No. S273887

# In the Supreme Court

*of the*

# State of California

MICHELLE HIMES

*Plaintiff-Petitioner,*

vs.

SOMATICS, LLC,

*Defendant-Opposing Party.*

On Request from the US Court of Appeals for the Ninth Circuit
For Answer to Certified Questions of California Law

## OPENING BRIEF ON THE MERITS

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## TABLE OF CONTENTS

Page

## TABLE OF AUTHORITIES

Page(s)

**Cases**

**Statutes**



**Rules**



**Regulations**



**Other Authorities**

TO BE FILED IN THE COURT OF APPEAL **APP-008**

| **COURT OF APPEAL** **APPELLATE DISTRICT, DIVISION** | COURT OF APPEAL CASE NUMBER: 21-55517 |
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| APPELLANT/ PETITIONER: MICHELLE HIMES<br>RESPONDENT/ REAL PARTY IN INTEREST: SOMATICS, LLC | |
| **CERTIFICATE OF INTERESTED ENTITIES OR PERSONS**<br>(*Check one*): [x] INITIAL CERTIFICATE [ ] SUPPLEMENTAL CERTIFICATE | |

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[ ] Continued on attachment 2.

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Date: 7/15/2022

Bijan Esfandiari
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## CERTIFIED QUESTION TO BE ANSWERED

Under California law, in a claim against a manufacturer of a medical product for a failure to warn of a risk, is the plaintiff required to show that a stronger risk warning would have altered the physician's decision to prescribe the product? Or may the plaintiff establish causation by showing that the physician would have communicated the stronger risk warnings to the plaintiff, either in their patient consent disclosures or otherwise, and a prudent person in the patient's position would have declined the treatment after receiving the stronger risk warning? *Himes v. Somatics, LLC*, 29 F.4th 1125, 1127 (9th Cir. 2022) (Certifying Question Order).

## INTRODUCTION

The underlying issue to be addressed in this case is whether California law continues to respect patient self-decision and autonomy; or have we come to a point where the law holds the ultimate consent of the patient to be *irrelevant* and the only thing that matters is a doctor's decision to administer a risky procedure to a patient (without regard to the patient's ultimate consent). Respondent contends that California law has deteriorated to such a point. Petitioner, Michelle Himes, on the other hand, contends that California continues to revere and respect patient autonomy

and informed consent, and deems it a vital foundation and a cornerstone of our Constitution, common law, statutory law, and medical and jurisprudential cannons. This continuing reverence of patient autonomy and consent should be reflected in the Court's answer to the certified question.

The certified question concerns the interplay between the learned intermediary defense and a plaintiff's causation burden in medical device products liability failure to warn claims. In answering the question, and consistent with the language from this Court's prior precedents, this Court should conclude that, when a device manufacturer *fails* to warn the intermediary, then (a) the manufacturer loses the protections afforded by the learned intermediary defense; (b) the manufacturer may not point to any conduct of the doctor to absolve itself of its own negligence; and (c) an injured plaintiff may meet her causation burden by establishing that, had she been warned of the true risks of the device by her doctor or the manufacturer, she would not have consented to the medical procedure.

## STATEMENT OF THE CASE

### I. Procedural History

This products liability and putative class action was initiated in the

United States District Court for the Central District of California on September 11, 2017, by Michell Himes ("Himes") and other injured plaintiffs who sustained brain damage, permanent cognitive impairment, and permanent memory loss caused by electroshock therapy (ECT). 5-ER-1191. Himes and the other plaintiffs alleged the manufacturer of the ECT device, defendant Somatics, LLC ("Somatics"), failed to provide adequate warnings to doctors and the public concerning the risks of permanent memory loss and further alleged Somatics' device was misbranded due to its failure to comply with applicable federal law governing medical devices. 5-ER-1210-6-ER-1213.

The claims of *two* of the plaintiffs were settled on the eve of trial (6-ER-1235), and after a successful appeal as to statute of limitation issues (5-ER-1134), Himes and others filed an amended complaint that included, among others, causes of action for negligence (failure to warn); and strict liability (failure to warn). 5-ER-1103.

Somatics thereafter filed a motion for summary judgment arguing, in part, that the failure to warn claims of Himes and the other plaintiff, Marcia Benjamin ("Benjamin"), were barred by the learned intermediary doctrine. 5-ER-953. Plaintiffs filed an opposition (2-ER-160), and Somatics filed a

reply (2-ER-16) and responded to Plaintiffs' separate statement by largely agreeing with Plaintiffs' statement of facts (2-ER-28).

On May 14, 2021, the district court granted Somatics' summary judgment motion as to causation (learned intermediary doctrine). 1-ER-3. Himes and Benjamin appealed the dismissal to the United States Court of Appeals for Ninth Circuit. 6-ER-1217. On April 1, 2022, the Ninth Circuit issued an Order affirming the dismissal as to Benjamin, however, as to Himes, the Ninth Circuit determined there was no controlling state precedent as to the interplay between the learned intermediary doctrine and causation. *Himes v. Somatics, LLC*, 2022 WL 989469, at *2-3 (9th Cir. Apr. 1, 2022). Specifically, the Ninth Circuit concluded that it was unclear if, to establish causation under California law, a plaintiff in a medical device failure to warn case can meet her proximate causation burden by establishing that, had the manufacturer warned her doctor, the doctor would have relayed the warnings to the plaintiff and, armed with the stronger warnings, plaintiff would not have consented to the procedure and thus would not have been injured; or must the plaintiff establish that, had the manufacturer warned her doctor, the doctor would not have prescribed and administered the procedure. *Id.*; see also *Himes*, 29 F.4th at

1126. The Ninth Circuit proceeded to issue an order certifying the following question to this Court:

> Under California law, in a claim against a manufacturer of a medical product for a failure to warn of a risk, is the plaintiff required to show that a stronger risk warning would have altered the physician's decision to prescribe the product? Or may the plaintiff establish causation by showing that the physician would have communicated the stronger risk warnings to the plaintiff, either in their patient consent disclosures or otherwise, and a prudent person in the patient's position would have declined the treatment after receiving the stronger risk warning?

*Himes*, 29 F.4th at 1127. On June 15, 2022, this Court granted the Ninth Circuit's request for certification.

## 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, but most 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 approximately a dozen more sessions of ECT but was subsequently lost to follow-up. 2-ER-30-31; 4-ER-671. In May 1938, Cerletti presented his experiment at the Medical

[1] The intentional creation of seizures was based on the mistaken belief that people with epilepsy did not suffer from schizophrenia. 4-ER-668. However, as medical experts and researchers have learned, "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-444.

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-671.

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-446. But, while the use of anesthesia and muscle relaxants mask 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-446.

As Himes' electrical engineering expert, Kenneth R. Castleman, Ph.D., 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 roughly *one-fifth* as much current as the *electric chair* and applies voltage that is *four hundred* times what is required to damage brain cells. 2-ER-47; 3-ER-471-72.

### B. Somatics Failed to Comply with FDA Regulations, Failed to Issue *Any* Timely Warnings to Himes' Doctor 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 simply to 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-675. 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]

[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

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-

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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-674-675. Notwithstanding the FDA's admonitions, Somatics proceeded to *falsely* promote its device in its promotional literature and website as having received FDA "Approval." 2-ER-35-36; 4-ER-628, 680. Even in its 2018 Regulatory Update, Somatics falsely states that its "safety experience with the Thymatron ECT device since 1984 *when FDA approved the Somatics Thymatron ECT device for marketing* show that more than 4,300 Thymatron devices have been sold worldwide. During that time Somatics has maintained complete safety files on the Thymatron device …" 4-ER-654, emphasis added.

ER-35; 3-ER-427-428; 4-ER-680 (emphasis added). Indeed, contrary to 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-912 (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 (emphasis added); 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 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-691 (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. 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-13; *see also* 2-ER-37-38; 4-ER-632; 4-ER-698; 4-ER-713-714.

The manuals Somatics prepared for its ECT device and distributed to the hospital where Himes received her ECT treatments, ***did not contain any warnings***. 3-ER-510 (manual given to Sharp Hospital - no warnings of any kind); *see also* 3-ER-387-390. In its ruling, the district court concluded Somatics had not provided *any* warnings to Himes' physician concerning the risk of brain injury or permanent memory loss. 1-ER-9.

Long before Himes' 2011 ECT procedures, 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-446-451; 3-ER-456-462; 3-

ER-474; 4-ER-661; 4-ER-713-714; 5-ER-912-913; 5-ER-1137; 5-ER-1153 (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 that "virtually all patients experience some degree of persistent and, likely permanent retrograde amnesia" and that "increasing evidence has accumulated that some degree of persistent memory loss [with ECT] is common." 2-ER-40; 4-ER-660. 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, 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

[3] As plaintiff's medical expert 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-450.

no evidence to support the risk of cognitive deficits. 2-ER-42; 4-ER-661.

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-387-390; 3-ER-510 (manual given to Sharp 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-45; 4-ER-874. Even this disclaimer was never timely given to the physicians or hospital where Himes received her 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-713. 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.

Given the foregoing undisputed evidence, the district court in the section of its summary judgment order outlining the "undisputed facts" made the following findings of fact:

> Over the years, Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia [and] cognitive impairment…associated with ECT. *Somatics never* investigated these complaints, nor did it submit adverse events to the FDA *or warn physicians and consumers of these risks*"

*See* 1-ER-4 (emphasis added). After making the above-mentioned finding of fact, the district court in its discussion section of the Order went on to

conclude that Somatics "did not provide any warnings to…Dr. Fidaleo concerning the risk of brain injury or permanent memory loss." 1-ER-9.

It was not until sometime in late 2018, *after* Somatics settled the claims of two brain injured plaintiffs (Deborah Chase and Jose 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-653) 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-653; 4-ER-658.

Unfortunately, these warnings, which could and should have been issued decades earlier, came too late for Himes who is but one of the many victims of Somatics' negligence.

### 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 administered ECT in April 2011 to attempt to treat her depression. 5-ER-949, 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-325, 332. 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 form 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

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[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-312-13.

[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 used during all of Himes' ECT procedures (which occurred between April 2011 and January 2012). *See* 3-ER-387-94, 510. While Dr. Fidaleo does not specifically recall reading the manual, he testified 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, his nurse technician had received

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 with] 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. More specifically, Dr. Fidaleo provided the following deposition testimony:

> Q. Doctor, you agree with me that the risk of brain injury is a

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training from Somatics personnel on the Thymatron ECT device, and his nurse technician, in turn, trained him based upon information he had obtained from these Somatics sources. 3-ER-333-35. Somatics has admitted the manual given to Sharp Hospital did not contain *any* warnings. *See* 3-ER-387-90, 510.

[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. 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-655-57).

serious risk?

A. I don't think it's a risk with the treatment, no.

Q. No. I'm asking -- I appreciate that. I'm asking a separate question, Doctor. Assuming that a drug or a device causes brain injury, would you agree with me that is a serious risk.

A. *Well, if it causes brain injury then you would be reluctant to use it if we knew of it*.

*See* 3-ER-337 (emphasis added).

Q. And if a medication or a procedure had a risk of the patient losing the ability to formulate new memories, is that a risk that you would have alerted patients to?

A. Yeah. If you can't perform new memory, that would be a real problem. I mean, that means the person is functioning in a demented way. So that would not be a safe procedure. Okay.

* * *

Q. If Somatics had informed you that the use of their ECT device could potentially cause patients to lose the ability to formulate new memories, is that --

A. That would be significant. But I would have to see it also

myself.

Q. But I'm asking you, Doctor, is that information you would have presented or at least informed your patients about?

A. *Yes, we would inform them*.

*See* 3-ER-340 (emphasis added).

Q. But you testified that had Somatics provided you warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories that you would have relayed those warnings to your patients as a good doctor would?

A. *They would -- they would be in the informed consent*.

*See* 3-ER-344 (emphasis added).

Q. …You agree with me that a patient who is present voluntarily in a hospital and is provided a medical option after being adequately informed, *that patient has the right to refuse treatment if they feel the risks outweigh the benefits*?

A. *Absolutely true*.

See 3-ER-345 (emphasis added). Notably, Himes (who was a voluntary patient) testified that, had she been so warned by Dr. Fidaleo concerning

the risk of permanent memory loss and brain damage, she would not have consented to the ECT shock administrations (and thus would not have been injured by ECT). 5-ER-948.

Between April 2011 and January 2012, Himes received a total of 26 separate ECT shock treatments at Sharp Hospital utilizing Somatics' Thymatron IV ECT device. 5-ER-946, 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 previously mentioned, each ECT session with Somatics' machine can produce electric current to a patient's head that is roughly *one-fifth* as much current as the *electric chair* and applies voltage that is *four hundred* times what is required to damage brain cells. 2-ER-47; 3-ER-473. 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-272-74; 5-ER-951.

## SUMMARY OF ARGUMENT

Under California law, manufacturers have a duty to warn consumers

about risks associated with their products. While manufacturers usually warn consumers directly, in the context of medical devices and drugs, this Court has recognized an *exception* referred to as the "learned intermediary" defense, wherein the device manufacturer may fulfill its duty to warn by instead warning the consumer/patient's doctor (i.e., the intermediary). *First*, as this Court's precedent provides, this Court should hold that, when the device manufacturer *fails* to warn the intermediary, then the manufacturer loses the protections afforded by the learned intermediary defense, and its duties revert to the traditional duties recognized for all manufacturers. That is, in addition to warning the doctor, a manufacturer must warn the consumer/patient directly.

*Second*, as this Court's prior precedent provides, this Court should affirm the principle that, when the manufacturer fails to provide adequate warnings to the doctor, it cannot point to any negligence of the doctor to absolve itself of its own negligence.

*Third*, when the manufacturer fails to warn the intermediary/doctor, an injured plaintiff may meet her causation burden by establishing that, had she been warned by either the manufacturer or her doctor (had the doctor been adequately warned), of the true risks associated with the

device, she would not have consented to the treatment.

To limit the causation inquiry exclusively to what the doctor would have done had the manufacturer provided him an adequate warning and to further limit the inquiry exclusively to whether the doctor would have ceased "prescribing" and "administering" the procedure had he been warned, would not only violate this Court's precedents concerning the autonomy of patients and the importance of patient consent, but would require an unwarranted *presumption* that a doctor would have administered electroshock therapy to a patient against the patient's will, even though the non-consensual administration of electroshock therapy would constitute a criminal act (battery) by the doctor, and California statutory law specifically prohibits doctors from administering electroshock therapy to patients without the patient's consent.

In sum, in answering the certified question, this Honorable Court should hold that:

(a) the protections of the learned intermediary defense are not afforded to manufacturers who fail to warn the intermediary doctor, and, if a manufacturer fails to warn the doctor, then the manufacturer must warn the patient/consumer;

(b) a manufacturer that has failed to warn the doctor cannot point to any actual or hypothetical conduct of the doctor to absolve itself of all liability; and

(c) even if this Court concludes that the hypothetical conduct of the doctor is somehow a *necessary* element of the plaintiff's causation burden (which as discussed *supra* it should not be in cases where the doctor was never warned), then one of the paths by which an injured plaintiff may establish causation is by showing that, had plaintiff's doctor been warned by the manufacturer, plaintiff's doctor would have communicated the stronger warnings to the plaintiff and, armed with the warning, the plaintiff testifies she would have declined the medical procedure and thus avoided the injuries caused by the procedure.

## 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. Fidaleo concerning the risk of brain injury or permanent memory loss." 1-ER-9. However, after concluding Somatics

failed to comply with its duties under California law to provide adequate warnings to doctors concerning its ECT device, the district court proceeded to dismiss Himes' failure to warn claims by misconstruing and misapplying the learned intermediary doctrine. Specifically, even though Himes established that, had Somatics adequately warned her doctor about permanent memory loss and brain damage risks, her doctor would have passed on those warnings to her and Himes (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 this was not sufficient under the learned intermediary doctrine to establish causation. 1-ER-10; 3-ER-344-45; 5-ER-948. Instead, the district court held that the *only* path for plaintiff to establish causation was to show the doctor would not have "prescribed" ECT. 1-ER-10. On appeal, Himes argued the district court's application of the learned intermediary doctrine and plaintiff's causation burden were erroneous as Himes could establish causation by showing that her doctor would have relayed the stronger warnings to her (had Somatics adequately warned him) and, armed with the stronger warnings, she would not have consented to the administration of ECT and thus would have avoided its

side-effects. The Ninth Circuit concluded "there is no controlling state precedent on this question" and certified the issue to this Court, which this Court accepted. *Himes*, 29 F.4th at 1127.

In answering the certified question, Himes respectfully contends this Honorable Court should *first* hold, consistent with language from its prior rulings, that the learned intermediary defense is *not* available to a device manufacturer that fails to provide adequate warnings to an intermediary. Here, given it is undisputed that Somatics failed to provide adequate warnings to Dr. Fidaleo concerning the risk of brain injury and permanent memory loss associated with ECT, Somatics should not be permitted to rely upon the learned intermediary defense.

*Second*, because the manufacturer has been negligent in its failure to warn the intermediary, under this Court's established precedent, the manufacturer should not be allowed to point to the doctor/intermediary's conduct to absolve itself of all liability for its own negligence.

*Third*, even if the learned intermediary doctrine were to apply under such facts (i.e., when it is established that the manufacturer failed to warn the intermediary), an injured plaintiff/patient can establish causation by demonstrating that, had an adequate warning been provided to her doctor,

the doctor would have relayed that warning to the patient, and the patient armed with the warning would have refused to undergo the treatment, and thus, would not have been injured by the administration of the device.

## I. A Manufacturer Cannot Assert the Learned Intermediary Defense When It Fails to Provide Adequate Warnings to Intermediaries, Rendering the Intermediaries "Un-Learned"

Under 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, 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 are 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). This Court has made 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. In *Anderson*, this 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, this Court has adopted what has been referred to as the "learned intermediary" defense. 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).[7]

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[7] While it is undisputed that, since the 1970's, this Court has adopted the learned intermediary doctrine, some courts have either ceased recognizing it or have established exceptions to the learned intermediary doctrine. *See Perez v. Wyeth Lab'ys Inc.*, 161 N.J. 1, 18 (1999); *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1218 (D.N.M. 2008) (direct-to-consumer advertising and consumers conducting their own medical research suggests the learned intermediary doctrine "is quickly becoming … outdated."); *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 470-471 (2007) (superseded by statute) (finding "justifications for the learned intermediary doctrine to be largely outdated and unpersuasive" due to "intense proliferation of direct-to-consumer advertising" and "the development of the internet as a common method of dispensing and obtaining prescription drug information.").

### A. Under This Court's 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 defense as follows:

> 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, this Court in *Stevens*, relying upon *Love*, adopted the learned intermediary defense 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 defense 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***" this Court specifically

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 patient's doctor. And, this makes sense. The purpose of the defense 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 this 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 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 the intermediary, 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 Himes' doctor, much less adequate warnings, concerning brain injury or

permanent memory loss. 1-ER-9; 3-ER-387-90, 510. Thus, under this Court's precedent, Somatics should not be allowed to invoke the learned intermediary defense. Any other rule would pervert the entire purpose of the learned intermediary defense, effectively shielding medical device and pharmaceutical manufacturers from liability even when they clearly did not warn the intermediary of a known or knowable risk.

Even though Himes cited *Love*, *Stevens* and *Hill II*, the district court's order (1-ER-3) failed to make any mention of this Court's binding *Stevens* decision and instead focused exclusively on *Hill II*. However, the district court's discussion of *Hill II* was deeply flawed.

First, the district court attempted to distinguish *Hill II* by explaining that *Hill II* 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 this Court in *Stevens*. *See Hill II*, 944 F. Supp. 2d at 953 (citing *Stewart* and *Love*). Thus, doctrinally, the district court was

incorrect in concluding that the *only* source of reasoning for *Hill II* is *Stewart*.

*Second,* even if *Hill II* 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 this Court in *Webb*. However, again, that is simply not true.

*Webb* involved an asbestos case wherein this 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. This Court reversed the trial court's ruling. In *Webb*, this Court 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. This 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 (i.e., establishing that the intermediary was already fully aware of the products risks), this 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." This Court's disapproval of *Stewart* was limited to the extent *Stewart* had not recognized the "narrow exception" noted above.

*Webb*, 63 Cal. 4th at 188.[8] However, here, Somatics has not argued (nor has it established) that Dr. Fidaleo was already aware of the risk of permanent memory loss and brain injury associated with the Somatics ECT machine. To the contrary, Dr. Fidaleo's testimony establishes he was not aware of these risks, and had he been warned of these risks by Somatics, he would have altered his conduct by relaying those risks to his patients, including Himes. 3-ER-337, 344-46.

Given it is undisputed that Somatics did not issue any warnings of brain injury and permanent memory loss to Dr. Fidaleo (1-ER-9; 3-ER-387-90, 510), and given Somatics has not argued nor has it established that Dr. Fidaleo was independently aware of these risks (indeed the evidence established that Dr. Fidaleo was 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.

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[8] Indeed, in *Webb*, after formally adopting the sophisticated intermediary defense, this 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.

The inapplicability of the learned intermediary defense under these circumstances has been confirmed by district courts applying California law[9] and, coincidently, recently endorsed by the Connecticut Supreme Court applying Connecticut law. *Glover v. Bausch & Lomb, Inc.*, 343 Conn. 513, 539, 275 A.3d 168, 183 (2022). In *Glover*, which involved the Connecticut Supreme Court answering a question certified by a federal court of appeal, the Court made the following holding concerning the learned intermediary defense in circumstances where the device manufacturer failed to issue adequate warnings and failed to properly and timely report adverse events:

> Although manufacturers may invoke the learned intermediary doctrine as a shield against claims that they failed to provide adequate warnings to users *as long as they provided such warnings to healthcare providers*…we see nothing in…or our case law that would indicate that the doctrine was intended to provide a shield against

[9] *See e.g., Hill II*, 944 F. Supp. 2d at 953–54 ("[T]he doctrine, 'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.'"); *A.S. v. Pfizer, Inc.*, 2013 WL 2384320, at *6 (E.D. Cal. May 30, 2013) (same); *Martin v. Merck & Co.*, 2005 WL 1984483, at *4 (E.D. Cal. Aug. 15, 2005) (same); *see also Salyards ex rel. Salyards v. Metso Mins. Tamper OY*, 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.").

> liability for foreseeable injuries caused by the *withholding* of information about inherently dangerous medical devices.

*Glover*, 343 Conn. at 539 (some emphasis added). *Glover* is consistent with how this Court has treated the learned intermediary or sophisticated intermediary defense – i.e., the defense applies when the manufacturer either complies with law and issues adequate warnings concerning the risks to the intermediary (doctor) or establishes that the intermediary (doctor) was already fully aware of the risks – otherwise, having failed to issue any warnings to the intermediary, the manufacturer cannot use the learned intermediary defense as a shield to avoid liability.

Consistent with the language from this Court's prior decisions in *Stevens*, *Brown,* and *Webb*, as well as the recent decision in *Glover*, this Court should conclude that, in circumstances such as this, where a drug or device manufacturer fails to provide adequate warnings to the intermediary as required by law, then the manufacturer may *no longer* seek shelter behind the learned intermediary defense.

### 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

While this Court has recognized the learned intermediary doctrine

since at least 1973 (*Stevens*), in the intervening 49 years, this Court has never dismissed a pharmaceutical or medical device products liability case on the theory the district court adopted (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 California cases on this point (*see* 1-ER-6-8), and in certifying the question, the Ninth Circuit likewise confirmed "[t]here is no controlling state precedent, and the question implicates important policy concerns." *Himes*, 29 F.4th at 1127; *see also Hill II*, 944 F. Supp. 2d at 953–54.

The dearth of published state law authority dismissing an action on these grounds is telling. Himes contends this Court's seminal decision in *Stevens* confirms that, under these facts (when the manufacturer has failed to provide adequate warnings to the doctor), the manufacturer cannot point to the doctor's conduct to escape liability for its own negligence.

*Stevens* was a wrongful death case wherein the decedent had died because 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 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. This Court held that any warning the manufacturer may have issued in its label was watered down by the manufacturer's overpromotion. This 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*, this 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. This 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 this Court in *Stevens* is confirmation that California law does *not* permit Somatics (which failed to provide warnings to Dr. Fidaleo) from escaping liability based on any intervening or negligent conduct of Dr. Fidaleo. 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.").[10]

The law from other jurisdictions is in accord. *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972) ("Correspondingly, having

[10] *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.") (internal citations omitted).

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 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)).

Tellingly, this principle finds support in the very first judicial decision that coined the phrase "learned intermediary." *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). The use of the term "learned intermediary" was first used by the Eighth Circuit's 1966 *Sterling* decision. In *Sterling*, the drug manufacturer, which had failed to warn the intermediary (i.e., doctor), sought to absolve itself of liability by pointing to the purported negligent conduct of the doctor. In rejecting the drug manufacturer's arguments, the Eighth Circuit held:

> 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.

*Sterling Drug*, 370 F.2d at 85 (emphasis added). Thus, consistent with this Court's decisions in *Stevens, T.H., and Stewart* and other extra jurisdictional decisions cited above, including the first learned intermediary defense case (*Sterling*), this Court should conclude that, in circumstances where the drug or device manufacturer has failed to issue adequate warnings to the intermediary doctor as required by law, then the conduct of the intermediary (i.e., whether the intermediary would have read the warning or what if anything the intermediary might have done had he or she been warned) cannot be cited by the negligent manufacturer to excuse and exonerate its own negligence. *Stevens*, 9 Cal. 3d at 69 ("[drug manufacturer] cannot be relieved of liability because of the intervening act of [the doctor] in prescribing the drug while cognizant of its dangers.") *T.H. v. Novartis Pharms.*, 4 Cal. 5th at 184 ("…Nor have we permitted a negligent actor to evade liability simply because another party may also be liable for a similar tort."); *Stewart*, 55 Cal. 2d at 864 (same); *see also Sterling Drug*, 370 F.2d at 85 (if drug manufacturer fails to warn doctors, the

manufacturer "*is liable regardless of anything the doctors may or may not have done.*").[11]

## II. Even If the Learned Intermediary Defense Were Applicable, Himes Established That Somatics' Failure to Warn her Doctor Was a Cause of Her ECT Induced Injuries

Even though Somatics failed to issue adequate warnings to Dr. Fidaleo, the district court, relying upon the learned intermediary defense, concluded Himes failed to establish causation. 1-ER-10. As outlined *supra*, given Somatics failed to issue any warnings to Himes' doctor, the district court erred in applying the learned intermediary defense to conclude that

[11] And this makes even more sense in today's environment where there are increasingly more and more financial and personal ties between doctors and medical device companies. *See e.g.* David W. McFadden, *The Devil is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy*, 140 J. URGICAL RESEARCH 1, 2 (June 1, 2007); *see also Murthy v. Abbott Lab'ys*, 847 F. Supp. 2d 958, 973, n.5 (S.D. Tex. 2012) (collecting other research and articles on this topic). In point of fact, in another ECT case being litigated by Plaintiff's counsel, the prescriber is personal friends with one of the owners of Somatics. Moreover, let us not forget that ECT practitioners make money administering ECT. Thus, it would be against their financial self-interest to testify that they would no longer "prescribe" ECT if they had been adequately warned. Under these circumstances, how could the law allow the products liability claims of a plaintiff who has been seriously injured by a medical device rise and fall upon the testimony of a single witness (who in some cases has personal and financial ties with the defendant manufacturer or otherwise has a financial interest to continue to practice his trade).

causation was lacking. *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 defense were applicable in these circumstances, in dismissing Himes' claims, the district court misconstrued the doctrine and Himes' 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-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 warnings was a cause of their injuries by demonstrating that, had their doctors been adequately warned, 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 Himes established. 3-ER-343-44; 5-ER-948; *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. Himes is Not Required to Show That, Had Somatics Warned, Her Doctor Would Not Have "Prescribed" ECT; Rather, Himes Can Establish Causation by Showing that, Had Somatics Warned, Her Doctor Would Have Relayed Those Warnings to Her, and Armed with the Warnings, Himes Would Have Refused ECT

In *Motus II*, the Ninth Circuit, 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*, the Ninth Circuit did not require plaintiffs to prove that their physician would not have prescribed the drug, rather, the 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* makes 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, Dr. Fidaleo testified that, had Somatics issued timely warnings of the risks of brain damage and permanent memory loss, he would have altered his conduct and would have relayed such warnings and risks to his patients, including to Himes. 3-ER-343-44. *In addition*, Himes has attested that, had she received warnings concerning brain damage or permanent memory loss from her doctor concerning ECT, she would *not* have consented to its administration. 5-ER-948. 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.*, 2012 WL 6004161, at *4 (E.D. Cal. Nov. 30, 2012) ("*Hill I*"); *see also Riera v. Somatics,*

*LLC*, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018)(5-ER-1148).

*Georges, Stanley, Hill* and *Riera* are instructive. In *Georges*, the district court affirmed a jury verdict and held a plaintiff 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 district 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, the Ninth Circuit subsequently *favorably* quoted *Stanley* on this very point. *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1239 (9th Cir. 2017) ("[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 grounds that the plaintiff's doctor would still have prescribed the drug even if he had received enhanced warnings. 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) ("[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* and Failed to Appreciate That *Motus* (a Wrongful Death Case) was Factually Distinguishable and Was Wrongly Decided

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 Ninth Circuit's *Motus I* decision. *See* 1-ER-8-9 (*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 (emphasis added). The fact that, in the face of stronger warnings, Dr. Fidaleo testified he would have altered the consent form discussions and would have relayed the warnings to Himes demonstrates that "the conduct" of the doctor would have been "altered" had he been warned. 3-ER-337, 344-45. And this altered conduct (i.e, relaying of warnings about brain damage and permanent memory loss by the doctor to the plaintiff) would have led to Himes refusing to consent to ECT and thus averting the ECT-induced injuries. 5-ER-948. 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). Likewise, the district court's reading of *Motus I* 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. 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*, 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 plaintiff is thankfully alive and has testified that, had she been adequately warned by her doctor, she would not have consented to the ECT (5-ER-948), 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. This critical distinction between *Motus I* and this case is another important reason the district court's reliance on *Motus I* was in error.

*Fourth*, and finally, *Motus I* (and the affirming *Motus II*) were wrongly decided on two major points. In *Motus* it was alleged that the manufacturer's drug caused the death (suicide) of the decedent and the manufacturer had failed to adequately warn doctors and patients of the suicide risk. Because it was a wrongful death case, the decedent was not alive to testify as to what he would have done had he been properly warned. As a *first error*, under this Court's established precedent, in circumstances where the conduct of the defendant causes the plaintiff to be unable to establish an element of the case (i.e., defendant causes the death so decedent is not able to testify as to what he would have done had he been warned), then the *burden should shift* to the defendant to show that its negligence did not cause the decedent's death. *See Haft v. Lone Palm Hotel*,

3 Cal. 3d 756, 765 (1970) ("we have concluded that after plaintiffs proved that defendants failed to provide a lifeguard or to post a warning sign, the burden shifted to defendants to show the absence of a lifeguard did not cause the deaths."); *see also Dimond v. Caterpillar Tractor Co.*, 65 Cal. App. 3d 173, 183 (1976) ("the law has stood ready to come to the aid of a hapless plaintiff who, through no fault of his own, is unable to provide direct evidence that defendant's breach of duty was a proximate cause of his injuries."). Thus, *Motus* erred by either refusing to adopt the heeding presumption as to causation (i.e., had a warning been provided by the manufacturer it would have been heeded) or refusing to shift the causation burden to the defendant given the defendant's conduct caused the death of the decedent and prevented him from being able to testify as to how he would have acted had the manufacturer adequately warned. *Haft*, 3 Cal. 3d at 765.

The *second* error in *Motus I* and *Motus II* is that, after concluding the manufacturer failed to warn the intermediary doctor, the district court and Ninth Circuit continued to point to the conduct of the intermediary (i.e., whether the doctor would have seen or read the warning had one been provided; what the doctor would have done had he been adequately

warned, etc.) to absolve the negligent manufacturer of all liability. As articulated in Section I(B), supra, once it is established the manufacturer negligently failed to warn the intermediary, under this Court's established precedent, it was error for the trial court to grant summary judgment and absolve the negligent manufacturer based on what the intermediary doctor might or might not have done had an adequate warning been issued. *Stevens*, 9 Cal. 3d at 69 ("[drug manufacturer] cannot be relieved of liability because of the intervening act of [the doctor] in prescribing the drug while cognizant of its dangers."); see also *T.H. v. Novartis Pharms.,* 4 Cal. 5th at 184 ("…Nor have we permitted a negligent actor to evade liability simply because another party may also be liable for a similar tort."); *Sterling Drug*, 370 F.2d at 85 (if drug manufacturer fails to warn doctors, the manufacturer "*is liable regardless of anything the doctors may or may not have done.*").

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In sum, this Honorable Court should conclude that, under California law, when a drug or device manufacturer fails to provide adequate warnings to the learned intermediary (doctor) as it is obligated to do, then the manufacturer loses the protections afforded by the learned intermediary defense. Furthermore, as this Court's prior precedent

provides, when the manufacturer fails to provide adequate warnings to the doctor, it cannot point to any negligence by the doctor to absolve its own negligence. When the manufacturer fails to warn the intermediary, an injured plaintiff may meet her causation burden by establishing that, had she been warned by either her doctor or the manufacturer of the true risks of the device, she would not have consented to the treatment.[12]

## 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 and Somatics' arguments, is the 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, *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

[12] And, in circumstances where the manufacturer's negligence has caused the death of the patient, the plaintiffs in a subsequent wrongful death action should either be able to rely upon circumstantial evidence or, alternatively, under authority such as *Haft*, the causation burden should be shifted to the manufacturer defendant that caused the death.

district court viewed Himes as no different than the poor soul Cerletti and Bini found wandering 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 the 1930s. California has 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). Himes was not an incompetent adult, nor had she been involuntarily committed. Himes went to her doctor voluntarily and only agreed to undergo multiple rounds of ECT after having the risks and benefits explained to her by Dr. Fidaleo. Dr. Fidaleo, however, did not know, or appreciate the full extent of the serious risks associated with ECT (including permanent memory loss and brain damage), because Somatics willfully failed to warn of these risks. Thus, Dr. Fidaleo was not able to relay these important warnings to Himes. 3-ER-337, 344-45. Dr. Fidaleo testified that, had Somatics issued such warnings, he would have relayed them to his patients, and Himes in turn testified that, had she been so warned, she would have refused to consent to ECT, as is her absolute right under California law. 3-ER-344-45; 5-ER-948; *Cobbs*, 8 Cal. 3d at 243 ("the

decision whether or not to undertake treatment is vested in the party most directly affected: *the patient*.") (emphasis added); *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 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, this 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. Himes was robbed of that fundamental "right of self-decision" because Somatics concealed the risks of brain damage and permanent memory loss

from her doctors and thus Himes was never informed of these risks. She was robbed a second time of that fundamental "right of self-decision" when the district court erroneously held that the decision of whether Himes would have consented to the ECT procedure is not relevant to the inquiry of her 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*)[13] and statutory law (CAL. WELF. & INST. CODE § 5326.85), Dr. Fidaleo would have "administered" ECT even *after* Himes refused to consent.[14] A simple recitation of 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*

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[13] *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).

[14] 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); see also CAL. CODE REGS. TIT. 22, § 70707(b)(5) (California Patient's Bill of Rights).

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.")

## IV. This Court Should Continue to Apply the Substantial Factor Test for Causation in Products Liability Cases Which Allows Plaintiff's Testimony to Establish Causation, As Opposed to Adopting the Ninth Circuit's Objective "Prudent Person" Standard

Himes pauses to comment on the Ninth Circuit's conclusion that, to establish causation, plaintiff must show that a "prudent person in the patient's position would have declined the treatment after receiving the stronger risk warning." *Himes*, 29 F.4th at 1127. While, here, the Ninth Circuit held "a reasonable jury could conclude that a prudent patient in Himes's position would have declined the treatment after receiving warnings about the risk of permanent memory loss, inability to formulate new memories, and brain damage[,]" *Himes*, 2022 WL 989469, at *3, Himes respectfully contends that the causation/consent should *not* be judged by

an objective prudent person standard.

This Court has long recognized that, in products liability and negligence cases, causation is established under the *substantial factor* test. *Mitchell v. Gonzales*, 54 Cal. 3d 1041, 1052-1053 (1991) (substantial factor test should be used for all negligence cases); *Rutherford*, 16 Cal. 4th at 968–69 ("California has definitively adopted the substantial factor test of the Restatement Second of Torts for cause-in-fact determinations."); *see also* Judicial Council of California Civil Jury Instruction (CACI) 1205 (strict liability) and CACI 1222 (negligence). Moreover, California courts have routinely allowed plaintiffs to establish causation by providing "self-serving" testimony as to how they would have altered their conduct in failure to warn cases. *Colombo v. BRP US Inc.*, 230 Cal. App. 4th 1442, 1454 (2014) (collecting cases). Accordingly, consistent with the above authority, this Court should hold that a plaintiff in a products liability failure to warn case may establish causation by her testimony that, had she been warned of the risks either from the intermediary or the manufacturer, she would not have agreed to the ECT procedure, and any credibility issues should be resolved by the jury.

The Ninth Circuit looked to this Court's decision in *Cobbs* to adopt

the objective prudent person standard for causation. *See Himes*, 2022 WL 989469, at *3, n.3 (citing to *Cobbs*, 8 Cal. 3d at 245). However, *Cobbs* was a medical malpractice case and, as previously discussed, after *Cobbs*, this Court in *Mitchell* and *Rutherford* recognized that, in negligence and products liability cases, causation can be established through the *substantial factor* test. California courts have permitted a plaintiff's "self-serving" testimony to establish causation in such products liability failure to warn cases. *Colombo,* 230 Cal. App. 4th at 1454 (in a products liability failure to warn case, plaintiff's self-serving testimony that, had an adequate warning been provided, she would have heeded the warning or refrained from the activity, was sufficient to establish that defendant's negligence in failing to warn was substantial factor in causing plaintiff's injuries).

There is also another factor as to why the objective factor test is not appropriate in this case. California law specifically provides that a doctor may not administer ECT without the express consent of the patient. 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."). Given the decision to undergo ECT treatment is a

personal choice (and one person may have greater risk tolerance than another), to suddenly apply an objective "prudent person" standard to whether a patient would have undergone ECT had she been adequately warned, runs afoul of Welfare & Institution Code Section 5326.85, which places consent *exclusively* in the hands of the patient.

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In sum, this Court should continue to apply the substantial factor test to causation in products liability failure to warn cases and, under the substantial factor test, the subjective testimony of the plaintiff that she would not have undergone the procedure had Somatics adequately warned of the risk of brain injury and permanent memory loss, is sufficient to establish causation and present the causation issue to the jury. Here, given that Himes has testified that, had she been warned of the risk of brain injury and permanent memory loss, she would not have consented to ECT, under the substantial factor test and cases such as *Colombo*, her testimony is sufficient to create a triable issue of fact for the jury to adjudicate.[15]

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[15] Alternatively, Himes suggests that, if an objective prudent person test standard is ever to be applied, it should *only* be reserved for wrongful death cases where the decedent is not able to provide testimony as to how

## CONCLUSION

In answering the certified question, this Court should conclude that, when a device manufacturer *fails* to warn the intermediary, then (a) the manufacturer loses the protections afforded by the learned intermediary defense; (b) the manufacturer may not point to any conduct of the doctor to absolve itself of its own negligence; and (c) an injured plaintiff may meet her causation burden by establishing that, had she been warned of the true risks of the device by her doctor or the manufacturer, she would not have consented to the medical procedure.

Dated: July 15, 2022

Respectfully submitted,

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he would have responded to an adequate warning. As discussed previously in Section II(B), *supra*, in such wrongful death cases, this Court, akin to *Haft*, 3 Cal. 3d at 765, should hold that the causation burden shifts to the defendant that caused the death (and hence created decedent's inability to testify as to causation); or, alternatively, this Court could consider utilizing the objective prudent person standard exclusively in wrongful death cases where the injured party (decedent) is unable to provide causation testimony.

## CERTIFICATE OF COMPLIANCE

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Dated: July 15, 2022

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

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**STATE OF CALIFORNIA**
Supreme Court of California

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