No. S273887

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

MICHELLE HIMES,

Plaintiff–Appellant,

v.

SOMATICS, LLC,

Defendant–Respondent.

On Request from the U.S. Court of Appeals for the Ninth Circuit
for Answer to Certified Questions of California Law

RESPONDENT'S BRIEF ON THE MERITS

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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

The undersigned certifies that the following persons or entities have either (1) an ownership interest of 10 percent or more in the party if it is an entity; or (2) a financial or other interest in the outcome of the proceeding that the justices should consider in determining whether to disqualify themselves, as defined in California Rules of Court, Rule 8.208:

Somatics, LLC is 50% owned by Richard Abrams, M.D., and 50% owned by Conrad Swartz, M.D.

Dated: July 19, 2022

Respectfully submitted,

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ISSUE CERTIFIED FOR REVIEW

This Court has granted the Ninth Circuit's request to decide the following question:

> 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).

INTRODUCTION

Plaintiff-Appellant Michelle Himes ("Plaintiff") is a crusader against electroconvulsive therapy ("ECT"), a long-established medical procedure used at the nation's top hospitals to treat serious mental health issues. In 2011, Plaintiff was suffering from [redacted]. After all other treatments failed, psychiatry specialist Dr. Raymond Fidaleo prescribed ECT as a last resort to save Plaintiff's life. Plaintiff later brought failure-to-warn claims against Defendant-Appellee Somatics LLC ("Somatics"), the manufacturer of the medical device Dr. Fidaleo

used to administer ECT, claiming that the treatment left her with brain injuries. Although medical professionals have testified that Plaintiff's claimed injuries are *not* possible side effects of ECT, Plaintiff has continued to decry the safety and effectiveness of psychiatric treatment.

Plaintiff isn't simply anti-psychiatry; she's anti-science. Throughout this case, she has sought the effective eradication of California's "learned intermediary doctrine"—a decades-old pillar of California law that recognizes the value of scientific expertise and distinguishes between trained medical professionals and laypeople. The doctrine, recognized in every state in the country, acknowledges that healthcare patients rely on the judgment of learned intermediaries—physicians—in deciding whether to use prescription medical products. The doctrine rests on the principle that *only physicians* have the specialized training necessary to interpret highly-technical manufacturer warnings and weigh the risks and benefits of prescription treatments. Under the doctrine, a plaintiff bringing a failure-to-warn claim against a medical manufacturer must prove three elements: (1) the manufacturer gave an inadequate warning *to her physician*; (2) she sustained an injury; and (3) the inadequate warning *caused the physician to prescribe* the product that injured her.

Plaintiff wants to get rid of the learned intermediary doctrine because she can't satisfy its third requirement: causation. During discovery, her claims

crumbled when Dr. Fidaleo testified unequivocally that, even if he'd received a stronger warning of Plaintiff's claimed injuries, he *still would have prescribed* ECT for Plaintiff's otherwise-untreatable, life-threatening health condition. He also testified he *didn't even read* Somatics's purportedly-inadequate disclosures. Based on this uncontradicted testimony, the district court granted Somatics's motion for summary judgment.

On appeal, Plaintiff raises two arguments. The first—which this Court never agreed to consider, and which the Ninth Circuit has already rejected—is that she needn't prove causation under the doctrine as long as she proves warning inadequacy. Plaintiff spends most of her brief trying to relitigate that issue, ignoring precedent confirming that warning inadequacy and causation are *separate* elements of her burden of proof.

The second argument—which is the actual basis for the certified question to this Court, and which Plaintiff only gets around to addressing near the end of her argument—is that the Court should delete the doctrine's existing causation element and replace it with a new element, under which Plaintiff's claims survive summary judgment as long as she makes self-serving declarations that she would've refused physician-prescribed treatment if her physician had relayed stronger warnings to her. Her theory challenges the very notion of physicians as *learned intermediaries*, who use their learning and training and clinical experience to help patients navigate the complex scientific

weighing of the risks outlined in technical manufacturer warnings against the benefits of treatment. Plaintiff's theory recasts physicians not as learned intermediaries, but as *mere messengers* who pass on warnings to patients, leaving patients to independently perform that scientific weighing.

This Court should reject Plaintiff's physicians-as-messengers theory. It demeans medical professionals and ignores the reality of physician-patient interactions. Plaintiff suggests that a physician-focused causation requirement assumes a physician will administer treatment without consent. To the contrary, it assumes a physician will obtain a patient's consent by using medical training and clinical experience to help the patient understand where treatment benefits outweigh risks. In fact, it's Plaintiff's alternate approach that threatens patients' rights by expanding manufacturer liability to a point that will impede patient access to life-sustaining treatment.

Accordingly, this Court should uphold the learned intermediary doctrine's requirement that a plaintiff challenging the adequacy of a medical manufacturer's warnings must offer evidence that a stronger warning would have changed her physician's prescription decision.

STATEMENT OF THE CASE

I. Factual Summary

A. Plaintiff's physician prescribed ECT for her life-threatening, otherwise-untreatable health conditions.

Plaintiff suffers from severe mental health issues including [redacted] 1-SER-3-4.[1] (Plaintiff's brief states only that she suffered from "depression," OB16, which doesn't remotely capture the extent of her illness.) Dr. Fidaleo has testified that Plaintiff was [redacted] 1-SER-3. [redacted]

[redacted]

1-SER-3. [redacted]

[redacted]

[1] "ER" refers to the excerpts of record. "SER" refers to the supplemental excerpts of record. Unless otherwise noted, this brief adds emphasis and removes internal citations, quotations, footnotes, and alterations.

1-SER-4.

Plaintiff's physicians tried numerous treatments but none [redacted] 1-SER-3-4; *see* 2-ER-159 (alternatives to ECT, including psychotherapy and medication, "have not been effective"); 5-ER-949 (no improvement despite "at least nine different antipsychotics and antidepressants" and repeated hospitalizations). In a last-resort effort to save Plaintiff's life, Dr. Fidaleo prescribed ECT using the Thymatron IV ECT Machine ("Thymatron"), manufactured by Somatics. 1-SER-5; 3-ER-380-81. Following treatment, Dr. Fidaleo reported that Plaintiff was "doing well" and had regained custody of her child. 3-ER-332. In this lawsuit, however, Plaintiff purports to have suffered brain injuries, including an inability to form new memories. She claims the disclosures accompanying the Thymatron didn't adequately warn of the risk of these injuries.[2]

B. Dr. Fidaleo testified that a stronger warning wouldn't change his prescription decision.

Somatics provided many warnings about risks associated with the Thymatron in (1) an operator's manual and (2) a patient information pamphlet. 5-ER-1079. But Dr. Fidaleo admitted he *never even read* either document, or

[2] Plaintiff's brief also incorrectly states that Somatics "misbrand[ed]" the Thymatron as FDA-approved. OB9-10. Plaintiff tried to bring misbranding claims in the district court but offered no evidence to support them; facing a summary judgment motion, she conceded to the claims' dismissal. *See* 2-ER-165. Her effort to resurrect those false claims here is inappropriate.

communicated with Somatics, before prescribing ECT. 5-ER-1004-1005, 1016-1017. He testified that he gave "attention" to manufacturers' safety information update letters (sometimes called "dear doctor" letters), 3-ER-336, but he didn't testify to ever receiving, let alone reading and relying on, a "dear doctor" letter from Somatics.

Dr. Fidaleo also testified unequivocally that, because Plaintiff faced an imminent risk of death [redacted] and was unable to function in her daily life, he *still would have prescribed ECT* even if he'd been aware of a warning of Plaintiff's claimed injuries. *See* 5-ER-1013 ("It wouldn't stop me."). Dr. Fidaleo explained that, even if he received a warning that ECT could hinder a patient's ability to form new memories, he would still need to *personally corroborate* this purported risk through his own clinical observations, and he had never seen such a side effect occur. *See* 5-ER-1014-1015 ("I would have to see it also myself. . . . [Y]ou go by what you see clinically. . . . I would be seeing that myself and I'm not seeing that with my patients.").

C. The medical community endorses the safety and effectiveness of ECT.

ECT is a therapy that involves the brief administration of a controlled dose of electricity to the brain. One of its uses is a last-resort treatment for patients with severe mental health issues like Plaintiff's. 5-ER-1104.

Plaintiff spends most of her opening brief attempting to distract the Court from the certified causation question by arguing that ECT is a dangerous, ineffective treatment administered without adequate warnings. To clarify: while Somatics has consistently disputed Plaintiff's accusations of warning inadequacy, this appeal isn't about whether Plaintiff has offered evidence of warning inadequacy. It's about whether, *even if* Plaintiff can prove warning inadequacy, her claims *still fail* because she can't prove that the inadequacy *caused her injuries*. Neither party has ever sought summary judgment on warning inadequacy, and factual disputes preclude resolution of that issue in Plaintiff's favor: medical professionals, including Plaintiff's own physician, testified that Plaintiff's purported injuries are *not* possible side effects of ECT, *see* 3-ER-337; 3-ER-341, and no warning is inadequate simply because it doesn't mention *nonexistent* risks, *see Carlin v. Superior Court*, 13 Cal. 4th 1104, 1115-16 (1996).

Moreover, Plaintiff's attacks on ECT are as baseless as they are irrelevant to the certified causation question. The medical community widely endorses ECT: For example, the Psychiatry Department at Weill Cornell Medicine confirms ECT is "one of the safest psychiatric treatments," "highly effective in severe depression," and "now delivered with highly advanced instruments and under brief anesthesia that minimizes any discomfort." *Information for Patients and Families*, WEIL CORNELL MEDICINE (last visited

Sept. 12, 2022), https://psychiatry.weill.cornell.edu/information-patients-and-families.

The National Institute of Mental Health, part of the U.S. Department of Health and Human Services, calls ECT "the best studied brain stimulation therapy" with "the longest history of use," noting that it has "major advantages . . . over medication," including that it "begins to work quicker." *Brain Stimulation Therapies,* NATIONAL INSTITUTE OF MENTAL HEALTH (last visited Sept. 12, 2022), https://www.nimh.nih.gov/health/topics/brain-stimulation-therapies/brain-stimulation-therapies. ECT "is usually considered . . . in cases where rapid response is needed," like "suicide risk." *Id.*

The Mayo Clinic similarly describes how ECT "can quickly reverse symptoms of certain mental health conditions" and "often works when other treatments are unsuccessful." *Electroconvulsive Therapy (ECT)*, MAYO CLINIC (last visited Sept. 12, 2022), https://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/about/pac-20393894. The Mayo Clinic notes that *modern* ECT—involving "anesthesia" and "a small amount of electric current"—sometimes unfairly bears a "stigma . . . based on *early treatments* in which high doses of electricity were administered without anesthesia." *Id.* The treatment "is much safer today" and "achieve[s] the most benefit with the fewest possible risks." *Id.*

The Cleveland Clinic agrees that ECT is "very safe" and "extremely effective." *Electroconvulsive Therapy (ECT)*, CLEVELAND CLINIC (last visited Sept. 12, 2022), https://my.clevelandclinic.org/health/treatments/9302-ect-electroconvulsive-therapy. ECT "works quickly," which is "especially helpful when a person has a very severe mental health condition that puts their safety in jeopardy." *Id.* Moreover, "extensive research shows it's an effective, safe technique"; indeed, "[e]xperts agree that ECT is one of the most effective treatments for mood disorders like depression" and is "especially effective at helping people with depression that resist other forms of treatment like medication or therapy." *Id.* Negative pop culture portrayals are inaccurate:

> ECT often has a negative connotation because of how it's been shown in movies, television shows and other media. These portrayals of ECT are usually inaccurate about how this procedure happens, whether or not it's painful or frightening and whether or not it's effective. These portrayals are not true-to-life, and they don't show how healthcare providers do this procedure safely and humanely.

Id.

In criticizing medical professionals' use of ECT, Plaintiff makes no meaningful effort to engage with scientific literature. Instead, she cites to the 1975 film *One Flew Over the Cuckoo's Nest*, OB8, invokes antiquated stereotypes of mental health treatment, offensively comparing ECT to the electric chair, OB8, and—when apparently unable to characterize the *modern* treatment with adequate melodrama—resorts to descriptions of animal testing

conducted 90 years ago in a foreign country, OB6-7.[3] The critical piece missing from Plaintiff's attack on ECT is, of course, science. But that is Plaintiff's whole point in this appeal—that you don't need a medically learned intermediary to determine whether a sophisticated scientific treatment is medically appropriate. Plaintiff asks this Court to hold that a layperson is qualified to make that highly technical determination, based not on years of specialized training and experience but rather on Hollywood movies and stories of dead animals from the 1930s.

Plaintiff notes that the FDA has certain labeling requirements for ECT manufacturers. OB11. She omits the fact that these requirements weren't established until more than seven years after her ECT treatment. 21 C.F.R. § 882.5940 (published in the Fed. Reg. on Dec. 26, 2018). She also omits that the now-required warning label states that "the incidence of permanent cognitive memory loss was *not* supported by the clinical literature." *Id*. The label further states that, while "ECT treatment may be associated with . . . memory loss, . . . [b]ased on the majority of clinical evidence, these side effects tend to go away within a few days to a few months after the last treatment with ECT." *Id*.

[3] Plaintiff also misleadingly states that a book by one of Somatics's founders "quoted" someone claiming ECT caused permanent memory loss. OB13. In fact, the book *criticized as inaccurate* an editorial making that claim, pointing out that the editorial didn't cite to supporting literature and explaining that such claims were "unproved." 4-ER-664.

Nothing in the label warns of the type of brain injury—including an inability to form new memories—that Plaintiff claims to have experienced.

Ultimately, however, this appeal doesn't require the Court to assess the medical evidence regarding the effectiveness and risks of ECT, or to determine whether ECT is capable of producing Plaintiff's claimed injuries such that a warning omitting such injuries could be inadequate. At issue is only whether—*even if* Plaintiff has met her burden to offer evidence of warning inadequacy—her claims *still* can't go to a jury because she hasn't met her burden to offer evidence that the inadequacy *caused* her injuries.

II. Procedural History

Plaintiff is the last of a group of six plaintiffs who sued Somatics in federal court. The others have either voluntarily dismissed their claims or lost at summary judgment (with judgment affirmed by the Ninth Circuit). *See* 1-ER-3-10; 6-ER-1235; 6-ER-1241; *Himes v. Somatics, LLC*, 2022 WL 989469, at *1-2 (9th Cir. Apr. 1, 2022).

In her operative fifth amended pleading, Plaintiff brought negligence and strict liability failure-to-warn claims, as well as adulteration/misbranding claims. 5-ER-1125-1131. Following discovery, Somatics moved for summary judgment on three grounds: (1) failure to create a triable issue on causation for the failure-to-warn claims; (2) failure to offer evidence to support the adulteration/misbranding claims; and (3) untimeliness. 5-ER-953-975.

Plaintiff subsequently conceded to the dismissal of the adulteration/misbranding claims. 2-ER-165.

The district court granted Somatics's motion for summary judgment, concluding that Plaintiff failed to offer causation evidence. 1-ER-3-10. The court recognized that California's learned intermediary doctrine requires evidence that a stronger warning would have altered the physician's prescription decision. 1-ER-9-10. The court declined to address timeliness. 1-ER-7.[4]

Appealing to the Ninth Circuit, Plaintiff argued that if a plaintiff establishes that a warning was inadequate, the learned intermediary doctrine disappears, removing the plaintiff's burden to establish causation under that doctrine. The Ninth Circuit rejected that argument, recognizing that the doctrine requires proof of *both* warning inadequacy and causation. *See Himes*, 2022 WL 989469, at *1 ("[E]ven when warnings are *assumed to be deficient*, in the context of prescription products, the analysis always relies on *the impact*

[4] Somatics moved for summary judgment on causation and timeliness, not warning adequacy. Accordingly, the district court decision "*assumes for purposes of this Order* that Defendant did not provide any warnings to . . . Dr. Fidaleo concerning the risk of brain injury or permanent memory loss." 1-ER-9. Plaintiff inappropriately deletes the first part of the sentence, pretending that the court "*concluded* that 'Defendant did not provide any warnings to . . . Dr. Fidaleo concerning the risk of brain injury or permanent memory loss.'" OB24 (quoting 1-ER-9). Plaintiff's misrepresentation of the decision reflects a disregard for candor to the Court.

of a hypothetical stronger warning on the physician."). The court recognized Plaintiff's purported interpretation of the doctrine as a crude attempt to bypass it altogether: "[B]ecause the adequacy of warnings is *always* challenged in failure-to-warn claims, if the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would *never* operate in California." *Id.*

Plaintiff also argued that, even where it is undisputed that a stronger warning wouldn't alter a physician's prescription decision, a plaintiff may establish causation solely through her own after-the-fact testimony that she would've refused the prescribed treatment if the physician had relayed the warning to her. The Ninth Circuit agreed with Somatics that the effect of a stronger warning couldn't be determined by a plaintiff's subjective post-hoc declaration. But the Ninth Circuit concluded that this Court had never squarely decided whether a plaintiff could establish causation through evidence that, under an objective standard, a prudent person in the plaintiff's position would have refused the prescribed treatment if the physician relayed a stronger warning—even if the physician would still have prescribed the treatment. Accordingly, the Ninth Circuit certified that question to this Court.

SUMMARY OF ARGUMENT

This Court should hold that, under the learned intermediary doctrine, a plaintiff bringing a failure-to-warn claim against a medical manufacturer must

prove that a stronger warning would have altered her physician's prescription decision.

All failure-to-warn claims, whether brought under a negligence or strict liability theory, require a plaintiff to prove causation. The plaintiff must establish that a manufacturer breached its duty to provide an adequate warning, that the plaintiff sustained an injury, *and* that "the absence of a warning *caused* the plaintiff's injury." *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 181 (2016); *see Merrill v. Navegar*, Inc., 26 Cal. 4th 465, 477 (2001) ("[P]laintiffs must show that [defendants] owed them a legal duty, that [defendants] breached the duty, and that the breach was *a proximate or legal cause of* their injuries.").

Where failure-to-warn claims involve "drugs or medical devices . . . supplied in the context of the doctor-patient relationship," California's "learned intermediary doctrine" controls how plaintiffs must satisfy the elements of their claims. *Webb*, 63 Cal. 4th. at 187 n.10. The doctrine recognizes that a patient relies on the judgment of an intermediary—a physician—in deciding whether to use a prescription-only product, as the physician has the scientific expertise necessary to determine whether the treatment benefits outweigh risks. *Carlin*, 13 Cal. 4th at 1116. Specialized training and experience enable the physician to help the patient understand when risks are too small to alter the treatment decision, even where the patient is fearful of the risks and

otherwise inclined to "object" to treatment. *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 n.6 (1992). Accordingly, courts applying California law have repeatedly held that plaintiffs cannot establish causation without evidence that, had their physicians received stronger warnings, the "physicians would have altered their *decision to prescribe*." *Guillen v. Eli Lilly & Co.*, 394 F. App'x 814, 816 (2d Cir. 2010) (applying California law).

Plaintiff spends most of her brief avoiding the question this Court agreed to answer. Instead, she argues that if she establishes warning inadequacy, she doesn't have to establish causation under the learned intermediary doctrine. This Court need not address that issue but, if it does, it should reject Plaintiff's argument for the same reasons as the Ninth Circuit: it makes no sense, ignores longstanding precedent, and would gut the doctrine. *See infra* Section I.

Plaintiff also briefly argues that she can prove causation through her physicians-as-messengers theory. Courts applying California law have repeatedly rejected this theory because it ignores the learned intermediary doctrine's central premise: that a scientifically-trained specialist, not a layperson, is best positioned to interpret the implications of technical manufacturer warnings. The doctrine recognizes that, hearing of any serious risk, a patient may initially blanch at receiving treatment. But a learned intermediary then steps in to help the patient understand where a treatment's benefits outweigh the risk. Plaintiff's theory baselessly presumes that Dr.

Fidaleo would *not* have performed that intermediary role, and would instead have acted only as a messenger, relaying the warning to her for her unlearned unilateral assessment as a layperson. Her arguments demean the value of medical expertise, ignore the realities of physician-patient interactions, and seek a dangerous expansion of manufacturer liability. *See infra* Section II.

Plaintiff also cannot establish causation through her physicians-as-messengers theory because her physician admitted that he *didn't even read* Somatics's purportedly-inadequate disclosures. Had Somatics included stronger warnings in those disclosures, Dr. Fidaleo wouldn't even have been aware of them such that he could relay them to Plaintiff. Although the certified question doesn't address this issue, Somatics respectfully requests that the Court exercise its discretion to consider it and confirm that, as a matter of California law, where a physician fails to read a manufacturer's disclosures, the absence of adequate warnings in those disclosures cannot be the cause of the plaintiff's injuries. *See infra* Section III.

Finally, Plaintiff argues that, if this Court endorses her physicians-as-messengers theory, then the Court should also review another question it didn't agree to answer: whether the Ninth Circuit erred in determining that a plaintiff cannot establish causation through *subjective* hindsight-influenced testimony. This Court needn't review that question but, if it does, it should

apply its precedent rejecting her proposed subjective standard. *See infra* Section IV.

ARGUMENT

I. Plaintiff must prove causation under the learned intermediary doctrine.

Plaintiff's claims plainly trigger California's "learned intermediary doctrine," which "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship." *Webb*, 63 Cal. 4th at 187 n.10. At the heart of the learned intermediary doctrine is an acknowledgement of the value of scientific training. The doctrine recognizes that patients properly rely on physicians' judgments in deciding whether to use prescription-only medical products. That's why a manufacturer's "duty to warn runs *to the physician,* not to the patient." *Carlin.*, 13 Cal. 4th at 1116. A "patient's expectations regarding the effects of [a prescribed product] are those related to him by his physician," *id.*, as the physician "in reality stands in the shoes of the ordinary consumer," *Plenger*, 11 Cal. App. 4th at 362 n.6.

Throughout, Plaintiff improperly describes this as the "learned intermediary *defense*," rather than the "learned intermediary doctrine." But it's not a defense: it's a doctrine that describes *what a plaintiff must prove* to succeed in failure-to-warn claims involving a prescription product. Plaintiff also describes the doctrine as "outdated," citing a West Virginia Supreme Court

decision. OB28. The case Plaintiff cites is no longer good law even in West Virginia. *See* W.Va. Code § 55-7-30 (2016) (overruling decision and adopting learned intermediary doctrine). Today, the learned intermediary doctrine applies in all fifty states, as well as D.C. and Puerto Rico.[5]

Plaintiff's primary argument is that the entire doctrine, and particularly its causation requirement, shouldn't apply to her claim if she offers evidence of warning inadequacy. That argument contravenes this Court's precedent requiring causation evidence, *see infra* Section I(A), and Plaintiff fails to identify any contrary authority, *see infra* Section I(B).

A. California precedent confirms Plaintiff's causation burden.

The Ninth Circuit already rejected Plaintiff's "argument that the learned intermediary doctrine does not apply whenever the manufacturer has not provided sufficient warnings to a physician." *Himes*, 2022 WL 989469, at *1. The reason was simple:

> Under California law, when drugs or medical devices are supplied in the context of the physician-patient relationship, the learned intermediary doctrine applies. . . . [E]ven when warnings are

[5] *See Guevara v. Dorsey Labs.*, 845 F.2d 364, 366 (1st Cir. 1988) (applying doctrine under Puerto Rico law); *Tyree v. Bos. Sci. Corp.*, 56 F. Supp. 3d 826, 829 n.3 (S.D.W. Va. 2014) (listing cases applying doctrine in D.C. and all states except West Virginia, New Mexico, and Vermont); W.Va. Code § 55-7-30 (2016) (adopting doctrine in West Virginia); *Silva v. Smithkline Beecham Corp.*, 2013 WL 4516160, at *3-4 (N.M. Ct. App. Feb. 7, 2013) (applying doctrine in New Mexico); *Leavitt v. Ethicon, Inc.*, 524 F. Supp. 3d 360, 368-69 (D. Vt. 2021) (predicting adoption of doctrine in Vermont).

> assumed to be deficient, in the context of prescription products, the analysis always relies on the impact of a hypothetical stronger warning on the physician. After all, because the adequacy of warnings is always challenged in failure-to-warn claims, if the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California.

Id. The Ninth Circuit has consistently held that, under the doctrine, a plaintiff "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 v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017); *see Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004) ("*Motus II*") ("the adequacy of [the manufacturer's] warnings is *irrelevant*" where "stronger warnings would not have altered the conduct of the prescribing physician"); *Latiolais v. Merck & Co.*, 302 F. App'x 756, 757 (9th Cir. 2008) (plaintiff must prove "causation under California's 'learned intermediary' doctrine").[6] Other appellate courts applying California law

[6] *Accord, 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."); *Rodman v. Otsuka Am. Pharm., Inc.*, 564 F. Supp. 3d 879, 891-93 (N.D. Cal. 2020), *aff'd*, 2021 WL 5850914 (9th Cir. Dec. 9, 2021); *Renteria v. Ethicon, Inc.*, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020); *Shahbaz v. Johnson & Johnson*, 2020 WL 5894590, at *12-14 (C.D. Cal. July 31, 2020); *Fischer v. Bos. Sci. Corp.*, 2020 WL 2300138, at *2 (C.D. Cal. Mar. 25, 2020); *Galinis v. Bayer Corp.*, 2019 WL 2716480, at *9 (N.D. Cal. June 28, 2019); *Andren v. Alere, Inc.*,

agree. *See, e.g., Gaghan v. Hoffman-La Roche Inc.*, 2014 WL 3798338, at *13-14 (N.J. Super. Ct. App. Div. Aug. 4, 2014); *Guillen*, 394 F. App'x at 816; *Neal v. Eli Lilly & Co.*, 394 F. App'x 823, 824-25 (2d Cir. 2010); *Misouria v. Eli Lilly & Co.*, 394 F. App'x 825, 826-27 (2d Cir. 2010).

That consistent analysis aligns with the precedent of this Court, which has long held that a causation requirement applies in *all* failure-to-warn claims, not just failure-to-warn claims involving medical manufacturers. *See Ramos v. Brenntag Specialties, Inc.*, 63 Cal. 4th 500, 509 (2016) (plaintiffs must establish "that defendants breached a duty to provide adequate warnings . . . *and* that such failure to warn caused plaintiffs' injury").[7] Indeed, Plaintiff's argument runs head-on into a core principle of *any* negligence or strict liability claim, not just one sounding in warning inadequacy: "[A]n essential element of a plaintiff's cause of action, whether based on negligence or strict liability, is the existence of a causal connection between defendant's act and the injury which plaintiff suffered." *Smith v. Lockheed Propulsion Co.*, 247 Cal. App. 2d 774, 780 (1967). While the learned intermediary doctrine clarifies how the

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2018 WL 1920179, at *4 (S.D. Cal. Apr. 24, 2018); *Tucker v. Wright Med. Tech., Inc.*, 2013 WL 1149717, at *15-16 (N.D. Cal. Mar. 19, 2013).

[7] *Accord Huitt v. S. California Gas Co.*, 188 Cal. App. 4th 1586, 1604 (2010); *Torres v. Xomox Corp.*, 49 Cal. App. 4th 1, 16 (1996).

causal connection requirement works for failure-to-warn claims against the manufacturer of a prescription product, the doctrine simply applies the centuries-old principle that the defendant's breach of its duty of care must produce the plaintiff's injury.[8] That's how widely Plaintiff asks this Court to deviate from established precedent: She asks the Court to uniquely excuse her from a requirement facing every other tort plaintiff. No California authority entitles her to that radical exemption.

Indeed, this Court has *already* confirmed that, specifically in the context of failure-to-warn claims against medical manufacturers, plaintiffs must prove not only inadequate warning but also causation. *Carlin v. Superior Court* held that, even where a manufacturer inadequately warns of a risk, the manufacturer is not liable if the medical community already knows of the risk. 13 Cal. 4th at 1116. After all, if a physician already knows of the risk and nevertheless prescribes, then the warning's inadequacy didn't cause the physician to prescribe. *See Guevara*, 845 F.2d at 367 ("[I]f the doctor knew of the danger already, the failure to warn could not have been the cause of the injury."). Similarly, *Ramirez v. Plough, Inc.* held that failure-to-warn claims against medical manufacturers can't survive summary judgment without a

[8] *See Chidester v. Consol. People's Ditch Co.*, 53 Cal. 56, 57 (1878) ("The law is well settled that in actions for negligence the damages to be recovered are only those of which the negligent act is the proximate cause.").

"causal connection between the representations or omissions that accompanied the product and plaintiff's injury." 6 Cal. 4th 539, 555-56 (1993). *Ramirez* found "no conceivable causal connection" where a drug was administered by someone who didn't read the label. *Id*.

Plaintiff makes no effort to distinguish California cases confirming that, under the learned intermediary doctrine, "claims about the failure to warn" have a "causation element" and thus a plaintiff's claim fails where "any failure by [the manufacturer] to inform [the physician] could not have caused [the plaintiff] any harm." *Gall v. Smith & Nephew, Inc.*, 71 Cal. App. 5th 117, 122, 124-125 (2021) (finding no triable issue on causation where the physician testified that a stronger warning wouldn't have "changed his thinking or decision making"); *see Plenger*, 11 Cal. App. 4th at 362 (acknowledging situations where a manufacturer fails to adequately warn of a risk and yet "the failure to warn the physician of that risk cannot be *the legal cause* of" the plaintiff's injuries; finding no causation where a physician was already aware of the undisclosed risk and prescribed anyway); *see also Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 96, 98-100 (2008) (confirming a plaintiff must prove "that [the manufacturer's] product information *was a causal factor* in [the physician's] decision to treat [the plaintiff] with [the product]"; stating that a physician's declaration that he didn't rely on a manufacturer's purported-

inadequate product information, if uncontradicted, would prevent the plaintiff from "establish[ing] causation").[9]

Plaintiff asserts that the learned intermediary doctrine can't apply where warnings are inadequate because then intermediaries are "no longer 'learned.'" OB31. But the word "learned" in "learned intermediary doctrine" doesn't refer to the physician's knowledge of a particular manufacturer-provided warning. It refers to the physician's medical training. *See Plenger*, 11 Cal. App. 4th at 362 n.6.

Tort liability in California, as in all states, requires that a plaintiff prove not only that a defendant committed a wrongful act but also that this wrongful act *caused* the plaintiff's injury. Where a plaintiff claims that a medical manufacturer breached its duty to adequately warn her physician, the plaintiff must prove a causal relationship between the inadequacy of the warning and her injury.

B. Plaintiff mischaracterizes California law in arguing that, as long as she has offered evidence of inadequate warnings, she needn't also offer evidence of causation.

Plaintiff's effort to avoid her causation burden relies substantially on *Love v. Wolf*, 226 Cal. App. 2d 378 (1964), along with three later decisions

[9] *Conte* found a triable issue on causation *only* because the physician contradicted his declaration by testifying that he "probably" did rely on the product information. *Id*. at 99.

quoting or agreeing with *Love*, OB29-30 (citing *Brown v. Superior Ct.*, 44 Cal. 3d 1049 (1988); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51 (1973); and *Carmichael v. Reitz*, 17 Cal. App. 3d 958 (1971)). Plaintiff quotes passages from these cases that articulate the unsurprising proposition that, if a manufacturer gives adequate warnings, it can't be held liable under the learned intermediary doctrine. But this proposition comports perfectly with California precedent establishing that summary judgment is appropriate where the plaintiff fails to show *either* inadequate warning or causation. None of these cases states that a plaintiff's failure to establish inadequate warning is the *only* way a manufacturer may be entitled to protection under the doctrine, or otherwise calls into question cases holding that a plaintiff must *also* show causation.

Love, in fact, expressly *confirms* the need for causation evidence even where warnings are inadequate. The plaintiff there claimed that the manufacturer had rendered its warnings inadequate by "overpromoting" a product to physicians, encouraging the physicians to "overprescri[be]" it in broader contexts than medically appropriate. 226 Cal. App. 2d at 399. *Love* recognized that at issue was *not only* whether such improper conduct of the manufacturer occurred *but also* whether this conduct was "an inducing, or proximate, cause of" the plaintiff's claimed injuries. *Id.* *Love* reasoned: "if such overprescription by the doctor *was not caused by* the over-promotion," then the

manufacturer "could not be held liable." *Id.* Notably, *Love* focused the causation inquiry on the effect on the physician's prescription decision.

Plaintiff also cites to *T.H. v. Novartis Pharmaceuticals Corp.*, but there this Court similarly confirmed that a plaintiff claiming that a warning label is deficient "still need[s] to prove that the . . . deficient label *proximately caused* the injury." 4 Cal. 5th 145, 186 (2017); *accord id.* at 156 (plaintiff must prove warning inadequacy "proximately caused physical injury"). Plaintiff points to *T.H.*'s statement that a negligent actor cannot avoid liability by pointing to the negligence of another actor who "should have picked up the slack and discharged the duty at issue," *id.*at 184,[10] arguing that therefore a manufacturer "cannot point to any negligence of the doctor to absolve itself of its own negligence," OB22. That argument misses the mark: Somatics has never argued that Dr. Fidaleo acted negligently at all, let alone that his negligence excused anyone else's. In the context of the learned intermediary doctrine, the "duty at issue" is exclusively a duty to warn physicians—not to ensure that the warning reaches patients. *Carlin*, 13 Cal. 4th at 1116. Requiring causation evidence doesn't 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 caused the injury.

[10] Plaintiff points to other decisions articulating that same principle. OB40-41 (citing *Stevens*, 9 Cal. 3d at 69; *Stewart v. Cox*, 55 Cal. 2d 857, 864 (1961)).

Unable to find support in this Court's precedents, Plaintiff turns to outlier district court decisions rejected by the Ninth Circuit. *Hill v. Novartis Pharms. Corp.* briefly summarized its understanding of the learned intermediary doctrine as a doctrine that "'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.'" 944 F. Supp. 2d 943, 953 (E.D. Cal. 2013) (quoting *Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23, 29 (2010)). But *Hill* failed to notice that *Stewart* didn't involve the learned intermediary doctrine. *Stewart* involved a different (if similarly-named) doctrine: the "sophisticated intermediary doctrine." This Court has cautioned that the "sophisticated intermediary doctrine" and the "learned intermediary doctrine" are *separate* doctrines under California law, and *only* the learned intermediary doctrine applies to prescription medical products involving the unique physician-patient relationship. *See Webb*, 63 Cal. 4th at 187 & n.10 (distinguishing between the two). *Hill* confused the doctrines, taking a description of one and applying it to the other.

Neither *Hill* nor *Stewart* remains good law. As discussed above, the Ninth Circuit has rejected *Hill*'s muddled analysis. *See Himes*, 2022 WL 989469, at *1. And this Court has rejected *Stewart*'s reasoning about the sophisticated intermediary doctrine, expressing "disapprov[al]" of the precise sentence quoted in *Hill*. *Webb*, 63 Cal. 4th at 188. This Court held that "*Stewart['s]* . . . assertion" that the sophisticated intermediary doctrine

"'applies only if a manufacturer provided adequate warnings to the intermediary'" simply "cannot be reconciled" with earlier precedent. *Id.* The Court explained that *Stewart* didn't account for situations in which "the manufacturer's failure to warn is not the legal *cause* of any harm," stressing that liability only occurs where "the absence of a warning *caused the plaintiff's injury*." *Id.* at 181-82.

Plaintiff also tries, and fails, to find support for her position outside California. She cites *Glover v. Bausch & Lomb, Inc.*, which rejected an argument that a manufacturer has no duty to report to the FDA because the learned intermediary doctrine only establishes a duty to warn physicians. 343 Conn. 513 (2022) (applying Connecticut law). *Glover* reasoned that the FDA, like physicians, could "occupy[] the best position to take or recommend precautions" to patients. *Id.* at 538. That reasoning has nothing to do with this appeal, where the question isn't whether a duty of care exists (it does: to adequately warn physicians), but whether an alleged failure to satisfy that duty *caused* an alleged injury. If anything, *Glover* stressed that plaintiffs had to show causation. *Id.* at 539 n.16 (factfinder must resolve "whether the manufacturer's failure to" report to the FDA "had a *causal relationship* to a plaintiff's injury"); *id.* at 555 (factfinder must resolve "whether the plaintiff's injury was foreseeable *and caused by* the defendants' conduct"); *see id.* at 539 (learned intermediary doctrine doesn't "provide a shield against liability for

foreseeable injuries *caused by* the withholding of information" (emphasis altered)). *Glover* found "persuasive" out-of-jurisdiction authority stating that "a plaintiff must demonstrate that the warning was inadequate *and* that the failure to adequately warn of the dangers was a *proximate cause* of his or her injuries." *Id*. at 543.

Plaintiff also cites old out-of-jurisdiction cases where the evidence was *unclear* on whether stronger warnings would have changed prescription decisions. *McCue v. Norwich Pharmacal Co*. rejected a defendant's speculation "that the physician might have disregarded" a stronger warning where the record suggested it was "far more likely" the warning would've changed the physician's prescription decision. 453 F.2d 1033, 1035 (1st Cir. 1972). *Hamilton v. Hardy* held that "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." 37 Colo. App. 375, 387 (1976), *overruled by State Bd. of Med. Examiners v. McCroskey*, 880 P.2d 1188 (Colo. 1994). Subsequent courts have cabined that reasoning. Cases like *Hamilton*, they say,

> should be followed in a failure to warn case when the evidence suggests that a physician *might have heeded* an adequate warning. In that case it is clear that the failure to warn could make a difference and would be a cause in fact of an injury. We recognize an important distinction, however, between a failure to warn case in which the physician might have responded to an adequate warning and one in which *it is affirmatively established that he*

> *would not have*. In the first case, there is evidence of causation; in the latter case there cannot be.

Stanback v. Parke, Davis & Co., 657 F.2d 642, 645-46 (4th Cir. 1981). Here, unlike in *McCue* and *Hamilton*, Dr. Fidaleo testified clearly that a stronger warning wouldn't change his prescription decision. 5-ER-1013.

Plaintiff's remaining out-of-state citations are a hodgepodge of old and overruled decisions. For example, the Eighth Circuit's 1966 *Erie* guess on Missouri law in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966), was wrong. *See Johnson v. Medtronic, Inc.*, 365 S.W.3d 226, 233 (Mo. Ct. App. 2012) (plaintiffs must prove any "inadequate warning was . . . the proximate cause of [their] injuries."); *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 420 (Mo. Ct. App. 1999) (same). The reality is that other jurisdictions consistently recognize the necessity of causation evidence. As the Texas Supreme Court recently explained, even when plaintiffs present sufficient evidence to show that a manufacturer's warning to "prescribing physicians was inadequate, [plaintiffs] still had to prove that the inadequate warning was the producing cause of [their] injuries." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012). Proving that a stronger warning "would have changed [the physician's] decision to prescribe" is "a critical element of [plaintiffs'] claims." *Id.* at 172; *accord, e.g., McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 382 (1974); *Sager v. Hoffman-La Roche, Inc.*, 2012 WL 3166630, at *15 (N.J. Super. Ct. App. Div.

Aug. 7, 2012); *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009). These cases recognize that the learned intermediary doctrine requires failure-to-warn plaintiffs to prove not only that a warning was inadequate, but also that the inadequate warning caused the alleged injury.

II. Causation should focus on the physician's prescription decision.

When Plaintiff finally reaches the question this Court agreed to address, OB45, she argues that a plaintiff can prove that a prescription product's allegedly inadequate warning *caused* an alleged injury without having to show that the stronger warning would've changed the physician's prescription decision. She argues that if Somatics had adequately warned her physician, he would've passed the warnings along, and she would've refused ECT when her physician prescribed it—as he testified he still would have.

As discussed below, this Court should reject Plaintiff's physicians-as-messengers theory. A causation analysis that focuses on *the physician's prescription decision* aligns with the learned intermediary doctrine's core principle that only physicians have the specialized training necessary to interpret highly technical manufacturer warnings. *See infra* Section II(A). Courts applying California law have repeatedly recognized that the doctrine's causation standard treats the physician's prescribing decision as the determinative factor. *See infra* Section II(B). Plaintiff falsely claims that this

workable approach threatens patient rights; she cannot explain how her inability to recover monetary damages from a medical manufacturer would hinder her ability to refuse medical treatment from a physician. *See infra* Section II(C). In fact, it's Plaintiff's theory that imperils patients by expanding manufacturer liability to a point that will impede patient access to life-sustaining treatments. *See infra* Section II(D).

A. A physician-focused approach aligns with the goals of California's learned intermediary doctrine.

Focusing causation on physicians' prescription decisions aligns with the learned intermediary doctrine's goals. At the core of the doctrine is the principle that patients should and do rely on physicians' prescription decisions. Under the doctrine, "it is through the physician that a patient learns of the properties and proper use of" prescription products, *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (1999), and a "patient's expectations regarding the effects of [a prescribed product] are those related to him by his physician," *Carlin*, 13 Cal. 4th at 1118. The doctrine recognizes that "[p]atients want to be able to *rely* entirely on their doctors' informed and independent judgments." *Gall*, 71 Cal. App. at 122. Because the physician assesses risks on behalf of the patient, "the prescribing doctor . . . in reality stands in the shoes of the ordinary consumer." *Plenger,* 11 Cal. App. 4th at 362 n.6; *accord Gall*, 71 Cal. App. at 122 (the doctrine's "motivating force" is a

recognition that "the doctor *interrupts* the ordinary commercial chain from the manufacturer to the final consumer"). Thus, it is the physician's conduct—not the patient's—that indicates the foreseeable effect of a manufacturer's warning.

The doctrine assumes patients' reliance on physicians because only physicians have the scientific training necessary to assess the medical implications of the "highly technical information on the adverse possibility associated with the use of" prescription products. *Plenger,* 11 Cal. App. 4th at 362 n.6; *see Carmichael*, 17 Cal. App. 3d at 989 (it is physicians who "in the exercise of their medical judgments decide to use" a manufacturer's product, as patients have a "limited understanding" and "no way to evaluate" product warnings). Physicians undergo years of medical school and residency training, garner clinical experience through medical practice, satisfy rigorous licensing requirements, and keep apprised of scientific literature in their fields. Physicians then levy this specialized training, knowledge, and experience to make treatment decisions for the patient. As the appellate court explained in *Gaghan*:

> Prescription [medical products] are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the [product], as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an

> individualized medical judgment bottomed on a knowledge of both patient and palliative.

2014 WL 3798338, at *13. Because the decision whether to use a prescription product "is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities," *Davis v. Wyeth Lab'ys, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968), "[t]he law and medical ethics both demand that doctors, for their patients' benefit, evaluate scientific information about" such products, *Gall*, 71 Cal. App. at 122. Here, the certified question asks whether causation should focus on the physician's prescription decision or on the hypothetical conduct of a prudent patient receiving an allegedly required stronger warning. But a standard that focuses on the physician's prescription decision *already* incorporates the element of prudence; the doctrine recognizes that prudent patients generally rely on their physicians' treatment decisions, precisely because such decisions require specialized knowledge that laypeople lack. Anyone who has ever tried to decide on their own how to manage a serious medical condition—like Plaintiff's—knows why "asking Dr. Google" doesn't empower patients or lead them to make more informed decisions.

Courts nationwide have recognized that the learned intermediary doctrine's "rationale" is that "only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative

advantages and disadvantages of a given form of prescription-based therapy." *Rite Aid Corp. v. Levy-Gray*, 162 Md. App. 673 (2005). That's because a prescription product's "performance safety depends on many variables, including the nature of the [product] itself, the patient's medical history, dosage, and combination with other medications, whose complex interplay is *beyond the comprehension of the ordinary consumer*." *Shanks v. Upjohn Co.,* 835 P.2d 1189, 1194 (Alaska 1992). "To expect the average citizen to know if he or she should take the [prescribed product] or when to stop taking it, or to understand the technical language so often necessary to explain [its] dangers . . . , is unreasonable. This is the basis for the 'learned intermediary' rule . . . ." *Brown v. Drake-Willock Int'l, Ltd.*, 530 N.W.2d 510, 516 (Mich. App. Ct. 1995).

As Congress acknowledged in creating a category of medical products solely obtainable through a physician's prescription, laypersons cannot perform the scientific risk-benefit analysis. After all, "a prescription drug" is by definition "a product whose distribution is limited precisely because its benefits and risks are to be assessed *only by licensed physicians* acting on behalf of particular patients whose individual physical condition and circumstances are known to them." *Coyle by Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 216 (1991). Indeed, the FDA—which requires warnings—has itself recognized that a prescription product warning "is written in technical language intended for health care professionals and is relatively inaccessible

to consumers," making its value to laypersons "questionable." 60 Fed. Reg. 42,581 (Aug. 16, 1995).

Physicians and laypersons will often react differently to manufacturers' warnings. The learned intermediary doctrine recognizes that a patient hearing of a risk of a serious side effect to a prescription treatment may immediately "object" to treatment—which can be dangerous where the medical necessity of treatment outweighs the risk. *Plenger*, 11 Cal. App. 4th at 362 n.6; *see Larkin v. Pfizer*, Inc., 153 S.W.3d 758, 764 (Ky. 2004) (upon hearing of even a "minute" risk, "the lay consumer might overreact . . . and forego beneficial, or even vital, medical treatment"). But a learned intermediary can step in after the patient's initial fear-based reaction and help the patient understand when treatment benefits outweigh risks. *Plenger*, 11 Cal. App. 4th at 362 n.6. Prescription product warnings are often long, complicated, blunt, and impersonal. A physician applies the broad set of complicated hypothetical risks to the individual patient before her. "The physician must tailor the warning about the [prescription product's] side effects to the patient in light of his or her specific medical needs and history. In turn, the patient relies on the physician's judgment to make an informed choice as to whether to take the drug." *Sager*, 2012 WL 3166630, at *14. The patient's uninformed initial reaction, even if it is an objection to the treatment, cannot be dispositive on causation because this initial reaction doesn't account for the

physician's subsequent role in counseling the patient and obtaining the patient's consent. *Id.*

Many prescription products have potential dire side effects, up to and including death, but are repeatedly utilized when physicians' learning and experience allows helps them persuade patients that the benefits of the treatment outweigh the risks. For example, it was true thirty years ago that "the vaccine for the Pasteur treatment of rabies . . . not uncommonly leads to very serious and damaging consequences when it is injected." *Plenger*, 11 Cal. App. 4th at 359 n.4. But "[s]ince the disease itself invariably leads to a dreadful death," physicians' "use of the vaccine [is] fully justified, notwithstanding the unavoidable high degree of risk." *Id.* Similarly, "two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects." *Brown*, 44 Cal. 3d at 1064. Indeed, every surgical operation requiring general anesthesia carries a risk of death. But patients don't all skip necessary surgeries because of that risk; they rely on physicians to tell them when risks are low enough—or benefits high enough—to undergo treatment.

To be sure, a layperson patient may believe in hindsight that she would've objected to treatment upon hearing of a risk. But that can't end the causation inquiry; the Court must still turn to the physician's testimony to determine whether the physician would have guided the plaintiff to overcome

her initial fear-based reaction. The patient's perspective cannot account for the learned intermediary's subsequent counseling, as the circumstances of her after-the-fact consideration (of whether she would have refused treatment upon hearing a warning) mirror the circumstances of a patient's initial reaction to a warning: the patient is engaging with the warning *alone*, considering it in its fear-inducing original form, unfiltered by the intermediary. In the actual circumstances of an exam room, the physician engages with that warning *for* the patient, creating a personalized version to address the patient's needs and concerns. A patient who never had that conversation with her physician—which is every patient claiming that an injury was caused by a physician's failure to relay an allegedly-required warning even when the physician says such warnings wouldn't alter the prescription decision—can't know what the learned intermediary's version of the warning would've sounded like. Nor can the patient know how they would've responded to the learned intermediary's version of the warning, contextualized for a patient whom the physician, by definition, thought should receive the treatment. Thus, the only non-speculative causation inquiry necessarily *must* focus on the physician's prescription decision.

Here, Dr. Fidaleo prescribed ECT for [redacted] 1-SER-3-4. Dr. Fidaleo testified that, even

if given a stronger warning of Plaintiff's claimed brain injury, he would've used his specialized knowledge, training, and clinical experience to determine that the benefits of treatment—i.e., [redacted] after all other treatments, including antipsychotics, antidepressants, hospitalizations, and psychotherapy, had failed—outweighed the risk of a type of non-life-threatening brain injury he had never seen occur in all his years of practice. 1-SER-3-5; 2-ER-63-64; 2-ER-159; 2-ER-172; 3-ER-328; 5-ER-949; 5-ER-1013-1015. Had Plaintiff initially blanched at hearing of the risk, Dr. Fidaleo would have performed his appropriate learned intermediary role in seeking to guide her to the lifesaving treatment. 5-ER-1013-1015. His testimony that a stronger warning *would not have altered his prescription decision* breaks the causal chain.[11]

[11] Plaintiff suggests that physicians will lie under oath about prescribing decisions because they have "financial and personal ties" to manufacturers. Plaintiff's counsel offers unsworn, citation-free representations that a physician involved in an entirely separate case "is personal friends with one of the owners of Somatics." OB44. But Plaintiff never presented any evidence that *Dr. Fidaleo* has ties to Somatics, or that physicians as a class should be presumed perjurers. Nor has Plaintiff offered any evidence (or authority) for the proposition that non-party physicians are more likely to perjure themselves than plaintiffs who sue seeking money damages.

B. Courts applying the learned intermediary doctrine have squarely rejected Plaintiff's physicians-as-messengers theory.

Unsurprisingly in light of the principles above, courts applying California's learned intermediary doctrine have routinely rejected Plaintiff's physicians-as-messengers theory. Courts overwhelmingly agree that plaintiffs "cannot demonstrate the causation required to survive summary judgment under California's learned intermediary doctrine" without "evidence that a different warning would have *altered the physicians' decisions to prescribe.*" *Thompson v. Janssen Pharms., Inc.*, 2017 WL 5135548, at *8 (C.D. Cal. Oct. 23, 2017), *aff'd*, 756 F. App'x 740 (9th Cir. 2019); *see Guillen*, 394 F. App'x at 816 (California law requires plaintiff to "demonstrate that her treating physicians would have altered their *decision to prescribe*"); *see also Love*, 226 Cal. App. 2d at 399 ("if . . . *over-prescription by the doctor* was not caused by" the manufacturer's "over-promotion" which rendered warnings inadequate, then the manufacturer "could not be held liable").[12]

[12] *Accord, e.g.*, *Neal*, 394 F. App'x at 825; *Misouria*, 394 F. App'x at 827; *Rodman*, 564 F. Supp. 3d at 893; *Galinis*, 2019 WL 2716480, at *11; *Colbath v. Merck & Co.*, 2022 WL 935195, at *4 (S.D. Cal. Mar. 29, 2022); *Westgate v. Coloplast Corp.*, 2018 WL 6380746, at *4 (C.D. Cal. Sept. 6, 2018); *Kent v. Pfizer Inc.*, 2017 WL 11672334, at *3 (S.D. Cal. Aug. 16, 2017); *Hill v. Davol Inc.*, 2016 WL 10988657, at *4 (C.D. Cal. Nov. 16, 2016); *Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1144 (S.D. Cal. 2016); *Dunson v. Cordis Corp.*, 2016 WL 3913666, at *5-6 (N.D. Cal. July 20, 2016); *Hammarlund v. C.R. Bard, Inc.*, 2015 WL 5826780, at *4-5 (C.D. Cal. Oct. 2, 2015); *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158-59 (S.D. Cal. 2015).

Appellate courts applying California law have rebuffed plaintiffs' efforts to pivot causation analyses away from physicians' prescribing decisions. For example, in *Gaghan v. Hoffman-La Roche Inc.*, the appellate court recognized that the physicians-as-messengers theory violates California's learned intermediary doctrine. *See* 2014 WL 3798338, at *14 (causation can't "be satisfied by proof that the doctor would have passed a stronger warning on to the patient rather than by proof that the doctor's decision to prescribe the medication would have been altered by a stronger warning"). *Gaghan* concluded that "California law focuses on the *prescribing decision* of the doctor as the learned intermediary," noting that "other jurisdictions have held similarly that the relevant conduct that would be altered by a stronger warning is *the doctor's decision to prescribe*." *Id.* at *15. Similarly, in *Gall*, the California Court of Appeal found no causation where the physician "testified that nothing about [later learning of a stronger] warning changed his thinking or decision making." 71 Cal. App. 5th at 124. Importantly, the physician also testified that, had he received the stronger warning prior to prescribing, he would've relayed it to the patient. *Id.* at 123. But *Gall* explained that failure-to-warn claims *against manufacturers* don't turn on whether physicians relay warnings. They turn on whether the supposedly insufficient warning altered the physician's conduct. *See id.* at 122 ("What [the physician] told [the patient]

is a different matter. That might be pertinent to [the patient's] lawsuit against [the physician], but that case is not before us.").

Appellate courts applying the learned intermediary doctrine under other states' laws agree. For example, in *Sager v. Hoffman-La Roche, Inc.*, an appellate court applying Florida law rejected Plaintiff's physicians-as-messengers theory as inconsistent with the doctrine. 2012 WL 3166630, at *5-7 (finding no causation where the physicians testified they would've prescribed a product even with a stronger warning but would've discussed the warning with their patients, and the patients testified they would've refused treatment upon hearing the warning). *Id.* *Sager* held that the physicians' testimony that they "would still have prescribed" broke the causal chain, explaining that, "[b]ecause drug manufacturers have a duty to warn the physician, not the patient, it is the prescribing physician's course of conduct that is most relevant to proximate cause." *Id.* at *15-18. *Sager's* reasoning aligns with a vast body of state supreme court and appellate precedent focusing causation on prescription decisions alone. *See, e.g.*, *Centocor*, 372 S.W.3d at 172 (applying Texas law) (plaintiff must show "that the presence of [a stronger warning] would have changed [the physician's] decision to prescribe"); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law) ("sole issue" under "the learned intermediary doctrine" is "whether an

adequate warning . . . would have deterred [the physician] from prescribing").[13]

Although the Ninth Circuit hasn't expressly held that causation turns only on the physician's prescription decision, the prescription decision has been the sole focus of every prior Ninth Circuit causation analysis in a learned intermediary doctrine case. *Wendell*, for example, focused its causation inquiry on evidence that a physician would've changed his "prescribing decisions." 858 F.3d at 1238. And *Latiolais* found no causation where the physician testified that the manufacturer's warnings "did not play a role in his *decision to prescribe* that medication." 302 F. App'x at 757. Finally, *Motus II*, where evidence showed that a stronger warning of suicide risk wouldn't have altered the physician's prescription decision, held that the plaintiff had "failed to establish proof that stronger warnings would have changed her husband's medical treatment or averted his suicide." 358 F.3d at 661.

Plaintiff both uses and abuses *Motus II*, saying it was "wrongly decided," OB55, but also that it held "that causation can be established by broader means" than a change in prescription decision, OB46. Both are inaccurate.

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[13] *Accord Strumph v. Schering Corp.*, 626 A.2d 1090 (N.J. 1993) (applying New Jersey law); *Mason*, 27 So. 3d at 77 (applying Florida law); *Silva*, 2013 WL 4516160, at *3-4 (applying New Mexico law); *Ebel v. Eli Lilly & Co.*, 321 F. App'x 350, 356 (5th Cir. 2009) (applying Texas law); *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 209 (5th Cir. 2008) (same); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (applying Louisiana law).

Motus II affirmed a trial court conclusion 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*." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 995-96 (C.D. Cal. 2001) ("*Motus I*"), *aff'd*, 358 F.3d 659 (9th Cir. 2004). *Motus II* doesn't identify any "broader means" of proving causation, and nothing in the case supports Plaintiff's assertion that "*Motus II* makes clear that the focus is on whether the doctor would have *relayed* the stronger warnings." OB47. As the Ninth Circuit recognized in its certification order, it has *no decisions* endorsing Plaintiff's physicians-as-messengers theory; prior decisions focused on a "change in *prescribing* conduct" and didn't "resolve whether anything less" could suffice. *Himes*, 29 F.4th at 1126-27.[14]

Moreover, while the Ninth Circuit itself hasn't directly addressed the physicians-as-messengers theory, district courts in the Ninth Circuit have rejected it: *Munoz v. American Medical Systems, Inc.* rebuffed arguments that,

[14] Plaintiff argues that it should be the *defendant's* burden to *disprove* causation "where the conduct of the defendant causes the plaintiff to be unable to establish [causation] (i.e., defendant causes the death so decedent is not able to testify as to what he would have done had he been warned)." OB55. But it's the physician's testimony, not the patient's, that's needed to establish causation. Moreover, no one involved in *this* appeal is deceased; Plaintiff's failure to prove causation isn't the result of any conduct by Somatics. Further, even if Somatics *did* bear the burden of proof (which it didn't), Somatics satisfied that burden through Dr. Fidaleo's testimony.

"if [the manufacturer] had provided stronger warnings, [the physician] would have shared those warnings with [the patient]," explaining that this theory "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." 2021 WL 1200038, at *4. Likewise, *Motus I* agreed that the relevant causation question for the physician is "would you have *prescribed*" the product with a stronger warning, not whether the allegedly required stronger warning is "the kind of information you would *pass on* to your patients." 196 F. Supp. 2d at 997.[15]

District courts across the country have similarly thwarted plaintiffs' "attempt[s] to displace the learned intermediary doctrine" with the physicians-as-messengers theory, finding no causation in cases where physicians testified

[15] Plaintiff incorrectly states that *Motus I* held "that establishing that the doctor would not have prescribed the drug or procedure is not the sole or exclusive means of establishing causation." OB54. *Motus I* only noted that the *initial* prescribing decision wasn't the only relevant prescribing decision, as a plaintiff might also establish causation through evidence that an adequately-warned physician would've stopped prescribing a treatment after early detection of an adverse reaction. *Id.* at 995. Whether initial or subsequent, the physician's prescribing decision remained the exclusive focus.

Plaintiff also stresses that *Motus I* involved a patient's death. But the case puts no weight on that in its analysis, and Plaintiff identifies no other case ever limiting *Motus I* that way. And for good reason: it makes no sense that the doctrine would impose a vastly *reduced* burden of proof on plaintiffs claiming injuries much less obvious than death.

that they would've relayed stronger warnings to patients but still prescribed, and patients testified they would've refused treatment upon hearing stronger warning. *Carnes v. Eli Lilly & Co.*, 2013 WL 6622915, at *5 (D.S.C. Dec. 16, 2013); *see id.* at *3, 5 (rejecting physicians-as-messengers theory because, despite plaintiffs' "attempt to shift focus to the patient's decision to take the prescription drug," the learned intermediary doctrine "requires the court to focus on *the physician's decision to prescribe*"); *accord Allain v. Wyeth Pharms.*, 2015 WL 178038, at *6 (N.D. Ala. Jan. 14, 2015) (rejecting physicians-as-messengers theory because "the question under the learned intermediary doctrine is not whether the patient would have taken the medication if they had been adequately warned but whether the physician *would have prescribed* the medication"); *Parkinson v. Novartis Pharms. Corp.*, 5 F. Supp. 3d 1265, 1273-74 (D. Or. 2014) (rejecting physicians-as-messengers theory because "the relevant inquiry is not whether Plaintiff would have taken [the treatment], but whether [the physician] *would have prescribed* [the treatment] if he had received a different warning"); *Garrison v. Novartis Pharms. Corp.*, 30 F. Supp. 3d 1325, 1336-37 (M.D. Ala. 2014) (physicians-as-messengers theory ignores "the learned-intermediary doctrine"; where a physician testifies that, even with a stronger warning, "he still would have prescribed," this "disrupts [the

plaintiff's] theory that [the manufacturer's] inadequate warnings were the proximate cause of her injuries").[16]

Plaintiff purports to have identified four outlier district court decisions supporting her physicians-as-messengers theory. The first is an earlier order by the district court *in this case*. *See* OB50. But as the district court made clear in the decision on appeal—which squarely considered Plaintiff's theory at length and rejected it—the district court concluded that her theory contravenes California law. 1-ER-10. The other three cases feature physicians' testimony that they would've made changes to *how* they prescribed medications: *Georges v. Novartis Pharms. Corp.* found a triable issue on causation where the plaintiff's physician testified he would've "changed his treatment practices" and "made prescriptions changes" based on stronger warnings. 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013). *Stanley v. Novartis Pharms. Corp*. found a triable issue on causation where physicians testified they would've changed how they prescribed a medication, including by prescribing "in a more conservative manner" with increased monitoring alongside the medication; the court recognized evidence that the physicians would've discussed the increased risks with their patients but didn't hold that

[16] *Cf. Curtin v. Ethicon, Inc.*, 2021 WL 825986, at *6-7 (D. Colo. Mar. 4, 2021) (no causation where physician testified that, although "he would have communicated the risk" to his patient, he still believed the product "was a safe and effective treatment" with an "acceptable risk profile").

such evidence *alone* established causation. 11 F. Supp. 3d 987, 1003 (C.D. Cal. 2014). *Hill v. Novartis Pharms. Corp*. found a triable issue on causation where, after getting a stronger 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 (E.D. Cal. Nov. 30, 2012).[17] Here, in contrast, Plaintiff offered no evidence that Dr. Fidaleo would've changed how he prescribed ECT.

In a last-ditch effort, Plaintiff lists several out-of-jurisdiction cases. OB51-52. Her list misleadingly includes circumstances with evidence of a change in prescription decision. *See McNeil v. Wyeth*, 462 F.3d 364, 372 (5th Cir. 2006) ("[The physician] testified that he *would not have prescribed the drug* had its label [contained a stronger warning]. Therefore, [the plaintiff] has raised a genuine issue of fact . . . ."). Moreover, her list ignores the vast body of precedent discussed above that squarely rejects her physicians-as-messengers theory.

[17] This is an earlier decision in the same case as the superseded and rejected decision of *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, which confused the learned intermediary doctrine with the sophisticated intermediary doctrine.

C. A physician-focused standard for claims against manufacturers does not eliminate a patient's right to refuse prescribed treatment.

Plaintiff attempts to re-frame her anti-psychiatry and anti-science crusade around "respect [for] patient self-decision and autonomy." OB2; *see* OB58-62. But she fails to explain how upholding the learned intermediary doctrine's causation requirements for claims *against manufacturers* will reduce patients' rights when interacting *with their physicians*.

Plaintiff wildly mischaracterizes the doctrine through her sensationalist claim that its causation standard "require[s] an unwarranted presumption that a doctor would have administered electroshock therapy to a patient against the patient's will." OB23. Under the doctrine, a physician doesn't administer treatment over the patient's objection; rather, the physician *obtains the patient's consent* to treatment by using medical expertise to persuade the patient that the benefits of treatment will outweigh even serious risks. *See supra* Section II(A).

Plaintiff's inability to recover monetary damages from a medical manufacturer won't prevent Plaintiff—or any patient—from refusing any treatment from any physician anytime. It won't prevent her from suing, or pressing criminal charges, against any physician who performs a medical procedure without her consent. Physicians have strong incentives to respect patient consent—not just because of medical ethics and general ethics, but

because performing medical procedures on non-consenting patients can lead to civil or criminal liability for the physician. Expanding potential liability for third-party manufacturers of prescription products wouldn't alter physicians' ethics and incentive structures. Plaintiff confuses her right to obtain money from Somatics with her right to refuse consent to Dr. Fidaleo.

This Court can and should respect *both* patient consent *and* the role of highly-trained medical experts in obtaining patient consent.

D. Plaintiff's physicians-as-messengers theory threatens patients' rights.

Plaintiff's physicians-as-messengers theory undermines the principles behind the learned intermediary doctrine and would allow failure-to-warn claims to reach a jury whenever (a) plaintiffs say they would've refused treatment if aware of a stronger warning and (b) doctors say they would've mentioned such a warning to the patient, even though they still would've prescribed the product and guided the patient to undergo treatment. This would dramatically reduce a plaintiff's evidentiary burden on causation. After all, most physicians will say they would've passed on a stronger warning if they'd received one, and most plaintiffs who have experienced an adverse side effect will say in hindsight that they never would've gotten the treatment if they'd received the warning they say they should've gotten. As a practical matter, then, adopting Plaintiff's causation standard would be equivalent to

saying that, if a plaintiff can find an expert who will opine that a warning wasn't strong enough, the case should go to a jury.

The minimum requirements for experts mean that not every wild claim goes to a jury. *See Sargon Enterprises, Inc. v. U.S.C.*, 55 Cal.4th 747, 769-72 (2012). But by nature, experts offer abstract opinions on warning adequacy. They aren't the treating physicians, who understand how a manufacturer's warning affects doctor/patient conversations and decisions about how to fight illness—and they certainly aren't the one physician who knows how the warning would've affected conversations and decisions with *this particular patient* in the doctor's care. It's that doctor—the one in the room where it happens—who best knows whether the supposedly missing words from the warning would've made any difference to the treatment plan. Requiring plaintiffs to get testimony from *that* doctor, in addition to an abstract expert opinion on warning adequacy, ensures that California courts won't be flooded by failure-to-warn trials in prescription product cases. That flood would enrich some lucky plaintiffs with otherwise weak claims, but it would harm most patients by significantly increasing the costs of drugs and medical devices—including those, like the device here, that are last-resort lifesaving treatments.

This Court has traditionally recognized that a plaintiff's interest in obtaining money from a medical manufacturer is in tension with the public's interest in ensuring the continued availability of life-sustaining medical

products. "[T]he broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." *Brown*, 44 Cal. 3d at 1063. As this Court has cautioned, excessive liability risks may deter manufacturers from producing medical products that patients need:

> Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering. . . . [T]he additional expense of insuring against [extensive manufacturer] liability. . . could place the cost of medication beyond the reach of those who need it most.

Id. Justice Kennard noted how strongly that principle applied in the failure-to-warn context, warning that subjecting medical manufacturers "to excessive liability . . . jeopardizes the important public interest of encouraging the development, availability, and affordability of beneficial prescription drugs," whereas "limiting somewhat the scope of liability for failure to warn of risks . . . will best assure that millions of other innocent people—those suffering from debilitating or even fatal diseases—will have available to them prescription drugs that sustain life or health." *Carlin*, 13 Cal. 4th at 1124, 1127 n.3 (Kennard, *J.*, concurring and dissenting).

Moreover, "[t]he possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical." *Brown*, 44 Cal. 3d at 1064. There are

"a host of examples of products which have greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments." *Id.*; *accord Carlin*, 13 Cal. 4th at 1127-28 (Kennard, *J.*, concurring and dissenting) (providing examples of prescription products withdrawn from the market, to the detriment of patients, due to costs of litigation and insurance). Plaintiff's position would harm the patients she purportedly champions.

Accordingly, this Court should confirm that the learned intermediary doctrine requires evidence that a stronger warning would have altered the physician's prescription decision.

III. A physician's failure to read purportedly-inadequate disclosures bars causation.

If this Court endorses Plaintiff's physicians-as-messengers theory (which it shouldn't), Somatics respectfully requests that the Court exercise its discretion to consider whether, as a matter of California law, a physician's failure to read a manufacturer's purportedly-inadequate disclosures bars causation even under that theory.

Even if California law authorized Plaintiff's theory, it can't work where there's no evidence that the physician would *even be aware* of a stronger warning that he could relay to the plaintiff. Here, Dr. Fidaleo *never read* Somatics's product information before prescribing. 5-ER-1004-05; 5-ER-1016-

17.[18] Where a physician fails to read the disclosures accompanying a manufacturer's product, the inadequacy of those unread disclosures cannot have caused the plaintiff's injury. *See Ramirez,* 6 Cal. 4th at 555-56 (no causation where person administering drug didn't read label); *Conte*, 168 Cal. App. 4th at 99 (no causation if physician gives uncontradicted testimony he didn't rely on manufacturer's disclosures); *Motus II*, 358 F.3d at 661 (no causation where "the doctor testified that he did not read the warning label that accompanied [the product] or rely on information provided by [the manufacturer] before prescribing").[19]

The Ninth Circuit assumed that Dr. Fidaleo would've been aware of a stronger warning from Somatics because he testified that he gave "attention" to *other* manufacturers' "dear doctor" letters. *Himes*, 2022 WL 989469, at *2. But there was no evidence at all that *Somatics* ever sent a "dear doctor" letter

[18] 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. Plaintiff offered no evidence that, had this technician read physician warnings in the manual, the technician would've relayed the warnings to Dr. Fidaleo.

[19] *See Grove v. Bos. Sci. Corp.*, 2016 WL 2889070, at *3 (S.D.W. Va. May 17, 2016) (under California law, "if a doctor did not read the warning, or if a doctor read but did not rely on the warning, then the chain of causation is broken"); *accord Latiolais v. Merck & Co.*, 2007 WL 5861354, at *3-4 (C.D. Cal. Feb. 6, 2007), *aff'd*, 302 F. App'x 756; *Renteria v. Ethicon, Inc.*, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020); *Tucker*, 2013 WL 1149717, at *16; *cf. Hernandez v. City of Beaumont*, 742 F. App'x 257, 260 (9th Cir. 2018); *Massok v. Keller Indus., Inc.*, 147 F. App'x 651, 660 (9th Cir. 2005).

to Dr. Fidaleo prior to Plaintiff's treatment, let alone that Dr. Fidaleo ever read and relied on a "dear doctor" letter from Somatics. Prior to Plaintiff's treatment, Somatics exclusively used manuals and pamphlets, not "dear doctor" letters, to provide disclosures about the Thymatron. 5-ER-1079. When Somatics updated its disclosures in 2013 to warn of "neurological complications," it did so in a manual provided to Dr. Fidaleo's hospital, not in a "dear doctor" letter. 2-ER-91. The Ninth Circuit's causation analysis thus improperly involved pure *speculation* that, if Somatics had issued a stronger warning before Plaintiff's treatment, it would've done so in a "dear doctor" letter—even though Somatics wasn't using "dear doctor" letters then.

This Court should clarify that the causation analysis in a learned intermediary doctrine case, as in any other case, cannot turn on such speculation. As this Court has warned, plaintiffs cannot establish causation on the basis of "speculation or conjecture." *Saelzler v. Advanced Grp. 400*, 25 Cal. 4th 763, 775-76 (2001).[20] The preliminary causation issue is whether the person administering the product read the warnings in the form the manufacturer used, not whether the person might've read warnings in some form the manufacturer didn't use. In *Ramirez*, for example, the Court didn't speculate whether the manufacturer could've reached the person

[20] *Accord Huitt*, 188 Cal. App. 4th at 1600.

administering the drug (who didn't read the drug's label) through some other means; it was dispositive that she didn't read the disclosures the manufacturer had *already* provided, using the manufacturer's habitual disclosure methods. 6 Cal. 4th at 555-56.; *cf. T.H.*, 4 Cal. 5th at 187 (plaintiff must show "that the physician actually relied on *the defendant's warning label*").[21]

This Court should hold that Plaintiff can't establish causation, even under her physicians-as-messengers theory, because her physician didn't read Somatics's purportedly-inadequate disclosures.

IV. A patient's subjective, hindsight-influenced testimony can't establish causation.

Plaintiff lastly argues that, if this Court endorses her physicians-as-messengers theory, it should reduce her evidentiary burden even further: She contends she shouldn't have to prove that a prudent person in her position would have refused treatment but should instead reach a jury by offering her

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[21] *See Motus I*, 196 F. Supp. 2d at 987 (rejecting argument that physician "obtained information from sources other than the package insert," including "'Dear Doctor' letters," because "[t]here [wa]s no evidence that he obtained information *about [the product at issue]* from" such letters); *see also Rodriguez v. Stryker Corp.*, 680 F.3d 568, 575-76 (6th Cir. 2012) (finding no causation where the physician testified he never read the product's accompanying instructions but had "seen" manufacturers' "dear doctor" letters; explaining that the plaintiff's argument that the manufacturer should've sent a "dear doctor" letter containing stronger warnings fails because, *inter alia*, the plaintiff "claims only that [the manufacturer] should have provided 'adequate' warnings, not warnings in . . . forms tailored to reach the practices of [plaintiff's] physician").

own subjective post-hoc declaration that she would have refused treatment, even if doing so were objectively unreasonable. OB62-65. Her argument ignores this Court's precedent deeming such testimony inherently unreliable.

Where a claim *does* turn on whether a patient would have refused prescribed treatment if adequately warned (such as a failure-to-obtain-informed-consent claim brought against a physician), this Court has long rejected subjective testimony due to the patient's hindsight bias:

> Since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined treatment. Subjectively he may believe so, with the 20/20 vision of hindsight, but we doubt that justice will be served by placing the physician in jeopardy of the patient's bitterness and disillusionment.

Cobbs v. Grant, 8 Cal. 3d 229, 245 (1972). The Court has held that "an *objective* test is preferable: i.e., what would *a prudent person in the patient's position* have decided." *Id.*; *see Arato v. Avedon*, 5 Cal. 4th 1172, 1186 (1993); *Truman v. Thomas*, 27 Cal. 3d 285, 291 (1980); *Flores v. Liu*, 60 Cal. App. 5th 278, 292-93 (2021); *Spann v. Irwin Mem'l Blood Centers*, 34 Cal. App. 4th 644, 657 (1995).

Other jurisdictions (in the context of claims directly against physicians) agree that causation can't involve "a subjective determination solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk." *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir. 1972). "[T]he answer

which the patient supplies hardly represents more than a guess, perhaps tinged by the circumstance that the uncommunicated hazard has in fact materialized." *Id.* at 790. That "speculative answer to a hypothetical question" is inherently less reliable than an "objective" test focusing on "what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance." *Id.* at 791. The objective test "ease[s] the fact-finding process and better assure[s] the truth as its product." *Id.*; *accord Univ. Med. Ctr., Inc. v. Shwab*, 628 S.W.3d 112, 129 & n.25 (Ky. 2021); *White v. Beeks*, 469 S.W.3d 517, 526 (Tenn. 2015); *Largey v. Rothman*, 540 A.2d 504, 510-11 (N.J. 1988); *Gerety v. Demers*, 589 P.2d 180, 194 (N.M. 1987); *Fain v. Smith*, 479 So. 2d 1150, 1154 (Ala. 1985); *Woolley v. Henderson*, 418 A.2d 1123, 1132 (Me. 1980); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 227 N.W.2d 647, 655 (Wis. 1975); *Funke v. Fieldman*, 512 P.2d 539, 550 (Kan. 1973).

Against that consistent, well-reasoned authority, Plaintiff cites *Colombo v. BRP US Inc.*, 230 Cal. App. 4th 1442 (2014), which has nothing to do with subjective testimony about materialized medical risks. The *Colombo* defendant argued that a jury improperly considered the plaintiffs' testimony that, if adequately warned of risks associated with a watercraft, they wouldn't have used it. *Id.* at 1454. *Colombo* rejected the defendant's argument where the defendant "did *not* challenge this evidence at trial," and where it also failed to "challenge on appeal" jury instructions authorizing consideration of the

evidence. *Id*. (emphasis in original). *Colombo* never held that subjective testimony alone established causation; it cited the testimony of an expert witness who framed causation in *objective* terms, addressing whether "others beside [the plaintiffs] would have heeded an adequate warning." *Id*. at 1455.[22]

Finally, Plaintiff asserts without meaningful elaboration that an objective standard "is not appropriate in this case" because "a doctor may not administer ECT without the express consent of the patient." OB64. Plaintiff doesn't—and can't—explain how this Court's use of an objective standard would authorize physicians to administer treatment without consent. An objective standard merely requires *reliable evidence* regarding consent.

As discussed in Section II above, for failure-to-warn claims against medical manufacturers, causation turns on a physician's prescription decision alone. However, if the Court adopts Plaintiff's physicians-as-messengers theory (which it shouldn't), then the Court should use an objective prudent-person standard.

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[22] Plaintiff also points to discussions of the "substantial factor" test in *Mitchell v. Gonzales*, 54 Cal. 3d 1041, 1052-1053 (1991), and *Rutherford v. Owens-Illinois, Inc*., 16 Cal. 4th 953, 968-99 (1997). But neither says anything about whether courts should apply an objective or subjective standard when assessing causation evidence, and neither involves patient consent to medical treatment.

While the Court should not adopt Plaintiff's physicians-as-messengers theory, if it does, it should also clarify that, as a matter of law, an objective prudent person would not refuse last-resort, life-saving treatment because of a small risk of side effects.[23] Plaintiff suffered from mental health conditions so severe that [redacted] 1-SER-3-4. Antipsychotics, antidepressants, hospitalizations, and psychotherapy all failed [redacted] 1-SER-3-5; 2-ER-63-64; 2-ER-159; 2-ER-172; 3-ER-328; 5-ER-949. As a last resort to save Plaintiff's life, Dr. Fidaleo prescribed ECT, 1-SER-3-5; 3-ER-328, having never previously seen Plaintiff's alleged brain injury occur as an ECT side effect in all his years of practice, *see* 5-ER-1015. No objectively prudent person would refuse a prescribed treatment where (1) the patient is facing a serious risk of death, (2) all other treatment options have failed, and (3) a physician prescribes and urges the use of a medical treatment to save the patient's life—and the doctor never previously saw a patient experience the alleged side effect.

[23] If this Court confirms that legal principle, then the Ninth Circuit will need to determine whether the case record satisfies the standard.

CONCLUSION

For the reasons discussed above, this Court should hold that a failure-to-warn claim against a medical manufacturer requires evidence that a stronger warning would have altered the physician's prescription decision.

Dated: September 14, 2022

Respectfully submitted,

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The foregoing is true and correct. Executed under penalty of perjury at New Haven, Connecticut.

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STATE OF CALIFORNIA
Supreme Court of California

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