. 2d at 1158; *Stanley*, 11 F.Supp.3d at 1003; *Hill I,* 2012 WL 6004161, at *4; *see also Riera*, 2018 WL 6242154, at *11.

Second, a close reading of *Motus I* demonstrates that, whether or not a doctor would have prescribed the medication is not a litmus test to establishing causation. Notably, *Motus I* discussed alternative sets of facts to establish causation, such as if the drug-induced injury occurred over time and the physician, having been properly warned, would have taken precautions or would have detected the injury earlier. *Motus I*, 196 F. Supp. 2d at 995 (discussing *McEwen v. Ortho Pharmaceutical Corp*., 270 Or. 375, 528 P.2d 522, 539 (1974) *and Stanback v. Parke, Davis* & Co., 657 F.2d 642, 646 (4th Cir. 1981)). Thus, even *Motus I* appreciated that establishing that the doctor would not have prescribed the drug or procedure is not the sole or exclusive means of establishing causation.

Third, and finally, there is an important factual distinction between

Motus I and the present case that is dispositive. *Motus I* was a *wrongful death* (suicide) case and thus the injured patient could not testify as to what he would have done had his doctor relayed enhanced warnings to him. Accordingly, unlike our case, which is a personal injury case, in which the plaintiffs are alive and have testified that, had they been adequately warned by their doctors, they would not have consented to the ECT (2-ER-293-94; 5-ER-945, 949), the patient in *Motus* was deceased and could not provide such testimony to fulfil the court's causation hurdle. The fact that the patient in *Motus I* could not provide testimony concerning how he would have reacted to stronger warnings relayed to him by his doctor may best explain why the district court in *Motus I* placed so much emphasis on whether the doctor would have "prescribed" the alleged suicide-inducing drug. It appears the court believed the primary means, if not the sole means, of proving causation in a death case such as *Motus I* was to establish that the doctor would not have prescribed the drug with a stronger warning. This critical distinction between *Motus I* and this case is another important reason the district court's reliance on *Motus I* was in error.

C. The Extra-Jurisdictional Authority on Which the District Court Relied Are Likewise Factually and Legally Distinguishable

In addition to *Motus I*, the district court relied upon three extra-jurisdictional cases. The *first* case, *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) (applying Mississippi law), involved a plaintiff who claimed her acne medication caused her seizures. Her doctor testified that, at the time he prescribed the medication, he was aware the drug may cause seizures. *Thomas*, 949 F.2d at 811. In addition, unlike the facts of this case, it does not appear any testimony was procured in *Thomas* as to whether her doctor would have relayed stronger warnings to her (indeed it appeared the doctor was already aware of the risks and did not warn her), nor did there appear to be any testimony as to how the plaintiff would have responded if provided enhanced warnings. Finally, *Thomas* does not suggest that the court was making the doctor's decision to prescribe a litmus test. Rather, the language of the court as to what is required for causation was far broader, including showing that an enhanced warning would have led to plaintiffs not "receiving" the drug. *Thomas*, 949 F.2d at 812. Furthermore, the Fifth Circuit has subsequently held that causation *can* be established by a plaintiff demonstrating that her treating physician

would have relayed the enhanced warnings to her and plaintiff, in turn, testifying she would not have taken the drug had she known of the new risks. *McNeil*, 462 F.3d at 373.

The *second* case, *Brown v. Johnson & Johnson*, No. 11-7-CV-01285-AWI-EPG, 2019 WL 2577296, at *9 (E.D. Cal. June 24, 2019), involved a pro se prisoner who alleged the defendant's drug caused him to develop gynecomastia and tardive dyskinesia. The court granted summary judgment by engaging in the same erroneous reading of *Motus I* as was done by the district court in our case (i.e., requiring the pro se prisoner-plaintiff to establish that his doctor would not have prescribed the drug had he been adequately warned). Further, *Brown* is factually distinguishable since the court there held that (unlike our case) plaintiff's prescribing physician was already aware of the risk of gynecomastia and tardive dyskinesia associated with the drug. *Id*.

The *third* case, *Guillen v. Eli Lilly* & Co., 394 F. App'x 814, 816 (2d Cir. 2010), is factually distinguishable. Unlike this case, the evidence in *Guillen* established the prescribing doctor was already aware of the risks alleged and chose not to warn. *Guillen*, 394 F. App'x at 816; *cf. Bravman v. Baxter Healthcare Corp*., 984 F.2d 71, 75 (2d Cir. 1993) ("Although the apparently

highly qualified Dr. Spencer testified that he would not have passed on the noise information to Bravman even if he had received it, that testimony is insufficient to resolve the proximate cause question. It is up to the trier of fact to determine whether, and the extent to which, Dr. Spencer's testimony on this point is credible, or even if it is, whether it would be found by a jury to be material…we do not think that the question of proximate cause can be determined properly on summary judgment.")

III. In Determining that Causation is Lacking, the District Court Impermissibly Concluded That the Doctors' Decision to "Prescribe" ECT Trumps the Patients' Right to "Refuse to Consent"

Perhaps the most disturbing flaw in the district court's order is its wholesale disregard of patient autonomy. The district court essentially concluded that, whether or not patients choose to consent to being placed under anesthesia and having a substantial amount of electrical current administered to their brains (current that is roughly *one-fifth* as much as the electrical current used in the electric chair for executions), *is not relevant* to their products liability failure to warn claims, and instead, the only thing that matters is if their doctors choose to administer ECT or not. In effect, the district court viewed Benjamin and Himes as no different than the poor sap Cerletti and Bini found wandering around the Rome train station in

1938, and to whom Cerletti and Bini decided to administer multiple rounds of ECT against his will and without consent, even as he pleaded "*Non una seconda! Mortifera*!"

Thankfully, we have come a long way since 1930s Italy. California law has long recognized that each patient has a right to refuse treatment. *Cobbs v. Grant*, 8 Cal. 3d 229, 243–44 (1972); *Riese v. St. Mary's Hosp. & Med. Ctr.*, 209 Cal. App. 3d 1303, 1317 (1987). Benjamin and Himes were not incompetent adults, nor had they been involuntarily committed. Both went to their doctors voluntarily and only agreed to undergo multiple rounds of ECT after having the risks and benefits explained to them by their doctors. Those doctors, however, did not know, or appreciate the full extent of the serious harms associated with ECT (including the harm of permanent memory loss and brain damage), because Somatics willfully failed to warn of these risks, thus, the doctors were not able to relay these important warnings to Himes and Benjamin. 3-ER-337, 344-45, 363-64. Both doctors testified that, had Somatics issued such warnings, they would have relayed them to their patients, and Himes and Benjamin testified that, had they been so warned, they would have refused to consent to ECT, as is their right under California law. 2-ER-293-94; 3-ER-344-45, 363-64; 5-ER-

945, 949; *Cobbs*, 8 Cal. 3d at 243 ("the decision whether or not to undertake treatment is vested in the party most directly affected: the patient."); *see also* CAL. WELF. & INST. CODE § 5326.85 ("No convulsive treatment shall be performed if the patient, whether admitted to the facility as a voluntary or involuntary patient, is deemed to be able to give informed consent and refuses to do so.") As one California court cogently held:

> [T]he right to give or withhold consent to medical treatment is protected by the common law of this state…and by the constitutional right to privacy...Treatment with antipsychotic drugs not only affects the patient's bodily integrity but the patient's mind, the 'quintessential zone of human privacy.'… We have seen that such treatment has profound effects—both intended and unintended—on mind and body. The right to refuse treatment with these drugs clearly falls within the recognized right to refuse medical treatment… this right is among those 'guaranteed all other persons by the ... Constitution and laws of the State of California'…

Riese, 209 Cal. App. 3d at 1317–18 (cleaned up; internal citations and brackets omitted). Furthermore, the Supreme Court has held that "the patient's right of self-decision is the measure of the physician's duty to reveal. That right can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice." *Cobbs*, 8 Cal. 3d at 244–45. Here, Himes and Benjamin were robbed of that fundamental "right of self-decision" because Somatics concealed the risks of brain

damage and permanent memory loss from their doctors and thus Himes and Benjamin were never informed of these risks by their doctors. They were robbed a second time of that fundamental "right of self-decision" when the district court erroneously held that the decision of whether Himes or Benjamin would have consented to the ECT procedure is not relevant to the inquiry of their failure to warn claims. 1-ER-10.

In essence, in order to conclude that causation is lacking, the district court had to presume and conclude that, in violation of California common law (*Cobbs*), criminal law (*battery*)[12] and statutory law (CAL. WELF. & INST. CODE § 5326.85), Drs. Fidaleo and Frankel would have administered ECT even *after* Himes and Benjamin refused to consent.[13] A simple recitation of

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[12] *Valdez v. Percy*, 35 Cal. App. 2d 485, 491 (1939) ("It is firmly established as the law that where a person has been subjected to an operation without his consent such an operation constitutes technical assault and battery."); *see also* CAL. PENAL CODE § 242 (battery)

[13] One could argue a doctor's repeated intentional *non-consensual* application of brain-injury-inducing electrical current to a person's brain would also constitute a violation of the Nuremberg Code and the International Covenants on Human Rights. *See Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 178 (2d Cir. 2009) ("the Nuremberg Code as part of the tribunal's final judgment against fifteen doctors who were found guilty of war crimes and crimes against humanity for conducting medical experiments without the subjects' consent… The Code created as part of the tribunal's judgment

such a presumption and conclusion is sufficient to refute it and, indeed, such a presumption is at odds with the evidence obtained in this case and the district court's prior ruling. *Riera*, 2018 WL 6242154, at *11 ("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 the 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.")

CONCLUSION

The district court's application and interpretation of the learned intermediary doctrine is at odds with California precedent, the precedent of this Court, the precedent of other district courts and indeed is even at odds with the district court's prior ruling in this action. On a broader scale, the district court's ruling (which *sub silentio* presumes and concludes that causation is lacking because plaintiffs' doctors would purportedly have

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therefore emphasized as its first principle that '*[t]he voluntary consent of the human subject is absolutely essential*.'") (emphasis added); see also CAL. CODE REGS. TIT. 22, § 70707(b)(5) (California Patient's Bill of Rights).

non-consensually administered brain damage-inducing electrical current to their patients against their will) is at odds with the evidence adduced in this case, and at odds with constitutionally rooted principles and laws governing the autonomy of patients. As the Court of Appeals most eloquently articulated in *Riese*:

> the forcible administration of powerful mind-altering drugs also involves moral and ethical considerations not solely within the purview of the medical profession, and must be measured by the social consensus reflected in our laws. Exemption of these decisions from such external evaluation would invest physicians with a degree of power over others that cannot be squared with the intent of our Legislature and with the great value our society places on the autonomy of the individual...
> Unless the incompetence of a person refusing drug treatment has been judicially established, '***it is the individual who must have the final say in respect to decisions regarding his medical treatment*** in order to insure that the greatest possible protection is accorded his autonomy and freedom from unwanted interference with the furtherance of his own desires.'

Riese, 209 Cal. App. 3d at 1324 (emphasis added). The district court committed grave error when it concluded that the purported decision of the doctors to recommend or prescribe ECT eviscerates the patients' constitutionally, statutory, and common law protected right to refuse to consent to the administration of ECT.

The district court's Order entered May 14, 2021, and resulting May

21, 2021, judgment should be reversed. Michelle Himes, Marcia Benjamin, and Daniel Benjamin[14] should have their Second (Negligence), Third (Strict Liability-Failure to Warn) and Fifth (Loss of Consortium) Causes of Action reinstated and be permitted to proceed to a trial on the merits.

Dated: August 26, 2021

Respectfully submitted,

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[14] In dismissing Daniel Benjamin's loss of consortium claim (Fifth Cause of Action), the district court essentially concluded that his cause of action rises and falls depending on the viability of his wife's negligence and strict liability failure to warn claims. *See* 1-ER-8 n.3. As outlined herein, given that the district court erroneously dismissed Marcia Benjamin's negligence and strict liability failure to warn claims, this Honorable Court should likewise reinstate Daniel Benjamin's loss of consortium cause of action.

STATEMENT OF RELATED CASES

Plaintiffs and their counsel know of no related cases pending in this Court.

Dated: August 26, 2021

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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CERTIFICATE OF FILING AND SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on August 26, 2021, I electronically filed the foregoing Appellants' Opening Brief via ECF, and service was accomplished on counsel of record by that means.

/s/ *Bijan Esfandiari*
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