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No. 21-55517

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MICHELLE HIMES; MARCIA BENJAMIN; DANIEL BENJAMIN, individually, and on behalf of all others similarly situated,

Plaintiffs–Appellants,

v.

SOMATICS, LLC,

Defendant–Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
No. 2:17-cv-06686-RGK-JC, Hon. R. Gary Klausner

ANSWERING BRIEF OF DEFENDANT–APPELLEE SOMATICS, LLC
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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Appellee Somatics, LLC discloses that it is 50% owned by Richard Abrams, M.D., and 50% owned by Conrad Swartz, M.D.

Dated: October 27, 2021

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INTRODUCTION

Plaintiffs-Appellants Michelle Himes ("Ms. Himes") and Marcia Benjamin ("Ms. Benjamin") suffered from severe mental health conditions which left them unable to function in their daily lives. After numerous other medical treatments proved unsuccessful, their physicians prescribed and administered electroconvulsive therapy ("ECT") as a last resort. Ms. Himes and Ms. Benjamin claim that this treatment left them with brain injuries and permanent memory loss. Ms. Benjamin's husband, Plaintiff-Appellant Daniel Benjamin, also claims to have suffered loss of consortium as a result of his wife's treatment.

Plaintiffs[1] brought California state law failure to warn claims against Somatics, LLC ("Somatics"), the manufacturer of a medical device called the Thymatron ECT Machine ("Thymatron"), which physicians use to administer ECT treatment. California has adopted the "learned intermediary doctrine," which recognizes that a healthcare patient relies on the medical judgment of a learned intermediary—a physician—in deciding whether to use a medical device. The doctrine

[1] This brief refers to Ms. Himes, Ms. Benjamin, and Mr. Benjamin collectively as "Plaintiffs."

requires a plaintiff bringing a failure to warn claim against a medical device manufacturer to prove two elements: (1) that the manufacturer provided an inadequate warning to the plaintiff's physician; and (2) that, if the physician had received an adequate warning, the physician would not have prescribed use of the device. *See, e.g.*, *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001) ("Motus I"), *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004) ("Motus II").

Plaintiffs' case crumbled during discovery. The parties offered conflicting evidence on whether ECT had caused Plaintiffs' claimed injuries and whether Somatics had given adequate warnings to the patients' physicians. But Somatics produced extensive *uncontradicted* evidence that heightened warnings would not, in any event, have changed what the physicians decided. The physicians testified unequivocally that they never relied on Somatics's warnings in prescribing ECT treatment and that they would have continued to prescribe the treatment even if they had received warnings about some risk of brain injury or permanent memory loss. The reason was simple: their patients were at risk of suicide, or too weak to even sit in a chair,

and no other treatment had worked. Ms. Himes's physician admitted he had *not even read* disclosures provided by Somatics before prescribing ECT. Recognizing that Plaintiffs had failed to offer any evidence sufficient to establish the second prong of California's learned intermediary doctrine—which courts refer to as the "proximate causation" prong—the district court properly granted Somatics's motion for summary judgment.

Plaintiffs now appeal, asking this Court to deviate twice from binding Ninth Circuit precedent. First, they ask the Court to jettison the two-pronged requirement under the learned intermediary doctrine, skipping the second prong—which requires them to prove proximate causation—and letting them prove only the first prong: inadequate warning. Second, in the alternative, they ask the Court to delete the existing second prong of the doctrine and replace it with a new second prong that they have made up, under which plaintiffs survive summary judgment whenever they make self-serving declarations that they would have refused a physician-prescribed treatment if only their doctors had relayed adequate warnings to them. California law bars both of these deviations, as this Court has recognized. *See, e.g.*, *Wendell*, 858 F.3d at

1238; *Motus II,* 358 F.3d at 661. Either would fundamentally change California's learned intermediary doctrine.

This Court should affirm the judgment below.

JURISDICTIONAL STATEMENT

Somatics agrees with Plaintiffs' jurisdictional statement. *See* Opening Brief ("OB") 2-3.

ISSUES PRESENTED

1. Whether the district court properly held that, under California law, a plaintiff bringing a cause of action based on a medical device manufacturer's failure to warn must prove *not only* inadequate warning *but also* that the inadequacy of the warning proximately caused the plaintiff's injury. (Yes.)

2. Whether the district court properly held that, to prove proximate causation under California's learned intermediary doctrine, a plaintiff must present evidence sufficient to establish that, if the plaintiff's physician had received an adequate warning, the physician would not have prescribed use of the medical device. (Yes.)

STATEMENT OF THE CASE

I. Factual Summary

A. Somatics manufactures medical devices.

Defendant-Appellee Somatics, LLC ("Somatics") manufactures a medical device called the Thymatron ECT Machine ("Thymatron"). Physicians use the Thymatron to provide ECT to patients suffering from certain severe mental health issues, including severe depression and catatonia. 5-ER-1104.[2] ECT administers a controlled dose of electricity to the brain to induce a deliberate grand mal motor seizure. 2-ER-29.

Plaintiffs' opening brief contains lengthy descriptions of early stages of development of ECT, including a description of animal testing in the 1930s in Italy. OB 9-10. In a section labeled "Factual Summary," Plaintiffs also argue that ECT is unsafe, citing to the 1975 Hollywood film *One Flew Over the Cuckoo's Nest*. OB 11. Reliability issues aside,

[2] This brief refers to Plaintiffs' excerpts of record as "ER" and refers to Somatics's supplemental excerpts of record as "SER."

Plaintiffs' purported "facts" on safety (nearly all of which Somatics disputes)[3] are not remotely germane to the instant appeal.

As clarified below, the instant appeal does not require this Court to resolve the parties' factual disputes as to whether Somatics knew or should have known that ECT treatment could produce Plaintiffs' claimed injuries, or as to whether Somatics adequately warned Plaintiffs' physicians. Those factual disputes were not resolved in the district court because they did not need to be resolved. At issue here is only what the district court did decide: that, even if there were a material factual dispute over whether the warning to physicians was adequate, Plaintiffs' claims still could not survive summary judgment because Plaintiffs offered no proof of proximate causation, i.e., they offered no proof that the doctors would have treated their patients any differently if they had

[3] *See Riera v. Somatics, LLC*, 2018 WL 6242154, at *9 (C.D. Cal. Sept. 14, 2018) (district court's prior acknowledgment that the parties in this case "present[ed] conflicting evidence about whether Somatics knew or should have known of the risk of brain damage and whether the existing warnings for memory loss and brain damage were adequate").

received different warnings. Accordingly, this factual summary focuses on the facts relevant to the causation issues presented on appeal.[4]

B. Plaintiffs claim to have sustained injuries after receiving physician-prescribed ECT treatment.

Ms. Himes received ECT treatment administered by Dr. Raymond Fidaleo at Sharp Mesa Vista Hospital between April 13, 2011, and January 9, 2012. 5-ER-1001. Plaintiffs' opening brief states only that Ms. Himes received this treatment for "depression," OB 19, but that does not remotely capture the extent of her mental illness. [redacted]

[4] In their "Factual Summary," Plaintiffs say Somatics misbranded the Thymatron by stating it had FDA approval. *See* OB 13 n.2. Plaintiffs tried to bring misbranding claims below but offered no evidence to support them; when faced with a motion for summary judgment on those claims, they *conceded* to dismissal. *See* 2-ER-165. Their baseless and dismissed allegation of misbranding is just another attempt to distract the Court from the causation issues on appeal.

[redacted] Following the treatment, Dr. Fidaleo reported that Ms. Himes was "doing well" and had regained custody of her child after a separation. 3-ER-332.

Ms. Benjamin received ECT treatment administered by Dr. Michael Frankel at Northridge Hospital between September 28, 2012, and March 4, 2013. 5-ER-1031. Dr. Frankel testified that she suffered from "severe anxiety and depression," including "panic attacks" that sent her to the emergency room. 3-ER-353-354. Her doctors tried numerous medications, but nothing worked. 3-ER-353-354. Her psychological symptoms became physically debilitating, leaving her "extremely weak"

to the point that she reported "she couldn't even sit in a chair." 3-ER-354. Dr. Frankel testified that her condition improved with ECT and that, following her treatment, she sent him a note stating, "Dr. Frankel, thank you for giving me my life back." 3-ER-359.

Ms. Himes and Ms. Benjamin now both claim to have suffered brain injuries and permanent memory loss as a result of their ECT treatment. 5-ER-1104-1105. Mr. Benjamin claims to have suffered loss of consortium due to his wife's ECT treatment. 5-ER-1111.

C. Plaintiffs' physicians testified that they did not rely on Somatics's warnings in prescribing ECT.

Somatics provided many warnings about health risks associated with the Thymatron device in (1) an operator's manual and (2) a patient information pamphlet. 5-ER-1079.[5]

[5] The record belies Plaintiffs' assertion that "[t]he manuals Somatics prepared for its ECT device and distributed to the two hospitals where plaintiffs received their respective ECT treatments[] did not contain any warnings." OB 15 (emphasis omitted). A review of the actual text of the manuals that both hospitals produced during discovery establishes that Somatics provided extensive warnings therein. *See, e.g.*, 2-ER-91 (manual given to Sharp Mesa Vista Hospital, containing warnings about numerous potential side effects including "neurological complications"); 3-ER-533 (manual given to Sharp Mesa Vista Hospital, containing warnings about the possibility for "seizure activity to continue in the brain" and cautioning that the Thymatron's estimates of seizure activity

When deposed in this case, Dr. Fidaleo admitted that he had never read the patient information pamphlet and that he also did not recall ever reading the manual for the Thymatron device that had been provided to his hospital. He further testified that he had never spoken with anyone at Somatics. 5-ER-1004-1005, 1016-1017.

Dr. Fidaleo stated unequivocally that, given the dire nature of Ms. Himes's condition, he would have prescribed ECT *notwithstanding* a risk of permanent memory loss. *See* 5-ER-1013 ("It wouldn't stop me. You have to take the whole thing. All drugs and all things have memory loss. If you forgot your wedding date, but you knew how to function, I wouldn't consider that a reason not to give treatment."). Dr. Fidaleo stressed that Ms. Himes's ECT treatment was a last resort due to the severity and dangers of her mental health condition, [redacted]

"are provided to aid, not replace, the physician's judgment"); 3-ER-527 (manual given to Sharp Mesa Vista Hospital, containing warnings about interactions between the Thymatron and a patient's medications); 3-ER-571-572 (manual given to Northridge Hospital, containing warnings about "retrograde amnesia," "personal memory loss," and "EEG abnormalities" that are lower with the Thymatron's technology than with other ECT technology); 3-ER-584 (manual given to Northridge Hospital, containing warnings about "cognitive side-effects" associated with longer duration seizures); 3-ER-587 (manual given to Northridge Hospital, containing warnings about "risks of skin burns" that are "reduced" due to the Thymatron's design).

[redacted]

When asked whether he would still prescribe ECT if he received a warning that the treatment could cause a brain injury that would impede a patient's ability to form new memories, Dr. Fidaleo said that, even with such a warning, he would still need to *personally corroborate* this purported risk through his own clinical observations. He testified that, in his own practice, he had never seen such a result from ECT. *See* 5-ER-1014-1015 ("I would have to see it also myself. . . . [Y]ou go by what you see clinically. . . . I don't see that. . . . I would be seeing that myself and I'm not seeing that with my patients.").

Likewise, at his deposition, Dr. Frankel flatly denied relying on any warnings from Somatics regarding the risks of ECT treatment:

> Q. Have you relied on any disclosure from Somatics, LLC, to inform you of the risks of ECT?
>
> A. No.

5-ER-1036.

Just like Dr. Fidaleo, Dr. Frankel stated that a risk of long-term cognitive impairment would not stop him from prescribing ECT because the treatment was a last resort for patients who were out of other options:

> A. . . . I have had patients who do complain of different cognitive disturbances over the years, who they may attribute to ECT treatments.
>
> Q. . . . And has that ever caused concern to you that ECT was causing long-term cognitive impairment?
>
> A. Not really, because almost every case we are very careful to make sure that every other treatment option has been exhausted before we do ECT.

5-ER-1037-1038.

In addition, Dr. Frankel testified that he did not pay much attention to safety information updates sent by manufacturers:

> Q. From time to time do you ever receive literature from a manufacturer informing you of updated safety information associated with their drug or device?
>
> A. We receive a good deal of literature from various drug companies, for example, but I don't pay terribly much attention to them.

5-ER-1044.

II. Procedural History

On September 11, 2017, Ms. Himes and three other plaintiffs—Jose Riera ("Mr. Riera"), Deborah Chase ("Ms. Chase"), and Diane Scurrah ("Ms. Scurrah")—filed the initial complaint in this action. 6-ER-1219. All plaintiffs claimed to have sustained injuries following ECT treatment.

6-ER-1212. They brought claims against Somatics as well as another manufacturer of ECT devices, Mecta Corporation ("Mecta"). 6-ER-1191.

On November 7, 2017, a first amended complaint added Ms. Benjamin and Mr. Benjamin as plaintiffs. 5-ER-1162-1190. The plaintiffs also moved to certify a class on December 10, 2017, but the district court denied that motion on March 19, 2018. 6-ER-1221, 1224. The plaintiffs amended their complaint twice more. 6-ER-1222, 1224.

On June 19, 2018, the district court dismissed the third amended complaint. 5-ER-1153-1161 The court first concluded that the claims of Ms. Himes, Ms. Benjamin, Mr. Benjamin, and Ms. Scurrah were time-barred, dismissing these claims with prejudice. 5-ER-1155-1158. The court then concluded that the claims of Mr. Riera and Ms. Chase were inadequately pled for failure to allege that either Mecta or Somatics had manufactured the specific ECT devices used in the case. 5-ER-1158-1160. The court dismissed claims against Mecta with prejudice but dismissed claims against Somatics without prejudice (as Mr. Riera and Ms. Chase had presented evidence suggesting they could amend to allege Somatics's manufacturing role but not Mecta's). 5-ER-1160-1161.

Following this order of dismissal, Mr. Riera and Ms. Chase filed a fourth amended complaint against Somatics, 6-ER-1226, before ultimately settling their claims and entering into a stipulation of dismissal, 6-ER-1235.

Ms. Himes, Ms. Benjamin, Mr. Benjamin, and Ms. Scurrah appealed the dismissal of their claims against Somatics to this Court. On October 30, 2018, this Court reversed the order dismissing their claims as untimely, reasoning that such dismissal was premature because the pleading did not identify the dates of the plaintiffs' alleged injuries. 5-ER-1134-1136. The pleading identified the dates of the plaintiffs' last ECT treatments, but this Court held that the district court could not presume that the plaintiffs *became injured* on those dates. Thus, the untimeliness of the plaintiffs' claims was not yet apparent on the face of the pleading. This Court remanded the case back to the district court. 5-ER-1136.

On remand, Ms. Himes, Ms. Benjamin, Mr. Benjamin, and Ms. Scurrah filed the operative fifth amended complaint against Somatics on June 15, 2020. 5-ER-1103-1131. The fifth amended complaint brought five claims labeled as follows: (1) "Negligence/Negligence (Adulteration

and Misbranding)"; (2) "Negligence/Negligence (Failure to Warn, Failure to Timely Investigate, Evaluate, and Report Adverse Events)"; (3) "Strict Product Liability—Failure to Warn"; (4) "Strict Product Liability (Adulteration and Misbranding)"; and (5) "Loss of Consortium." 5-ER-1125-1131. Ms. Scurrah later voluntarily dismissed her claims, leaving Ms. Himes, Ms. Benjamin and Mr. Benjamin (i.e., Plaintiffs) as the only three plaintiffs remaining in the case. 6-ER-1241.

Somatics moved for summary judgment on all of Plaintiffs' claims. 5-ER-953-975. First, Somatics argued that the claims were time-barred. 5-ER-963-968. Second, Somatics argued that California's learned intermediary doctrine barred the failure to warn claims. 5-ER-968-971. Third, Somatics argued that Plaintiffs failed to adequately plead the adulteration and misbranding claims. 5-ER-971-972.

In their opposition motion, Plaintiffs conceded to the dismissal of their claims for negligence and strict liability arising from adulteration and misbranding (claims one and four as set forth above). That left only the claims for negligence and strict liability arising from failure to warn (claims two and three), and Mr. Benjamin's related claim for loss of consortium (claim five). 2-ER-165.

On May 14, 2021, the district court granted Somatics's motion for summary judgment, dismissing Plaintiffs' three remaining claims. 1-ER-3-10. It concluded that Plaintiffs had failed to meet their burden to establish proximate causation under California's learned intermediary doctrine. The district court declined to reach the timeliness issue. 1-ER-7.

On May 18, 2021, Plaintiffs filed their notice of appeal. 6-ER-1217–1218. On May 21, 2021, the district court entered judgment. 1-ER-2.

SUMMARY OF ARGUMENT

This case involves a straightforward application of Ninth Circuit precedent regarding California's learned intermediary doctrine. The doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship." *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187 n.10 (2016). Under the doctrine, "[a] plaintiff asserting causes of action based on a failure to warn must prove *not only* that no warning was provided or the warning was inadequate, *but also* that the inadequacy or absence of the warning caused the plaintiff's injury." *Wendell*, 858 F.3d at 1238 (emphasis added).

Here, the district court properly held that Plaintiffs could not survive summary judgment by *only* offering evidence that Somatics provided inadequate warnings to Dr. Fidaleo and Dr. Frankel; Plaintiffs bore a burden to *also* offer evidence to demonstrate proximate causation. On appeal, Plaintiffs' attempts to avoid the proximate causation requirement mischaracterize and ignore binding precedent.

The district court also properly held that Plaintiffs failed to meet their proximate causation burden. To prove proximate causation under the learned intermediary doctrine, a plaintiff must "demonstrate that the inclusion of an adequate warning would have altered [the physician's] decision to prescribe." *Motus I*, 196 F. Supp. 2d at 991; *see Wendell*, 858 F.3d at 1238; *Motus II*, 358 F.3d at 661. Plaintiffs failed to identify a shred of evidence that, if Somatics had given further warnings about brain injury and memory loss, Dr. Fidaleo and Dr. Frankel would not have prescribed ECT to Ms. Himes and Ms. Benjamin. The physicians testified *directly to the contrary*: that they had not relied on Somatics's warnings in prescribing ECT and that, even with a heightened warning, they still would have prescribed ECT as a last resort because their

patients were in dire straits without it. Thus, the district court correctly granted summary judgment on Plaintiffs' failure to warn claims.

Plaintiffs protest that they can establish causation through their own self-serving assurances that, if their physicians had relayed adequate warnings about brain injury and memory loss, they would have refused the treatment. But that would simply gut the learned intermediary doctrine. As the district court properly recognized, Plaintiffs cannot escape the long line of learned intermediary doctrine cases, which require a plaintiff to prove proximate causation by showing that, if a doctor had received an adequate warning, they would not have prescribed the treatment.

This Court should reject Plaintiffs' invitation to reinvent the wheel. Ninth Circuit and California Supreme Court case law already outlines the scope of a plaintiff's burden to prove proximate causation when bringing a failure to warn claim against a medical device manufacturer. Following that precedent, the district court properly held that Plaintiffs failed to meet their burden here. This Court should affirm.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's grant of a motion for summary judgment. *Momox-Caselis v. Donohue*, 987 F.3d 835, 840 (9th Cir. 2021). "Summary judgment is appropriate when, with the evidence viewed in the light most favorable to the non-moving party, there are no genuine issues of material fact, so that the moving party is entitled to judgment as a matter of law." *Sandoval v. Cty. of San Diego*, 985 F.3d 657, 665 (9th Cir. 2021) (internal quotation marks omitted); *see* Fed. R. Civ. P. 56(a).

ARGUMENT

I. The district court properly held that Plaintiffs must offer evidence of proximate causation to survive summary judgment.

Plaintiffs attack the core of California's learned intermediary doctrine. They argue that all they need to do is offer evidence of an inadequate warning, and that they do not have to offer evidence that the inadequate warning proximately caused their alleged injuries. *See* OB 30-44. This argument fails because this Court has issued binding precedent stating that, under California law, a plaintiff must prove *both* inadequate warning and proximate causation, and Plaintiffs fail to identify any contrary authority.

A. California law requires a plaintiff bringing a failure to warn claim against a medical device manufacturer to prove *not only* inadequate warning *but also* proximate causation.

California has adopted the "learned intermediary doctrine," which applies where, as here, a plaintiff brings a failure to warn claim against the manufacturer of a physician-prescribed medical device. *See, e.g.*, *Webb*, 63 Cal. 4th at 187 n.10 (the doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship"). Under the learned intermediary doctrine, a medical device manufacturer has "a duty to warn physicians of risks that are known or scientifically knowable at the time of the [product's] distribution." *Wendell*, 858 F.3d at 1238. That duty to warn "runs *to the physician*, not to the patient." *Carlin v. Superior Ct.*, 13 Cal. 4th 1104, 1116 (1996) (emphasis in original). A manufacturer has no obligation to ensure that its warning actually reaches the patient. *Id.*

In focusing failure to warn claims on the relationship between the manufacturer and the physician, the learned intermediary doctrine recognizes that "[i]t would be virtually impossible for a [medical] manufacturer to comply with [a] duty of direct warning" to the patient, "as there is no sure way to reach the patient." *Plenger v. Alza Corp.*, 11

Cal. App. 4th 349, 362 n.6 (1992) (internal quotation marks omitted). The doctrine also recognizes that a patient is often poorly suited to evaluate a manufacturer's warnings and would be prone to refuse treatment unnecessarily:

> Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the [manufacturer's product], he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the [product], thereby jeopardizing his life.

Id. (internal quotation marks omitted).

Binding Ninth Circuit precedent clarifies the burden that a plaintiff bears at summary judgment when bringing a failure to warn claim against a medical manufacturer. In *Wendell v. GlaxoSmithKline LLC*, this Court explained that a plaintiff must offer enough evidence to make *two* showings: (1) inadequate warning and (2) proximate causation. *Wendell*, 858 F.3d at 1238. *Wendell* stressed that these are two separate and independently-necessary requirements, and satisfying the first does not erase the second:

> "A plaintiff asserting causes of action based on a failure to warn must prove *not only* that no warning was provided or the warning was inadequate, *but also* that the inadequacy or absence of the warning caused the plaintiff's injury."

Wendell, 858 F.3d at 1238 (quoting *Motus I*, 196 F.Supp.2d at 991) (emphasis added). *Wendell* further explained that, to prove proximate causation, the plaintiff must demonstrate that the physician would not have prescribed the medical product at issue if given an adequate warning. *See id.* at 1238 (focusing the proximate causation inquiry on evidence that the physician would have changed his "prescribing decisions" by prescribing an alternative medication that lacked the same adverse health risks).

In recognizing that California law imposes a proximate causation requirement *in addition* to an inadequate warning requirement, *Wendell* adhered to this Court's binding decision in *Motus II*. There, this Court stated plainly that a plaintiff could not survive summary judgment with evidence of inadequate warnings alone, but also had to prove proximate causation: "[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 II*, 358 F.3d at 661. *Motus II* affirmed the district court's holding that "[t]he burden is on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's

decision to prescribe the product for the plaintiff." *Motus I*, 196 F. Supp. 2d at 995–96 (internal quotation marks and alteration omitted)). This Court was unequivocal that, where a plaintiff fails to offer such evidence of proximate causation, "the adequacy of [the manufacturer's] warnings is *irrelevant* to the disposition of th[e] case." *Motus II*, 358 F.3d at 661 (emphasis added).

This Court similarly recognized in *Latiolais v. Merck & Co.* ("*Latiolais II*") that, to survive summary judgment, a plaintiff must prove "causation under California's 'learned intermediary' doctrine." 302 F. App'x 756, 757 (9th Cir. 2008). *Latiolais II* held that a district court properly granted summary judgment where a physician testified that the manufacturer's warnings "did not play a role in his decision to prescribe that medication." *Id.* The physician had stated that, given his patient's "pressing medical condition," he "would have prescribed" the product at issue even with a heightened warning. *Latiolais v. Merck & Co.*, 2007 WL 5861354, at *4 (C.D. Cal. Feb. 6, 2007) ("*Latiolais I*"), *aff'd*, 302 F. App'x 756 (9th Cir. 2008). The court reasoned that this statement was, "under *Motus,* . . . determinative of whether the prescribing doctor's

treatment or conduct would have changed in light of an allegedly more appropriate warning." *Id*.

District courts within the Ninth Circuit have adhered to this Court's precedent on the *two*-pronged nature of a plaintiff's burden under the learned intermediary doctrine, requiring evidence of proximate causation even where the plaintiff has already offered evidence of inadequate warning. *See, e.g.*, *Munoz v. Am. Med. Sys., Inc.*, 2021 WL 1200038, at *2 (C.D. Cal. Mar. 30, 2021) ("Where the learned intermediary doctrine applies, the plaintiff must prove that: (1) no warning was provided or the warning was inadequate, *and* (2) the inadequate warning was the proximate cause of her injury." (internal quotation marks omitted) (emphasis added); *Galinis v. Bayer Corp.*, 2019 WL 2716480, at *9 (N.D. Cal. June 28, 2019) ("A plaintiff seeking to hold a manufacturer strictly liable for failure to warn must prove that no warning was provided or that the warning was inadequate, *and* that the inadequate warning caused her injury." (emphasis in original).[6]

[6] *See also Brown v. Johnson & Johnson*, 2019 WL 2577296, at *5 (E.D. Cal. June 24, 2019), *report and recommendation adopted sub nom. Brown v. Johnson & Johnson, Inc.*, 2019 WL 3943980 (E.D. Cal. Aug. 21, 2019) ("A plaintiff asserting causes of action based on a failure to warn must

This body of law accords with the California Supreme Court's decision in *Ramirez v. Plough, Inc.*, which upheld summary judgment on a failure to warn claim. 6 Cal. 4th 539 (1993). *Ramirez* involved a drug's purportedly inadequate warning label, and the California Supreme Court reasoned that summary judgment was proper where the drug was administered by someone who had not read the label. *Id.* at 555-56. The Court explained that, as long as the product warnings remained unread, there was simply "no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury." *Id.* at 556.

The Ninth Circuit's precedent also follows the logic of *Carlin v. Superior Court*, 13 Cal. 4th 1104 (1996), in which the California Supreme

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prove not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury. That is, *assuming an inadequate warning*, 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." (quotation marks and citations omitted) (emphasis added)); *Baker v. Bayer Healthcare Pharms., Inc.*, 2013 WL 6698653, at *4 (N.D. Cal. Dec. 19, 2013) ("A plaintiff asserting causes of action for failure to warn must prove not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of a warning caused the plaintiff's injury." (internal quotation marks omitted)).

Court recognized that inadequate warning is not the only element of a plaintiff's burden of proof under the learned intermediary doctrine. *Carlin* stated that, even where a manufacturer indisputably failed to provide a warning of a risk, the manufacturer still could not be held liable if that risk was already known to the medical community. *Id.* at 1116. *Carlin* identified a situation with a missing causal link: where the physician already knew of the risk, the inadequacy of a manufacturer's warning plainly could not be the cause of the physician's decision to prescribe. *See Guevara v. Dorsey Lab'ys, Div. of Sandoz, Inc.*, 845 F.2d 364, 367 (1st Cir. 1988) ("[I]f the doctor knew of the danger already, the failure to warn could not have been the cause of the injury.").[7]

Here, as the district court properly concluded, there can be no reasonable dispute that the learned intermediary doctrine applies to Plaintiffs' claims against Somatics. 2-ER-8. Somatics manufactures

[7] The Second Circuit has interpreted California law the same way. It has repeatedly held that a plaintiff bringing a failure to warn claim under California law must prove not only inadequate warning but also proximate causation. *See Guillen v. Eli Lilly & Co.*, 394 F. App'x 814, 816 (2d Cir. 2010) (applying California law); *Neal v. Eli Lilly & Co.*, 394 F. App'x 823, 824-25 (2d Cir. 2010) (same); *Misouria v. Eli Lilly & Co.*, 394 F. App'x 825, 826-27 (2d Cir. 2010) (same).

medical devices used for ECT. Both Plaintiffs received their ECT treatment with medical devices as prescribed and administered by their physicians, Dr. Fidaleo (for Ms. Himes) and Dr. Frankel (for Ms. Benjamin). Plaintiffs now allege injuries suffered as a result of inadequately-disclosed risks. These failure to warn claims fall into precisely the context that triggers the learned intermediary doctrine, as the doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship." *Webb*, 63 Cal. 4th at 187 n.10.

The district court correctly recognized that, under this Court's binding precedent, Plaintiffs could only survive summary judgment by demonstrating *both* that (1) Somatics did not provide adequate warnings to Dr. Fidaleo and Dr. Frankel; *and* (2) if Dr. Fidaleo and Dr. Frankel had received adequate warnings, they would not have prescribed ECT to Ms. Himes and Ms. Benjamin. 2-ER-9-10.

B. Plaintiffs mischaracterize case law and ignore binding precedent in arguing that, as long as they have offered evidence of inadequate warning alone, they need not *also* offer evidence of proximate causation.

Plaintiffs erroneously protest that the learned intermediary doctrine does not apply because Somatics provided inadequate warnings to their physicians. *See* OB 29. In fact, the learned intermediary doctrine

applies whenever a plaintiff brings a failure to warn claim against a medical device manufacturer, alleging injuries after administration of the device by a physician.[8] *See, e.g.*, *Webb*, 63 Cal. 4th at 187 n.10; *Motus I*, 196 F. Supp. 2d at 990. When a plaintiff brings a failure to warn claim against a medical manufacturer and triggers the learned intermediary doctrine, she then must come forward with evidence of both (1) inadequate warning *and* (2) proximate causation. *See Wendell*, 858 F.3d at 1238; *Motus II*, 358 F.3d at 661; *Latiolais II*, 302 F. App'x at 757.

Satisfying one of these two requirements is not enough. As discussed at length in Section I(A) above, "inadequacy of the warning and causation are *separate* elements of Plaintiffs' affirmative burden." *Tucker v. Wright Med. Tech., Inc.*, 2013 WL 1149717, at *16 (N.D. Cal. Mar. 19, 2013) (emphasis in original); *see also Rodman v. Otsuka Am. Pharm., Inc.*, 2020 WL 2525032, at *8 (N.D. Cal. May 18, 2020) ("*[E]ven if a warning was inadequate*, a product defect claim based on insufficient

[8] The learned intermediary doctrine does not apply where a patient administers the medical device to herself, outside a hospital setting. *See Dreifort v. DJO Glob. Inc.*, 2019 WL 5578240, at *8 (S.D. Cal. Oct. 28, 2019) ("The doctrine does not apply to medical devices intended to be operated by the patient outside the medical environment." (internal quotation marks omitted)). That is not the case here.

warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." (internal quotation marks omitted) (emphasis added)). The Ninth Circuit has resoundingly rejected the notion—pressed by Plaintiffs here—that proof of inadequate warnings absolves a plaintiff of the responsibility to prove proximate causation. *See Motus II*, 358 F.3d at 661 (where a plaintiff fails to establish proximate causation, "the adequacy of [the manufacturer's] warnings is irrelevant to the disposition of th[e] case"); *accord Wendell*, 858 F.3d at 1238.[9]

Notably, Plaintiffs do not even attempt to distinguish *Wendell*, the most recent binding precedent they ask this Court to disregard. Instead,

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[9] Plaintiffs also assert that, "if adequate warnings were not given to anyone, the [learned intermediary doctrine] defense is unavailable" because "any intermediary is, by definition, no longer 'learned.'" OB 34 (emphasis omitted). They offer no authority for their novel theory. And it makes no sense. The word "learned" in the "learned intermediary doctrine" does not refer to the physician's knowledge of a particular warning provided by a manufacturer. It refers to the physician's medical training and consequent superior ability, relative to the patient, to assess benefits and risks. *See Plenger*, 11 Cal. App. 4th at 362 n.6. The physician remains "learned" regardless of whether he or she has received a specific adequate warning, and the learned intermediary doctrine applies whenever the physician prescribes and administers a manufacturer's drug or device in a hospital setting. *Webb*, 63 Cal. 4th at 187 n.10.

Plaintiffs rely on four much-older decisions—*Brown v. Superior Court*, 44 Cal. 3d 1049 (1988), *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51 (1973), *Carmichael v. Reitz*, 17 Cal. App. 3d 958 (Ct. App. 1971), and *Love v. Wolf*, 226 Cal. App. 2d 378 (Ct. App. 1964)—none of which supports Plaintiffs' argument. Plaintiffs quote passages from all four cases that stand for the unsurprising proposition that, if a manufacturer has given adequate warnings, it cannot be held liable under the doctrine. *See, e.g.*, *Brown*, 44 Cal. 3d at 1062 ("The manufacturer cannot be held liable if it has provided appropriate warnings . . . ."). [10] This proposition comports perfectly with *Wendell* and *Motus II*, which state that summary judgment is appropriate where the plaintiff fails to show *either* inadequate warning or proximate causation. None of Plaintiffs' four cases states that a plaintiff's failure to establish inadequate warning is the *only* way a manufacturer may be entitled to protection under the learned

[10] *See also Stevens*, 9 Cal. 3d at 65 ("'[I]f 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.'" (quoting *Love*, 226 Cal. App. 2d at 395)); *Love*, 226 Cal. App. 2d at 395 (same); *Carmichael*, 17 Cal. App. 3d at 994 ("[T]he manufacturer of an ethical drug discharges its duty of warning if it adequately warns the doctor . . . , and there is no duty to directly warn the patient.").

intermediary doctrine, or otherwise calls into question this Court's binding holdings that a manufacturer is *also* entitled to protection if the plaintiff fails to show proximate causation.

Plaintiffs place particularly misguided emphasis on *Stevens*, which addressed an "overpromotion" claim not raised here. In *Stevens*, a woman died of bone marrow failure after taking a drug, and the drug manufacturer had previously warned doctors in writing of this risk. 9 Cal. 3d at 57-58. But the manufacturer had also implemented an aggressive campaign of salesmen personally visiting doctors, where they deceptively "counter[ed]" the written warnings and minimized the risk. *Id.* at 58, 67. *Stevens* held that "an adequate warning . . . may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given." *Id.* at 65. Even if the doctor knew of the drug's dangers, he had been "induced to prescribe the drug" by an in-person campaign that "employ[ed] both direct and subliminal advertising" to "consciously or subconsciously influence[]" and "allay the fears of the medical profession which were raised by knowledge of the drug's dangers." *Id.* at 68-69.

Stevens's analysis of the effect of overpromotion evidence does not support Plaintiffs' argument that they need not prove proximate causation. Plaintiffs here have not argued or offered any evidence to establish that Somatics engaged in overpromotion; this is a traditional medical warnings-adequacy case. Moreover, "[t]he logic of an overpromotion theory is that the manufacturer's aggressive marketing caused a physician to discount a known risk when prescribing a [medical product] to a patient." *Motus I*, 196 F. Supp. 2d at 999. An "overpromotion theory" is inapplicable where, as here: there was no overpromotion; the doctors testified that they did not even rely on what the manufacturer said in its warnings; and the doctors testified that even if they had gotten beefed-up warnings they still would have prescribed the medical device. *See id*.[11]

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[11] Plaintiffs' discussion of *Stevens* exemplifies their strategy of quoting out-of-context sentences from California cases analyzing completely different legal questions. Plaintiffs cite *T.H. v. Novartis Pharms. Corp.*, where the California Supreme Court held only that a manufacturer who failed to update a drug label was not free from liability just because the successor manufacturer *also* failed to update the label. 4 Cal. 5th 145, 184 (2017). *Novartis* had nothing to do with whether the learned intermediary doctrine requires proof that an adequate warning would have changed a physician's conduct. *Novartis* stated that "we have never allowed a defendant to excuse its own negligence as a matter of law

Finally, Plaintiffs incorrectly rest their effort to avoid California's proximate causation requirement on a line of dicta in a nonbinding district court decision issued before *Wendell: Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943 (E.D. Cal. 2013). *Hill* briefly summarized the learned intermediary doctrine, stating that "the doctrine, 'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.'" *Hill*, 944 F. Supp. 2d at 953 (quoting *Stewart v. Union Carbide Corp.*, 190 Cal.App.4th 23, 29 (2010)).[12]

But *Hill* failed to notice that *Stewart* did not involve the learned intermediary doctrine. *Stewart* involved a different (if similarly-named)

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simply by asserting that *someone else* should have picked up the slack and discharged the duty at issue." *Id.* In the context of the learned intermediary doctrine, the "duty at issue" is exclusively to warn the physician—not to ensure the warning reaches the patient. *See Carlin*, 13 Cal. 4th at 1116. Requiring proof of proximate causation does not pass the manufacturer's burden of warning the physician onto someone else; it simply ensures that the manufacturer's failure to meet that burden actually causes the alleged injury.

[12] *Hill* also quoted a California appellate court decision, *Love v. Wolf*, *solely* for the proposition that, "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." *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, 953 (E.D. Cal. 2013) (quoting *Love v. Wolf*, 226 Cal.App.2d 378, 395 (1964)). As noted above, *Love* did not state that a plaintiff need not prove proximate causation in addition to inadequate warning.

doctrine called the "sophisticated intermediary doctrine." The California Supreme Court has cautioned that the "sophisticated intermediary doctrine" and the "learned intermediary doctrine" are *separate* doctrines under California law. *See Webb*, 63 Cal. 4th at 187 & n.10 (distinguishing between the two). The "sophisticated intermediary doctrine" applies to shield some product suppliers from liability in contexts involving "sufficiently sophisticated" buyers. *Id.* at 180. But it is only the "learned intermediary doctrine"—and not the "sophisticated intermediary doctrine"—that "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship." *Id.* at 187 n.10. *Hill* confused the two doctrines, taking a description of one and applying it to the other.

Stewart and *Hill* have been rejected and superseded. The California Supreme Court rejected *Stewart*'s reasoning about the sophisticated intermediary doctrine, with the precise sentence from *Stewart* quoted in *Hill* being expressly "disapproved." *Webb*, 63 Cal. 4th at 188. *Webb* dismissed the statement from *Stewart* (and *Hill*) that the learned intermediary doctrine "applies only if a manufacturer provided adequate warnings to the intermediary." *Webb* recognized that "[t]his

assertion cannot be reconciled" with earlier precedent. *Id*. Moreover, the muddled description of the learned intermediary doctrine set out by the district court in *Hill* has been superseded by the subsequently-issued binding precedent of *Wendell*, which clarified a plaintiff's two-pronged burden to establish *both* inadequate warning *and* proximate causation.[13]

Plaintiffs' argument also runs head-on into a core principle of *any* negligence or strict liability claim, not just one premised on a manufacturer's failure to warn under the learned intermediary doctrine. A plaintiff must always prove that the wrong *caused* the injury. *See Smith v. Lockheed Propulsion Co.*, 247 Cal. App. 2d 774, 780 (1967) ("It is axiomatic that an essential element of a plaintiff's cause of action, whether based on negligence or strict liability, is the existence of a causal

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[13] At least one other district court was misled like *Hill*. *See A.S. v. Pfizer, Inc.*, 2013 WL 2384320, at *6 (E.D. Cal. May 30, 2013) (quoting the same line from *Stewart* after confusing it for a learned intermediary doctrine case) (later superseded by *Wendell* and *Webb*). District courts have now caught up. *See Shahbaz v. Johnson & Johnson*, 2020 WL 5894590, at *13 (C.D. Cal. July 31, 2020) ("Plaintiff cites only one case [(*Hill*)] for the proposition that the learned intermediary doctrine applies *only if* the manufacturer provided an adequate warning to the intermediary. . . . [T]his authority is incorrect to the extent that it suggests that the learned intermediary doctrine has no effect where plaintiffs allege that warnings are inadequate." (citations, alterations, and internal quotation marks omitted)).

connection between defendant's act and the injury which plaintiff suffered."); *see also Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001); *Steinle v. United States*, 11 F.4th 744, 746 (9th Cir. 2021). While the learned intermediary doctrine clarifies how the causal connection requirement works in the context of a claim brought against a medical device manufacturer, the doctrine simply applies the familiar causation principle that the defendant's breach of its duty of care must have produced the plaintiff's injury. That makes plain just how widely Plaintiffs ask this Court to deviate from established precedent. They ask this Court to ignore the causation requirement set out clearly in its learned intermediary doctrine precedent. But they also ask this Court to uniquely excuse them from a requirement facing every single other plaintiff in a negligence or strict liability case.

II. The district court has never held that Dr. Fidaleo and Dr. Frankel received inadequate warnings.

The first prong of the learned intermediary doctrine requires a plaintiff to establish inadequate warning. Plaintiffs falsely state that "the district court correctly concluded that 'Defendant did not provide any warnings to Dr. Frankel and Dr. Fidaleo concerning the risk of brain

injury or permanent memory loss.'" OB 28 (quoting 1-ER-9) (emphasis omitted).

They arrive at this false statement by cutting out the beginning of the district court's sentence, which stated that it "*assumes for purposes of this Order* that Defendant did not provide any warnings to Dr. Frank[el] and Dr. Fidaleo concerning the risk of brain injury or permanent memory loss." 2-ER-9 (emphasis added). The court proceeded under that assumption because Somatics did not move for summary judgment based on Plaintiffs' failure to create a triable issue on inadequate warning. Rather, Somatics moved for summary judgment based only on Plaintiffs' failure to create a triable issue on proximate causation. 1-ER-7.[14] The adequacy of Somatics' warnings was not at issue on the motion, which is why the district court assumed inadequate warning for the purpose of analyzing causation. As the district court found in an earlier decision, Somatics and Plaintiffs have "present[ed]

[14] Somatics also moved for summary judgment on the timeliness issue, which the district court did not resolve. If this Court were to conclude, contrary to *Wendell* and *Motus II*, that Plaintiffs only had to prove inadequate warning, and did not need also to prove proximate causation, then it would remand to the district court to consider Somatics's summary judgment argument that the claims are untimely.

conflicting evidence about whether there is a known or substantial risk of brain injury and permanent memory loss" that would render provided warnings inadequate. *Somatics, LLC*, 2018 WL 6242154, at *11.

III. The district court properly held that Plaintiffs failed to establish proximate causation.

Plaintiffs failed to adduce *any* evidence to demonstrate that, if Dr. Fidaleo and Dr. Frankel had received adequate warnings, they would not have prescribed and administered ECT to Ms. Himes and Ms. Benjamin. Although Plaintiffs take the position that they can survive summary judgment without such evidence, proposing an alternate causation theory focused on conduct of the patient, *see* OB 45-59, Ninth Circuit precedent forecloses this argument.

A. Plaintiffs failed to adduce evidence that a heightened warning would have altered their physicians' prescription decisions.

As discussed in Section I(A) above, the Ninth Circuit has clarified that, to establish proximate causation under California's learned intermediary doctrine, a plaintiff must demonstrate that her physician *would not have prescribed* the medical product at issue with the benefit of adequate warnings. *Compare Latiolais II*, 302 F. App'x at 757 (no proximate causation where physician's "deposition testimony indicates

that the [manufacturer's warnings] did not play a role in his decision to prescribe that medication"), *with Wendell*, 858 F.3d at 1238 (proximate causation where physician's testimony suggested a heightened warning would have changed his "prescribing decisions" in that he would have prescribed a different medication with a "better safety profile").

Motus II is particularly instructive that a plaintiff's proximate causation burden is to demonstrate a warning's effect on *the physician's decision to prescribe*. There, the Ninth Circuit affirmed a district court's holding that, under California's learned intermediary doctrine, a defendant manufacturer is entitled to summary judgment "[i]f it is not genuinely disputable that [the physician] would have prescribed [the product] to [the plaintiff] even if [the manufacturer] had provided an adequate warning." *Motus I*, 196 F. Supp. 2d at 991. The plaintiff has the burden "to demonstrate that the inclusion of an adequate warning would have altered [the physician's] decision to prescribe," because California has not adopted a rebuttable presumption to that effect. *Id.*[15]

[15] *Accord In re Aredia & Zometa Prod. Liab. Litig.*, 2009 WL 2497692, at *2 (M.D. Tenn. Aug. 13, 2009) ("California has not adopted a rebuttable presumption that the physician would have heeded an adequate warning. Thus, Plaintiff has to adduce evidence that . . . treating physicians would

Summary judgment is therefore proper where the plaintiff fails "to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed *the treating physician's decision to prescribe the product for the plaintiff*." *Id.* at 995–96 (internal quotation marks and alteration omitted)) (emphasis added).[16]

Accordingly, district courts interpreting California law have focused causation inquiries exclusively on evidence pertaining to physicians' decisions to prescribe. *See, e.g.*, Brown, 2019 WL 2577296, at *8 ("[To demonstrate that the inadequate warning caused the plaintiff's injuries, the plaintiff must show a causal link between the warning label and *the physician's decision to prescribe the drug*" (emphasis added)); *Thompson v. Janssen Pharms., Inc.*, 2017 WL 5135548, at *8 (C.D. Cal.

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have acted differently had Defendant provided an adequate warning . . . ." (citation omitted)).

[16] The Second Circuit has also repeatedly held that, under California law, a plaintiff must offer evidence that her physician would have made a different prescribing decision. *See, e.g.*, *Guillen*, 394 F. App'x at 816 (summary judgment appropriate where plaintiff "has failed to demonstrate that her treating physicians would have altered their *decision to prescribe* [the drug at issue] had a different warning been provided by [the manufacturer]") (applying California law) (emphasis added); *Neal*, 394 F. App'x at 825 (same); *Misouria*, 394 F. App'x at 827 (same).

Oct. 23, 2017), *aff'd*, 756 F. App'x 740 (9th Cir. 2019) ("[A] plaintiff must . . . establish that a different warning would have *changed the prescribing physician's decision*, and failure to provide such evidence warrants summary judgment for the defendant. . . . Plaintiffs have provided no evidence that a different warning would have altered the *physicians' decisions to prescribe* . . . . Therefore, they cannot demonstrate the causation required to survive summary judgment under California's learned intermediary doctrine." (emphasis added)).[17]

In this case, the district court properly applied Ninth Circuit precedent and recognized that Plaintiffs failed to meet their burden to present evidence that, if they had received an adequate warning from

[17] *See also Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1144 (S.D. Cal. 2016) ("In order to prove causation, a plaintiff must allege that the inadequate warning or lack of warning about the medical device risk would have *altered the prescribing physician's decision to use the product*." (emphasis added)); *In re Zyprexa Prods. Liab. Litig.*, 2009 WL 3596982, at *11 (E.D.N.Y. Oct. 20, 2009) (granting summary judgment where plaintiff "offered no evidence suggesting that his physicians would have *altered their prescription decisions* had [the defendant's] warning been different, as required under California's learned intermediary doctrine" (emphasis added)); *cf. Galinis*, 2019 WL 2716480, at *11 (proximate causation established by physician's testimony that, had she been warned about a risk of blood clots, she "'would not prescribe" the drug at issue and indeed stopped prescribing it to other patients "'as soon as [she] got this information"').

Somatics, Dr. Fidaleo and Dr. Frankel would not have prescribed ECT to Ms. Himes and Ms. Benjamin. In fact, while Somatics bore no burden to offer evidence to *negate* causation,[18] the evidentiary record teemed with such evidence. Both physicians testified unambiguously that they did not rely on Somatics's warnings and that a heightened warning would not alter their prescribing decisions.

Dr. Fidaleo—who prescribed ECT to Ms. Himes—testified that he had never read Somatics's information pamphlet containing warnings, that he did not recall ever reading the manual for the Thymatron device that Somatics provided to his hospital, and that he had never spoken to anyone from Somatics. 5-ER-1004-1005, 1016-1017. Dr. Fidaleo also explained that Ms. Himes's ECT treatment was a necessary last resort due to her worsening mental health condition, [redacted] Given the dire nature of Ms. Himes's condition, Dr. Fidaleo testified clearly that he would have prescribed ECT notwithstanding a risk of permanent memory loss:

[18] "A defendant need not produce its own evidence; pointing to an absence of evidence on the Plaintiff's part is sufficient." *Rodman*, 2020 WL 2525032, at *8 (internal quotation marks omitted).

> *It wouldn't stop me.* You have to take the whole thing. All drugs and all things have memory loss. If you forgot your wedding date, but you knew how to function, I wouldn't consider that a reason not to give treatment.

5-ER-1013 (emphasis added). When asked whether he would still prescribe ECT if he received a warning that the treatment could impede a patient's ability to form new memories, he responded that—*even with such a warning*—he would still need to independently corroborate the warning through his own clinical observations and he had never seen such a result from ECT in his own practice:

> *I would have to see it also myself.* . . . [Y]ou go by what you see clinically. . . . I don't see that. . . . I would be seeing that myself and *I'm not seeing that* with my patients.

5-ER-1014-1015 (emphasis added).

Dr. Frankel—who prescribed ECT to Ms. Benjamin—similarly testified, unequivocally, that he had not relied on any warnings from Somatics regarding the risks of ECT:

> Q. Have you relied on any disclosure from Somatics, LLC, to inform you of the risks of ECT?
>
> A. No.

5-ER-1036. Dr. Frankel also stated that a risk of long-term cognitive impairment would not hold him back from prescribing ECT because the treatment was a last resort for patients who were out of other options:

> [A.] . . . I have had patients who do complain of different cognitive disturbances over the years, who they may attribute to ECT treatments.
>
> Q. . . . And has that ever caused concern to you that ECT was causing long-term cognitive impairment?
>
> A. Not really, because almost every case we are very careful to make sure that every other treatment option has been exhausted before we do ECT.

5-ER-1037-1038. Dr. Frankel further admitted that he did not pay attention to manufacturers' updated safety warnings:

> Q. From time to time do you ever receive literature from a manufacturer informing you of updated safety information associated with their drug or device?
>
> A. We receive a good deal of literature from various drug companies, for example, but I don't pay terribly much attention to them.

5-ER-1044.

Dr. Fidaleo's admissions that he did not even *read* Somatics's disclosures, let alone otherwise rely upon them, are particularly fatal to Ms. Himes's claims. This Court has held that a defendant is entitled to summary judgment where a prescribing physician "testifie[s] that he did

not read the warning label that accompanied [the drug] or rely on information provided by [the manufacturer] before prescribing the drug." *Motus II*, 358 F.3d at 661; *see also Latiolais I*, 2007 WL 5861354, at *2-3 (no proximate causation where a physician testified that he "could not recall" reading warnings, as "[t]he controlling *Motus* case states that where the prescribing doctor fails to read warnings or rely on information provided by the drug manufacturer before prescribing the drug, a plaintiff cannot show any alleged failure to warn by the drug manufacturer caused harm to the patient taking the drug").

Courts have repeatedly recognized that, "[w]here a physician did not read the manufacturer's product warnings, there is no causal connection on the failure to warn claim as a matter of law." *Renteria v. Ethicon, Inc.*, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020); *see Hexum v. Eli Lilly & Co.*, 2015 WL 4943959, at *8 (C.D. Cal. Aug. 18, 2015) (defendant entitled to summary judgment where "the only basis for a jury to find that [the physician] read [the drug's] label prior to prescribing [the drug] to [the plaintiff] is speculation"); *see also Tucker*, 2013 WL 1149717, at *16 ("Where the physician did not read the

warnings, adequacy [of those warnings] is irrelevant . . . ."); *cf*. *Ramirez*, 6 Cal. 4th at 556 (no causation due to failure to read label).

Similarly, Dr. Frankel's uncontradicted admission that he did not pay attention to safety information sent by medical manufacturers, let alone rely on that information, precludes a showing of proximate causation on Ms. Benjamin's claims (and her husband's related loss of consortium claim). A plaintiff "cannot credibly urge that a doctor who finds it unnecessary to determine whether or not a warning is present would be likely to take into account the new warning once it is provided." *Latiolais I*, 2007 WL 5861354, at *4. On such facts, "no reasonable jury could conclude that such a warning might otherwise have caused [the physician] to alter his prescription decision." *Id*.

In sum, Dr. Fidaleo's and Dr. Frankel's repeated clear statements that they did not rely on Somatics's warnings in prescribing ECT, and would in any event prescribe ECT notwithstanding a risk of long-term cognitive injury or permanent memory loss, plainly break the causal chain between the warnings and their prescription decisions. Given this evidence—and, more importantly, given the absence of any conflicting evidence that a heightened warning would have altered the physicians'

prescribing decisions—the district court correctly held that Plaintiffs failed to establish proximate causation.

B. Ninth Circuit precedent forecloses Plaintiffs' proposed alternate causation prong.

On appeal, Plaintiffs do not even attempt to identify evidence that adequate warnings would have changed their physicians' decisions to prescribe ECT. Instead, unable to climb the mountain of contrary evidence, Plaintiffs seek yet another exception to this Court's learned intermediary doctrine precedent: Plaintiffs argue that, even if they cannot demonstrate that their physicians would not have prescribed ECT with adequate warnings, they can still survive summary judgment through a demonstration that, if Somatics had adequately warned their physicians, the warnings would have reached Plaintiffs, who would have refused ECT when their physicians prescribed it. Plaintiffs offer their own self-serving assurances that, if *they* were armed with adequate warnings, they would have ignored their physicians' medical advice and refused consent to prescribed treatment. They propose, therefore, an alternate causation prong—one based on conduct of the patient rather than the physician.

As a preliminary matter, even if California law permitted this alternate causation prong (which it does not), Plaintiffs' argument has no basis in the record on appeal. There is no evidence that Plaintiffs' prescribing physicians would *even be aware* of heightened warnings from Somatics, such that they could relay such warnings to Plaintiffs. As described above, Ms. Himes's prescribing physician, Dr. Fidaleo, testified that he did not even read disclosures from Somatics, and Ms. Benjamin's prescribing physician, Dr. Frankel, testified that he did not pay attention to the safety mailings sent to him by drug manufacturers.[19]

Moreover, binding Ninth Circuit precedent forecloses Plaintiffs' argument. Plaintiffs' alternate theory of proximate causation guts the learned intermediary doctrine, putting the patient in the doctor's shoes. This Court squarely rejected that approach in *Motus II*. There, a patient

[19] Dr. Fidaleo testified that a non-physician worker at his hospital—a nurse technician who trains physicians in the mechanics of using the Thymatron—"refers to the [manual] if there is an issue." 3-ER-326, 333. Plaintiffs identify no evidence in the record that, had this technician come across warnings for physicians in the manual, the technician would have relayed these warnings to Dr. Fidaleo, who would have then relayed the warnings to Plaintiffs, who would have then have refused treatment prescribed by Dr. Fidaleo. Thus, even if Plaintiffs could establish causation through this ridiculous game of telephone—which they most certainly cannot—Plaintiffs still fail to explain how Dr. Fidaleo would be aware of the warnings.

committed suicide after his doctor ("Dr. Trostler") prescribed Zoloft. This Court agreed with the district court that the plaintiff failed to establish proximate causation because there was no evidence that warnings by Pfizer, the manufacturer, influenced Dr. Trostler's decision to prescribe. *See Motus II*, 358 F.3d at 661 (focusing on physician's admission "he did not read the warning label that accompanied Zoloft or rely on information provided by Pfizer's detail men before prescribing the drug"). The district court decision affirmed by this Court explained:

> If it is not genuinely disputable that Dr. Trostler *would have prescribed* Zoloft to Mr. Motus even if Pfizer had provided an adequate warning about the risk of suicide, then Ms. Motus cannot prove proximate cause, and Pfizer is entitled to summary judgment.

Motus I, 196 F. Supp. 2d at 991 (emphasis added); *see also id.* at 992 ("[The manufacturer] may prevail by showing that Plaintiff lacks evidence establishing that an adequate warning would have affected [the physician's] *decision to prescribe* [the drug].").

Motus I and *Motus II* squarely rejected the precise argument that Plaintiffs raise here—that California law lets a plaintiff establish proximate causation by showing that a patient's physician would have relayed an adequate warning to the patient:

> Plaintiff's lawyer did ask Dr. Trostler: "If you had been told that Zoloft can cause an increased risk in suicide during the first few weeks of drug treatment, *is that the kind of information you would pass on to your patients*?" Dr. Trostler responded, "Yes." Plaintiff argues that this response creates a genuine issue as to whether Dr. Trostler would have changed his behavior had Pfizer provided adequate warnings. The Court does not agree. Given that this case is about the sufficiency of the warnings accompanying Zoloft, the appropriate question would have been: "If Zoloft's package insert had contained a warning that Zoloft can cause an increased risk in suicide during the first few weeks of drug treatment, *would you have prescribed* Zoloft to Mr. Motus?"

Id. at 997 (emphasis added).[20] In affirming that analysis, *Motus II* foreclosed Plaintiffs' effort to gut the learned intermediary doctrine.[21]

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[20] Plaintiffs' opening brief incorrectly states that the district court in *Motus I* "discussed alternative sets of facts to establish causation" and "appreciated that establishing that the doctor would not have prescribed the drug or procedure is not the sole or exclusive means of establishing causation." OB 55. *Motus I* only noted that the *initial* prescribing decision was not the only relevant prescribing decision, as a plaintiff might also establish causation through evidence that an adequately-warned physician would have ceased prescribing a drug or device after detecting early warning signs of an adverse reaction. *See Motus I*, 196 F. Supp. 2d at 995. Whether initial or subsequent, the physician's prescribing decisions remained the exclusive focus of the causation inquiry under *Motus I*.

[21] Plaintiffs unsuccessfully attempt to distinguish *Motus II* by stressing that it involved a patient's death. *See* OB 56. No language in *Motus II* restricts its holding to cases in which patients died, and Plaintiffs are unable to identify any single subsequent case that has ever interpreted *Motus II* in such a limited way. And for good reason: it makes absolutely

Since *Motus II*, courts in this Circuit have continued to reject the alternate causation theory that Plaintiffs press here. In *Munoz v. American Medical Systems, Inc.*, for example, the court noted:

> In a final attempt to create a triable issue of material fact, Plaintiff claims that if Defendant had provided stronger warnings, [Plaintiff's physician] would have shared those warnings with Plaintiff. She contends that this demonstrates that [the physician] would have altered his treatment, and that this proves causation.

2021 WL 1200038, at *4 (C.D. Cal. Mar. 30, 2021) (citations omitted). The court dismissed this argument swiftly because California's learned intermediary doctrine focuses only on the physician's prescribing decision:

> Plaintiff's argument ignores that where there is a learned intermediary, the issue of causation concerns whether the physician would have altered his recommendation concerning treatment, not whether he would have shared the stronger warnings with his patient. *See, e.g.*, *Motus*, 196 F. Supp. 2d at 997. [The physician's] testimony that he would have passed along the additional information to Plaintiff is insufficient on its own to deny summary judgment. *See id.* (finding testimony that the physician would have provided additional warnings to the plaintiff did not raise a triable issue of fact on the issue of causation).

Id.

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no sense that California's learned intermediary doctrine would impose a vastly reduced burden of proof on plaintiffs claiming less obvious injuries.

As *Motus II* and *Munoz* recognized, the learned intermediary doctrine rests on the principle that patients will and should rely on physicians to assess the risks of medical products. Under the doctrine, "'it is through the physician that a patient learns of the properties and proper use of the [products].'" *Rodman*, 2020 WL 2525032, at *7 (quoting *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (1999)). A patient may, "in his limited understanding," make an irrational, unpredictable decision to refuse treatment unwisely without the benefit of a physician's guidance. *Plenger*, 11 Cal. App. 4th at 362 n.6 (internal quotation marks omitted). But a physician uses medical expertise to properly assess medical risks; thus, "the prescribing doctor . . . in reality stands in the shoes of the ordinary consumer." *Id.* (internal quotation marks omitted). It is the physician's conduct—not the patient's—that indicates the foreseeable effect of the manufacturer's warning under the learned intermediary doctrine. Where a plaintiff "focuses on whether the warning was sufficient to apprise *him* of the risks of" a medical product, such that the plaintiff could have made his or her own safer medical decisions, the "Plaintiff confuses the issue." *Brown*, 2019 WL 2577296, at *9.

Both *Motus II* and *Wendell* state 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*." *Wendell*, 858 F.3d at 1238 (internal quotation marks omitted) (emphasis added)); *Motus II*, 358 F.3d at 661 (emphasis added). Seeking to avoid the natural effect of these statements, Plaintiffs argue that the relevant "conduct of the prescribing physician" could be something other than the "prescribing physician's" act of "prescribing"—namely, the physician's act of relaying risks to the patient, which (Plaintiffs contend) would then lead the patient to refuse consent to the prescribed procedure. But, as noted above, *Motus II* affirmed an express rejection of that very argument. Moreover, both *Motus II* and *Wendell*, along with *Latiolais II*, focus exclusively on evidence that a physician would have changed his or her decision to prescribe the medical product at issue.

Ultimately, Plaintiffs fail to distinguish the deluge of Ninth Circuit case law interpreting California's learned intermediary doctrine law to focus proximate causation exclusively on a physician's decision to prescribe, not on a patient's conduct in response to that decision.

C. Plaintiffs identify no other legal authority for their proposed alternate causation prong.

Plaintiffs offer no support for their incorrect assertion that "under California law . . . plaintiffs can also establish that a lack of warning was a cause of their injuries by demonstrating that, had their doctors been adequately warned by Somatics, the doctors would have relayed the stronger warnings to plaintiffs and plaintiffs relying upon the stronger warnings would not have consented to the procedure." OB 46 (emphasis omitted). In support, Plaintiffs cite only four non-binding district court decisions, and none comes close to establishing that Plaintiffs can show proximate causation without evidence that their physicians would make prescription changes.

In *Georges v. Novartis Pharms. Corp.*, the district court concluded that the plaintiff raised a triable issue as to proximate causation, noting evidence that the plaintiff's physician would have changed his decision to prescribe if given adequate warning:

> [Plaintiff's] treating physician, Dr. Waisman, testified that he changed his treatment practices once he was aware of the risk . . . . [T]he facts here differ from the facts in *Motus,* where the plaintiff's doctor testified that he did not read a drug's package insert warning of side effects before prescribing it. It was unlikely that the doctor in *Motus* would have *made*

> *prescription changes* based on a warning label he did not read, but Dr. Waisman has made no such statement here.

988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013) (citations omitted) (emphasis added). *Georges* is distinguishable from this case, where Plaintiffs have offered no evidence that Dr. Fidaleo and Dr. Frankel would "made prescription changes" with a heightened warning.

Second, in *Stanley v. Novartis Pharms. Corp.*, the district court found that a plaintiff had adduced adequate evidence of proximate causation based on evidence that the physicians would have changed how they prescribed the medication itself, including by prescribing increased monitoring alongside the medication. 11 F. Supp. 3d 987, 1003 (C.D. Cal. 2014). *Stanley* pointed specifically to a physician's testimony "that he would now prescribe the drug in a more conservative manner, which would include dental monitoring." *Id.* *Stanley* also recognized that there was evidence that the physicians would have discussed the increased risks with their patients, but *Stanley* did not hold that such evidence alone could satisfy the causation burden. Here, unlike in *Stanley*, Plaintiffs offer no evidence that Dr. Fidaleo or Dr. Frankel would have prescribed any increased monitoring alongside their ECT treatment or otherwise changed their prescription decisions.

Third, Plaintiffs point to *Hill v. Novartis Pharms. Corp.*, 2012 WL 6004161 (E.D. Cal. Nov. 30, 2012), an earlier decision in the same case as *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943 (E.D. Cal. 2013, in which the court confused the learned intermediary doctrine with the sophisticated intermediary doctrine. The *Hill* analysis of the learned intermediary doctrine predates *Wendell* and has been squarely rejected by other courts, as discussed above. In the earlier *Hill* decision, the plaintiff survived summary judgment based in part on evidence that, after getting an adequate warning, the plaintiff's physician changed his instructions accompanying prescriptions to "instruct[] patients to inform their health care provider of upcoming dental exams and to inform their dentists they are receiving zoledronic acid." 2012 WL 6004161, at *4. Here, in contrast, Plaintiffs offer no evidence that Dr. Fidaleo or Dr. Frankel, if given adequate warnings, would have changed the instructions accompanying their prescriptions.

Fourth, Plaintiffs point to two sentences in an earlier decision by the district court in this case, which Plaintiffs claims supports their alternate theory of causation. *See* OB 51. But as the district court made clear in the decision on appeal—which squarely considered Plaintiffs'

alternate causation theory at length, and rejected it—the district court *did not* find Plaintiffs' theory consistent with California's learned intermediary doctrine. *See* 1-ER-10.

In a last-ditch effort, Plaintiffs cite a handful of cases applying the learned intermediary doctrine under other states' (not California's) laws, including the Sixth Circuit's decision in *Payne v. Novartis Pharms. Corp.*, 767 F.3d 526 (6th Cir. 2014). *Payne* highlights the problem with Plaintiffs' out-of-state approach: it applied Tennessee law and took great pains to limit its reasoning to that law, explaining:

> Causation issues in failure-to-warn cases present particularly knotty problems. . . . Not only are these cases enormously fact-specific and fact-intensive, they are *state*-specific: the same set of facts that could get a plaintiff to the jury in one jurisdiction could very well result in summary judgment for the drug manufacturer in another. Woe to the party in a failure-to-warn case who thinks that cases from other jurisdictions will guarantee victory in her own.

Id. at 528 (emphasis in original).

Ultimately, under California law, the operative question is whether Plaintiffs' doctors would still have prescribed ECT to Plaintiffs if they had gotten the kind of warnings that Plaintiffs say they should have gotten. A patient may or may not follow or fill a prescription for any number of reasons. But that is not the question under California's

learned intermediary doctrine. The district court correctly concluded that Plaintiffs failed to establish proximate causation because they offered no evidence that Dr. Fidaleo and Dr. Frankel would have chosen not to treat their patients with ECT if differently warned.

IV. Plaintiffs' autonomy argument is a red herring.

Plaintiffs conclude their brief with a melodramatic suggestion, again relying on stories of 1930s Italy: if this Court confirms that California law requires plaintiffs to produce evidence that an adequate warning would have altered their physicians' prescribing decisions, then patients everywhere will experience an erosion of their right to refuse consent to prescribed treatment. *See* OB 59-63.

This argument is nothing more than an attempt at distraction. If a physician administers medical treatment without a patient's consent, the patient may well have a claim against the physician. But that has nothing to do with the warning obligations of the *manufacturer*, whose duty to warn extends only to the physician.

CONCLUSION

California law requires a plaintiff bringing a failure to warn claim against a medical device manufacturer to prove *not only* that the

manufacturer provided an inadequate warning to her physician *but also* that the physician would not have prescribed use of the medical device if provided an adequate warning. The district court properly recognized that Plaintiffs failed to satisfy that burden here. This Court should affirm the district court's judgment.

Dated: October 27, 2021

Respectfully submitted,

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STATEMENT OF RELATED CASES

Somatics, LLC is not aware of any other related cases pending in this Court.

Dated: October 27, 2021

Respectfully submitted,

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Dated: October 27, 2021

/s/ *Jonathan M. Freiman*
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I hereby certify that on October 27, 2021, a copy of the foregoing brief was filed electronically and served by e-mail upon all parties.

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