

**IN THE SUPREME COURT OF
CALIFORNIA**

MICHELLE HIMES,
Plaintiff and Appellant,

v.

SOMATICS, LLC,
Defendant and Respondent.

S273887

Ninth Circuit

21-55517

Central District of California

2:17-cv-06686-RGK-JC

June 20, 2024

Justice Groban authored the opinion of the Court, in which
Chief Justice Guerrero and Justices Corrigan, Liu, Kruger,
Jenkins, and Evans concurred.

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S273887

Opinion of the Court by Groban, J.

In a typical products liability case, a manufacturer owes a duty to warn the end user “about the hazards inherent in their products.” (*Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 64.) For manufacturers of prescription drugs and many medical devices, however, the “duty to warn runs to the physician, not to the patient.” (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1116, italics omitted (*Carlin*); accord, *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 164 (*T.H.*)). Thus, these manufacturers have a duty to warn physicians of the risks associated with their products but need not warn the patient regarding those same risks. The primary rationale for this rule, called the “learned intermediary doctrine,” is that physicians, not their patients, are best positioned to understand “the relevant benefits and risks associated with various prescription drugs and medical devices.” (Rest.3d Torts, Products Liability, § 6, com. d, p. 147.) Once a manufacturer has fulfilled its duty to warn the physician, “[t]he duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.” (*Id.*, com. b, p. 146.)

This case involves a question not of duty, but of causation: If a prescription drug or medical device manufacturer has breached its duty under the learned intermediary doctrine to provide an adequate warning (or any warning at all) to the

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physician, how must the plaintiff prove that the failure to warn caused his or her injury? We granted a request from the United States Court of Appeals for the Ninth Circuit to determine whether the plaintiff is “required to show that a stronger risk warning would have altered the physician’s decision to prescribe the product,” or whether the plaintiff may instead establish causation “by showing that the physician would have communicated the stronger risk warning[] 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* (9th Cir. 2022) 29 F.4th 1125, 1127 (*Himes*).)

We answer these questions as follows: A plaintiff is not required to show that a stronger warning would have altered the physician’s decision to prescribe the product to establish causation. Instead, a plaintiff may establish causation by showing that the physician would have communicated the stronger warning to the patient and an objectively prudent person in the patient’s position would have thereafter declined the treatment. The causation analysis, however, must take into consideration whether the physician would still recommend the prescription drug or medical device for the patient, even in the face of a more adequate warning. In other words, where the evidence shows that the physician would have continued to recommend the treatment notwithstanding the stronger warning, the plaintiff must prove that an objectively prudent person in the patient’s position would have declined treatment despite the physician’s assessment that the benefits of the treatment for the patient would still outweigh any risks disclosed by a stronger warning. As in the informed consent context, the test is what an objectively prudent person in the

patient's position would have done in light of all the information presented and is not determined by the plaintiff's subjective belief as to what he or she might have done with the benefit of hindsight. (See *Cobbs v. Grant* (1972) 8 Cal.3d 229, 245 (*Cobbs*).

I. BACKGROUND

Plaintiff Michelle Himes sued defendant Somatics, LLC, for negligence, strict liability, and loss of consortium, alleging that Somatics failed to provide an adequate warning regarding certain risks associated with undergoing electroshock or electroconvulsive therapy (ECT). An ECT device "is a prescription device . . . used for treating severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head." (21 C.F.R. § 882.5940(a) (2018).) ECT has been used for decades in severe cases of depression. Prior to prescribing ECT, Himes's physicians prescribed at least nine different antipsychotics and antidepressants to treat her depression, but her condition worsened. She was hospitalized several times for severe depression or suicidal ideation. Eventually, Himes enrolled in an inpatient program where Dr. Raymond Fidaleo determined ECT was appropriate for her and administered it to her on 26 different occasions. Himes asserts that she was warned only that ECT could cause short-term memory loss, and that Somatics failed to disclose to her physician that its ECT device could cause "permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome." She further avers that Somatics's failure to warn caused her to suffer these injuries.

Somatics moved for summary judgment, assuming for the purpose of its motion that even if Himes could establish that (1)

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ECT is capable of causing permanent brain damage and memory loss in patients; (2) Himes's ECT treatments caused her to suffer permanent brain damage and memory loss; and (3) Somatics failed to adequately warn Dr. Fidaleo of the risk of permanent brain damage and memory loss, then Himes would still be unable to "establish a causal link between [her] purported injuries" and Somatics's alleged failure to warn. More specifically, Somatics argued that, under the learned intermediary doctrine, a plaintiff "cannot survive summary judgment if stronger warnings would not have altered the physician's decision to prescribe the treatment at issue" and "Dr. Fidaleo's deposition testimony makes it clear that he still would have recommended ECT even if he had been informed of" the risk of permanent brain damage and memory loss. The district court agreed with Somatics, finding that Himes must prove "that the non-disclosed risks" regarding Somatics's ECT device must be "sufficiently high that it would have changed the treating physician's decision to prescribe the product.'" (*Riera v. Mecta Corporation* (C.D.Cal., May 14, 2021, No. 2:17-CV-06686-RGK-JC) 2021 WL 2024688, p. *5.) Because Himes failed to present evidence showing "that a more detailed warning as to the risks" would have changed Dr. Fidaleo's decision "to administer ECT" to her, the district court granted summary judgment. (*Ibid.*)

On appeal, the Ninth Circuit agreed with the district court that Himes failed to present evidence tending to show Dr. Fidaleo would have altered his decision to prescribe ECT to Himes if Somatics had issued a stronger warning about its ECT device. (*Himes, supra*, 29 F.4th at p. 1126.) There was, however, a genuine dispute of material fact as to whether Dr. Fidaleo would have been alerted to a stronger warning and

would have passed along the warning to Himes. (*Ibid.*) The Ninth Circuit accordingly concluded that the disposition of this appeal “hinges on the resolution of the causation standard.” (*Ibid.*) Specifically, if “a plaintiff must show that stronger manufacturer warnings would have altered the physician’s prescribing conduct, Himes’s claims fail. If, on the other hand, a plaintiff can establish causation by showing that a physician would have communicated the stronger warning to the patient and that a prudent person in the patient’s position would have declined the treatment after receiving the stronger warning, Himes’s claims survive summary judgment.” (*Ibid.*) We granted the Ninth Circuit’s request to answer state law questions regarding the proper causation standard. (Cal. Rules of Court, rule 8.548(a).)

II. DISCUSSION

A. The Learned Intermediary Doctrine

The learned intermediary doctrine provides that manufacturers have a duty to warn physicians, but not the physicians’ patients, about certain risks accompanying use of their prescription drugs and many medical devices. (*T.H.*, *supra*, 4 Cal.5th at p. 164, accord, Rest.3d Torts, Products Liability, § 6, subd. (d).) The manufacturer need not “warn of risks that are ‘merely speculative or conjectural, or so remote and insignificant as to be negligible.’ ” (*T.H.*, at p. 164, quoting *Carlin*, *supra*, 13 Cal.4th at p. 1116.) Nor must the manufacturer warn of risks that are already known to the medical community. (*Carlin*, at p. 1116; *Gall v. Smith & Nephew, Inc.* (2021) 71 Cal.App.5th 117, 122 (*Gall*); *Plenger v. Alza Corp.* (1992) 11 Cal.App.4th 349, 362 (*Plenger*).) But the manufacturer is required to warn physicians of any non-negligible risks that are generally unknown to the medical

community, as this will “allow the health-care provider, and thereby the patient, to make an informed choice whether to utilize the drug or medical device.” (Rest.3d Torts, Products Liability, § 6, com. d, p. 148.)

Once the manufacturer has fulfilled its duty to warn the physician of non-negligible risks, “[t]he duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.” (Rest.3d Torts, Products Liability, § 6, com. b, p. 146; see also *Cobbs, supra*, 8 Cal.3d at p. 245 [physicians must divulge to patients “whatever information is material” to the treatment decision].) The patient cannot sue the manufacturer for failing to warn him or her directly: As long as the manufacturer has adequately warned the patient’s physician of the non-negligible risks of its prescription drug or medical device, the manufacturer has fulfilled its duty to warn. (*T.H., supra*, 4 Cal.5th at p. 164; *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1062, fn. 9 (*Brown*).) Moreover, “[t]he manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his [or her] duty to transmit these warnings to the patient.” (*Brown*, at p. 1062.) In such circumstances, “the patient has a claim against the doctor, but not against the manufacturer.” (2 Dobbs, *The Law of Torts* (2d ed. 2011) § 466, p. 959 (Dobbs on Torts).)

The learned intermediary doctrine recognizes that, “[w]hile the ‘ordinary consumer’ may have a reasonable expectation that a product such as a machine he [or she] purchases will operate safely when used as intended, a patient’s expectations regarding the effects of [a prescription] drug [or medical device] are those related to him [or her] by his [or her]

physician, to whom the manufacturer directs the warnings regarding the drug’s [or medical device’s] properties.” (*Brown, supra*, 44 Cal.3d at pp. 1061–1062.) “[P]atients are generally persons unlearned in the medical sciences” and, therefore, have “an abject dependence upon and trust in [their] physician[s] for the information upon which [they] rel[y]” when deciding on a particular course of treatment. (*Cobbs, supra*, 8 Cal.3d at p. 242.) Unlike the patient, the physician has medical expertise which enables him or her to “understand the significance of the risks involved and to assess the relative advantages and disadvantages” of a particular treatment. (Rest.3d Torts, Products Liability, § 6, com. b, p. 146.) The physician thus acts as a learned intermediary between the manufacturer and the patient by recommending a course of treatment based not only on the warnings relayed by the manufacturer, but also on the physician’s own medical training and experience as well as the patient’s particular needs and risk factors. (*Ibid.*)

The doctrine does not create an immunity from a prescription drug or medical device manufacturer’s general duty of care owed to patients, however. Pursuant to the doctrine, the manufacturer fulfills its general duty of care owed to the patient by providing an adequate warning to the patient’s physician. If the manufacturer fails to provide an adequate warning to the patient’s physician, then the patient may sue asserting negligence for breach of its general duty of care or asserting strict liability for marketing a product that has been rendered defective due to the inadequate warning. (See *Brown, supra*, 44 Cal.3d at p. 1069, fn. 12; accord, *Dobbs on Torts*, § 466, p. 959.) To succeed on a negligent failure-to-warn claim, the plaintiff has the burden to prove that “a reasonably prudent manufacturer would have known and warned about” the risk.

(*Carlin, supra*, 13 Cal.4th at p. 1112.) To succeed on a strict liability failure-to-warn claim, the plaintiff need only prove that the manufacturer “did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.” (*Ibid.*) Whether asserting a negligent or a strict liability failure-to-warn claim, the plaintiff must also establish that the manufacturer’s failure to warn “[was] a substantial factor in causing [the plaintiff’s] injury.” (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 69 (*Stevens*); accord, *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479.) Subsumed within the causation analysis are a number of inquiries, including whether the prescription drug or medical device is capable of causing the injury in anyone; whether the prescription drug or medical device caused the patient’s injury in particular; and whether the manufacturer’s failure to warn caused the patient to use the product. (See *Onglyza Product Cases* (2023) 90 Cal.App.5th 776, 781, fn. 3, 791; see also *Carlin*, at p. 1116; *Gall, supra*, 71 Cal.App.5th at p. 122; *Plenger, supra*, 11 Cal.App.4th at p. 362.)

In this case, Somatics assumed, solely for the purpose of its summary judgment motion, that Himes will be able to show that its ECT device caused the complained-of injury and that Somatics inadequately informed Himes’s physician of the risk of this injury. In addition, the Ninth Circuit already determined that “no reasonable juror could find that [Himes’s] physician would have altered his decision to prescribe the treatment.” (*Himes, supra*, 29 F.4th at p. 1126.) The Ninth Circuit, however, found that there is a genuine dispute of material fact as to whether Himes’s physician “would have learned of stronger

warnings and communicated them to Himes.” (*Ibid.*)¹ We therefore address here only whether a plaintiff may establish causation by showing that, had the manufacturer provided an adequate warning to the patient’s physician, the physician would have relayed the warning to the patient and an objectively prudent person in the patient’s position would have rejected the treatment, notwithstanding the fact that the patient’s physician still would have recommended the treatment. We do not decide whether a plaintiff may establish causation through other means or based on circumstances not encompassed within the Ninth Circuit’s certified question. We also note that, regardless of how we resolve the causation question at issue here, Himes will still need to prove that Somatics’s ECT device caused her injury and that Somatics was required to and failed to adequately inform Himes’s physician of the risk of this injury to prevail on her failure-to-warn claim.

Himes attempts to bypass the causation question at issue by incorrectly framing the learned intermediary doctrine as either a defense or an exception to a manufacturer’s usual duty to warn the end user directly of the risks involved in using

¹ At oral argument, Somatics’s counsel asserted that the Ninth Circuit erred on this point, claiming that the undisputed facts show that Himes’s physician never read any of the informational materials Somatics sent to him. Counsel further argued that, where the evidence shows that a physician would not have read a stronger manufacturer warning, this breaks the causal chain. It is not our role, however, to resolve issues of fact upon review of a certified question of law. (*Vu v. Prudential Property & Casualty Ins. Co.* (2001) 26 Cal.4th 1142, 1153 (*Vu*.) Moreover, the legal question of whether the causal chain is broken where a physician testifies that he or she would not have read or otherwise been alerted to a stronger warning is outside of the scope of the certified question before us.

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consumer products. In doing so, Himes claims that if a manufacturer fails to provide an adequate warning to the physician, then the doctrine is rendered inapplicable, and the manufacturer must warn the patient directly. Himes further asserts that because Somatics failed to warn her physician, Somatics should have warned her directly of the risks of ECT and she need not prove that the failure to warn her physician caused her injury.

The Ninth Circuit rightly rejected this argument in its unpublished memorandum accompanying its certification order. (*Himes v. Somatics, LLC* (9th Cir., Mar. 7, 2022, No. 21-55517) 2022 WL 989469, p. *1.) As the recent appellate court decision in *Amiodarone Cases* (2022) 84 Cal.App.5th 1091 correctly held, the learned intermediary doctrine is neither a defense nor an exception to a traditional duty rule, and it does not cease to apply where a plaintiff alleges that a manufacturer failed to provide an adequate warning to the patient’s physician. (*Id.* at 1104–1106.) It instead “defines the scope of a manufacturer’s duty to warn in context of prescription drugs” or medical devices (*id.* at p. 1104) by providing that the manufacturer’s “duty to warn runs *to the physician*, not to the patient” (*Carlin, supra*, 13 Cal.4th at p. 1116). If the manufacturer fails in its duty to adequately warn a physician of the non-negligible risks associated with its prescription drugs or medical devices, the manufacturer’s duty to warn the physician does not transform, retroactively, into a duty to warn the patient. (*Amiodarone Cases*, at p. 1106.) Instead, the manufacturer’s failure to warn the patient’s physician results in a breach of its general duty of care to the patient under negligence principles or a breach of its obligation to market a product free from defects under strict liability principles. The patient may seek to hold the

manufacturer liable by showing that the breach caused the patient's injury. (*Brown, supra*, 44 Cal.3d at p. 1069, fn. 12; accord, Dobbs on Torts, § 466, p. 959.)

Himes's assertion that, absent a warning to her physician, Somatics had a duty to warn her directly of the risks of ECT is inconsistent with a fundamental principle underlying the learned intermediary doctrine. As the Courts of Appeal have repeatedly recognized, an ordinary patient like Himes has "no way to evaluate" the "highly technical information" provided by the manufacturer, and her unmediated response to such information may "jeopardiz[e] [her] life." (*Carmichael v. Reitz* (1971) 17 Cal.App.3d 958, 989 (*Carmichael*); accord, *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 319; *Plenger, supra*, 11 Cal.App.4th at p. 362, fn. 6; *Fogo v. Cutter Laboratories, Inc.* (1977) 68 Cal.App.3d 744, 754.) For this reason, "[t]he law and medical ethics both demand that doctors, for their patients' benefit, evaluate scientific information about prescription drugs and [many medical devices]" (*Gall, supra*, 71 Cal.App.5th at p. 122) and relay any material information to their patients (*Cobbs, supra*, 8 Cal.3d at p. 245). Thus, the "absence of an adequate warning about a prescription drug [or medical device] to a physician" does not "result in a duty to provide a warning to the patient." (*Amiodarone Cases, supra*, 84 Cal.App.5th at p. 1106.)

The cases on which Himes relies do not hold otherwise. Most of the decisions Himes cites stand for the unremarkable principle that, where a manufacturer gives adequate warnings to a physician, it fulfills its duty to warn and does not need to ensure that the warning reaches the patient. (*Carlin, supra*, 13 Cal.4th at p. 1116; *Stevens, supra*, 9 Cal.3d at p. 65; *Brown, supra*, 44 Cal.3d at p. 1062; *Carmichael, supra*, 17 Cal.App.3d at p. 994; *Love v. Wolf* (1964) 226 Cal.App.2d 378, 395.) And

while the court in *Hill v. Novartis Pharmaceuticals Corp.* (E.D.Cal. 2013) 944 F.Supp.2d 943 claimed that the learned intermediary doctrine “ ‘applies only if a manufacturer provided adequate warnings to the intermediary’ ” (*id.* at p. 953), it quoted *Stewart v. Union Carbide Corp.* (2010) 190 Cal.App.4th 23 for this principle — a decision involving the distinct sophisticated intermediary doctrine and which we disapproved of on this very point. (*Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167, 188.)

We accordingly reject Himes’s assertion that Somatics had a duty to warn her directly of the risks of ECT and turn to the Ninth Circuit’s certified question regarding causation.

B. Causation

It is well settled that a plaintiff must prove the failure to warn was a substantial factor in causing the injury. (*Stevens, supra*, 9 Cal.3d at p. 69.) The substantial factor causation standard “ ‘subsumes the “but for” test,’ ” under which “the plaintiff must prove that, *but for* the alleged negligence, the harm would not have happened.” (*Viner v. Sweet* (2003) 30 Cal.4th 1232, 1239.) But it also “reach[es] beyond” the “ ‘but for’ test . . . to satisfactorily address other situations, such as those involving independent or concurrent causes in fact.” (*Rutherford v. Owens-Illinois, Inc.* (1997) 16 Cal.4th 953, 969.) It is a “relatively broad” standard, “requiring only that the contribution of the individual cause be more than negligible or theoretical.” (*Id.* at p. 978.) The question posed by the Ninth Circuit does not involve any alleged independent or concurrent causes of Himes’s injury, and so we focus on how Himes may be able to prove that, but for Somatics’s failure to warn her physician, Himes would not have been injured.

The Ninth Circuit asks whether Himes is required “to show that a stronger risk warning would have altered the physician’s decision to prescribe the product,” or whether she may instead establish causation “by showing that the physician would have communicated the stronger risk warning[] 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, supra*, 29 F.4th at p. 1127.) We hold that a plaintiff may establish causation by showing that the physician would have communicated the stronger warning to the patient and an objectively prudent person in the patient’s position would have thereafter declined the treatment notwithstanding the physician’s continued recommendation of the treatment.

Somatics argues that a plaintiff must show that the patient’s physician would have changed his or her prescribing decision to establish causation. In Somatics’s view, the patient’s own decision as to whether to accept the recommended treatment is irrelevant, meaning that if the patient’s physician testifies that he or she would not have changed his or her prescribing decision, then there can be no liability. Somatics believes its view of causation best aligns with the learned intermediary doctrine given the doctrine’s recognition that patients generally rely on their physicians’ medical expertise when deciding on a particular course of treatment. (*Gall, supra*, 71 Cal.App.5th at p. 122; see also *Cobbs, supra*, 8 Cal.3d at p. 242.) According to Somatics, the doctrine assumes patients’ reliance on physicians because a patient has no way to evaluate “highly technical information” on the risks associated with drugs or medical devices and “might actually object” to using a

drug or medical device even where the patient's life is in danger. (*Carmichael, supra*, 17 Cal.App.3d at p. 989.)

We cannot wholly discount the essential role of patient choice in medical treatment decisions, however. Although we have long acknowledged that patients have “an abject dependence upon and trust in [their] physician[s] for the information upon which [they] rel[y]” (*Cobbs, supra*, 8 Cal.3d at p. 242), we have also emphasized that “the decision whether or not to undertake treatment is vested in the party most directly affected: the patient” (*id.* at p. 244). Our informed consent rule thus requires physicians to disclose to their patients “the risks inherent in the procedure [they are] prescribing, the risks of a decision not to undergo the treatment, and the probability of a successful outcome of the treatment.” (*Id.* at p. 243.) But once the physician discloses this information, it is “reserved to the patient alone” to weigh the disclosed risks against the patient's own “fears and hopes” in deciding whether to undergo the recommended treatment. (*Ibid.*) Implicit in our informed consent rule is the recognition that patients will sometimes opt out of the medical treatments their physicians recommend, as is their right. (See *id.* at p. 245 [casual connection between physician's failure to obtain informed consent and injury arises “if it is established that had revelation been made consent to treatment would not have been given”].) If Somatics were correct that the physician's prescribing decision is all that matters, and the patient's own decision as to whether to undergo the treatment after having learned of the risks is irrelevant, then there would be no need for the informed consent rule.

Like our informed consent jurisprudence, the learned intermediary doctrine affirms patient autonomy in medical treatment decisions. The doctrine's rationale is that warnings

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pertaining to prescription drugs and medical devices should be relayed to patients by their physicians — rather than by the manufacturer — because physicians are in a better position to assist patients in deciphering and evaluating the warnings. (Rest.3d Torts, Products Liability, § 6, com. b, p. 146.) The underlying goal is to adequately inform patients of material risks so that they can make “an informed choice as to therapy.” (*Ibid.*) Stated differently, by ensuring that physicians will assist patients in understanding manufacturer warnings relating to material risks and in balancing those risks against the benefits of treatment, the doctrine enables patients to make intelligent treatment decisions.

We have previously indicated that the patient’s role in deciding his or her own course of treatment does not disappear in the context of the learned intermediary doctrine. Specifically, in *Finn v. G. D. Searle & Co.* (1984) 35 Cal.3d 691, we suggested that a jury might be able to find causation in the context of a manufacturer’s failure to warn the plaintiff’s physician of the dangers of a certain drug if the jury determined that, had the physician been warned, the physician “would have (or should have) refrained from prescribing the drug, *or th[e] plaintiff would have refrained from taking it.*” (*Id.* at p. 702, italics added.) While not binding on us, we also find persuasive other courts’ observations that the learned intermediary doctrine does not “allow health care professionals to substitute their judgment for that of their patients.” (*Gilliland v. Novartis Pharmaceuticals Corp.* (S.D. Iowa 2014) 34 F.Supp.3d 960, 972 (*Gilliland*)). Nor does it “assume[] that a doctor will issue a prescription” to “an informed patient who is unwilling to risk a medical product’s side effects.” (*Hrymoc v. Ethicon, Inc.* (Super.Ct.App.Div. 2021) 467 N.J.Super. 42, 90 [249 A.3d 191,

220], *affd. as mod.* (2023) 254 N.J. 446 [297 A.3d 1245] (*Hrymoc*.) Thus, the doctrine does not “obviate the need to consider whether the plaintiff-patient’s decision concerning her recommended course of treatment would have been different, assuming that the warning at issue had been more adequate” and was deemed material enough to be passed along to the patient by the physician. (*Gilliland*, at p. 972.)²

That said, our holding does not remove the physician’s expertise from consideration in the causation analysis. Instead, our holding takes into account the essential role of the physician’s recommendation in the patient’s treatment decision. The learned intermediary doctrine recognizes that patients are often influenced by their physician’s treatment recommendations and that a physician may be able to assuage a patient’s fears or persuade the patient that the benefits of treatment outweigh any risks. (See *Brown, supra*, 44 Cal.3d at p. 1061.) The causation analysis must accordingly consider whether an objectively prudent person in the patient’s position would have declined the treatment even where his or her physician would have advised the patient that the treatment would still be in the patient’s best interests, notwithstanding the risks conveyed by a stronger warning. Because our holding acknowledges the role of both the physician and the patient in medical treatment decisions, it comports with the learned intermediary doctrine’s recognition that treatment decisions are

² We caution that other states’ requirements for proving a failure-to-warn claim in the context of the learned intermediary doctrine may differ from California law, and our citation to extra jurisdictional cases or secondary sources in this opinion does not constitute an endorsement of all statements of law set forth in those authorities.

made collaboratively by patients and their physicians, and the physician acts as an “intermediary” who helps the patient in appreciating and weighing the benefits and risks of treatment. Indeed, the very premise of the doctrine is that the physician will assist the patient in understanding material information conveyed by the warning “so that the patient can make an informed choice as to therapy.” (Rest.3d Torts, Products Liability, § 6, com. b, p. 146.)

But as another court aptly observed, “no one disputes that it is up to the individual patient to decide whether to undergo a given treatment therapy” (*Gilliland, supra*, 34 F.Supp.3d at p. 972, fn. 21), and we therefore cannot presume that an objectively prudent person in the patient’s position will follow the physician’s treatment recommendations in all circumstances. (See also *Payne, supra*, 767 F.3d at p. 532 [causation in both informed consent and failure-to-warn cases “ultimately rests with the patient’s decision to take or reject the medication”]; *Hrymoc, supra*, 249 A.3d at p. 220 [“[T]he ‘prescribing decision’ . . . logically entails . . . a patient’s assent to follow that recommendation” and “it should not be assumed that a doctor will issue a prescription [to] an informed patient who is unwilling to risk a medical product’s side effects”].) Although the learned intermediary doctrine provides that a manufacturer has no duty to warn the patient directly of the risks inherent to its prescription drugs or medical devices, it does so with the understanding that the physician is best positioned to communicate any material risks conveyed by the warning to the patient. The doctrine does not stand for the principle that, once the manufacturer breaches its duty to warn the physician, the patient’s medical treatment decisions become irrelevant to the causation analysis. To conclude otherwise

“would frustrate the purpose of the learned intermediary rule, which is to enable patients to make informed and intelligent decisions whether to undergo a recommended therapy by balancing the probable risks against the probable benefits of the course of treatment proposed by their physicians.” (*Gilliland*, at p. 972.) In sum, under the learned intermediary doctrine, the physician’s judgment and advice remains central to the causation analysis, but the ultimate decision of whether to go forward with the treatment resides with the patient.

Somatics contends that “a vast body” of out-of-state decisions hold that a plaintiff may prove causation only by showing that an adequate warning would have altered the physician’s decision to prescribe the prescription drug or medical device. While we rely in this opinion on several non-California decisions, the analysis of which we find to be persuasive (see *T.H.*, *supra*, 4 Cal.5th at p. 175), we disagree with Somatics that there exists a “near unanimity of agreement” regarding the particular issue before us (*Moradi-Shalal v. Fireman’s Fund Ins. Companies* (1988) 46 Cal.3d 287, 298). A few decisions from other states’ supreme courts suggest that a plaintiff must prove that an adequate warning would have altered the physician’s prescribing decision, but none of these decisions expressly considered Himes’s theory of causation. (*Janssen Pharmaceutica, Inc. v. Bailey* (Miss. 2004) 878 So.2d 31, 58; *Strumph v. Schering Corp.* (N.J. 1993) 626 A.2d 1090, adopting dissent issued in *Strumph v. Schering Corp.* (N.J.App.Div. 1992) 606 A.2d 1140, 1148 (dis. opn. of Skillman, J.); *Seley v. G. D. Searle & Co.* (1981) 67 Ohio St.2d 192, 201 [423 N.E.2d 831, 838–839].) Other state supreme court decisions appear to suggest that the causation question is not limited to determining whether the warning would have altered

the physician's prescribing decision. For example, Somatics relies on *Centocor, Inc. v. Hamilton* (Tex. 2012) 372 S.W.3d 140, but this decision could be read as supporting Himes's view. In *Centocor*, the Texas Supreme Court found causation lacking both because there was "no evidence that [the patient's] prescribing physicians *or* [the patient] would have acted differently had [the manufacturer] provided a different warning." (*Id.* at p. 171, italics added.) The court explained that the patient's actions indicated "she would likely have continued" treatments even if she had been warned of the risk. (*Id.* at p. 173.) The court in *Centocor* also cited approvingly to *McNeil v. Wyeth* (5th Cir. 2006) 462 F.3d 364, wherein the Fifth Circuit held that, "[w]here the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, *and where the plaintiff would have rejected the drug if informed*, the inadequate labeling could be a 'producing' cause of the injury, because it effectively sabotages the function of the intermediary." (*Id.* at p. 373, italics added; see also *Centocor*, at p. 170.) This suggests that the Texas Supreme Court considered the patient's decision as to whether to undergo the recommended treatment to be relevant to the causation analysis. The Utah Supreme Court's decision in *Barson v. E.R. Squibb & Sons, Inc.* (Utah 1984) 682 P.2d 832 similarly suggests that causation may not be limited to the prescribing doctor's decision. There, the court found sufficient evidence for a "jury to conclude that had [a] . . . proper warning been given" the plaintiff would not have injected the drug, based in part on the plaintiff's testimony that "she had expressed strong concern over taking any drugs during her pregnancy, but allowed the [drug] injections after being assured by [her doctor] that they

were safe.” (*Id.* at p. 836.) The remaining states’ supreme courts have simply not had occasion to consider the causation question before us.

Somatics fares no better by pointing to federal decisions applying state law. Somatics relies, for example, on *Odom v. G.D. Searle & Co.* (4th Cir. 1992) 979 F.2d 1001, but in *Odom* causation was lacking because the physician had independent knowledge of the risk, such that a stronger manufacturer warning regarding the risk would not have changed the physician’s conduct in any manner — not even by motivating the physician to pass along the warning to the patient. (*Id.* at p. 1003.) Somatics additionally relies on *Sager v. Hoffman-La Roche, Inc.* (N.J.Super.Ct.App.Div., Aug. 7, 2012, No. A-3427-09T4) 2012 WL 3166630, but the court in *Sager* seems to have misinterpreted a Florida appellate court decision in determining that causation is established only by showing an adequate warning would have changed the physician’s prescribing decision. (See *id.* at pp. *16–*17.) The case on which *Sager* relied, *Hoffmann-La Roche Inc. v. Mason* (Fla.Dist.Ct.App. 2009) 27 So.3d 75, in fact found that the inadequate warning could not be a cause of the patient’s injuries because the physician was already aware of the risk. (*Id.* at p. 77.) Thus, “the question of whether a different warning could have prevented the plaintiff’s injury in some manner other than by changing the physician’s decision to prescribe — e.g., by prompting the physician to pass along a more detailed warning, or to reduce the dosage — was not before the *Mason* court.” (*Guenther v. Novartis Pharmaceutical Corp.* (M.D.Fla. 2014) 990 F.Supp.2d 1299, 1304.) Finally, while several federal court decisions on which Somatics relies seem to focus on the physician’s prescribing decision, most do not consider whether

causation may also be established by showing a physician would have passed along a manufacturer's warning to the plaintiff and that an objectively prudent person in patient's position would have rejected the treatment based on the relayed warning. In *Wendell v. GlaxoSmithKline LLC* (9th Cir. 2017) 858 F.3d 1227, for example, the Ninth Circuit found evidence that a stronger warning would have influenced the physician's prescribing practices, and therefore had no need to consider an alternative theory of causation. (*Id.* at pp. 1238–1239.)

Indeed, only a few cases expressly reject Himes's theory of causation. Most of these decisions do not explain why causation must be limited to proving that the physician would have changed his or her prescribing decision in view of the stronger warning. (See, e.g., *Munoz v. American Medical Systems, Inc.* (C.D.Cal., Mar. 30, 2021, No. 220CV01640ODWJPRX) 2021 WL 1200038, p. *4; *Carnes v. Eli Lilly and Co.* (D.S.C., Dec. 16, 2013, No. CA 0:13-591-CMC) 2013 WL 6622915, p. *5; *Allain v. Wyeth Pharmaceuticals, Inc.* (N.D.Ala., Jan. 14, 2015, No. 2:14-CV-00280-KOB) 2015 WL 178038, p. *6.) The court in *Garrison v. Novartis Pharmaceuticals Corp.* (M.D.Ala. 2014) 30 F.Supp.3d 1325, for example, concluded without further elaboration that the physician's testimony that he would have passed a stronger warning along to the patient was irrelevant because the physician testified that he still would have prescribed the treatment notwithstanding the stronger warning. (*Id.* at p. 1336.) As another example, the court in *Stewart v. Boston Scientific Corp.* (S.D.W.Va., Oct. 6, 2015, No. 2:12-CV-03686) 2015 WL 5842762 reasoned that a plaintiff must prove the physician would have changed his or her prescribing decision because “ [i]t is *the physician* who is best situated to weigh the potential risks associated with a [product] against the possible

benefits of the [product] and the unique needs and susceptibilities of each patient.’” (*Id.* at p. *6.) This reasoning, however, merely restates the rationale underpinning the learned intermediary doctrine’s rule that the manufacturer’s duty to warn runs only to the physician. It does not explain why proof of causation must hinge on the physician’s prescribing decision to the exclusion of the patient’s own independent decision regarding whether to consent to the recommended treatment. We find more persuasive the out-of-state authority that takes into consideration, at least in some manner, the role of the patient in the medical treatment decision. (See, e.g., *Thacker v. Ethicon, Inc.* (6th Cir. 2022) 47 F.4th 451, 461; *Payne, supra*, 767 F.3d at pp. 531–532; *In re Prempro Products Liability Litigation* (8th Cir. 2009) 586 F.3d 547, 569–570; *Toole v. McClintock* (11th Cir. 1993) 999 F.2d 1430, 1433; *Gilliland, supra*, 34 F.Supp.3d at p. 972; *Mongeon v. Ethicon, Inc.* (D.Mass. 2020) 456 F.Supp.3d 298, 303; *Fields v. Eli Lilly and Co.* (M.D.Ala. 2015) 116 F.Supp.3d 1295, 1308–1309.) We accordingly reject Somatics’s assertion that “causation turns only on the physician’s prescription decision.”

At the same time, we recognize that patients often rely on their physician’s expertise and judgment in making medical treatment decisions, and so the causation analysis should take into consideration any evidence about what the physician would have communicated to the patient regarding the treatment and the allegedly undisclosed risks, including any evidence that the patient’s physician would have still recommended the treatment even if the manufacturer had provided an adequate warning of the alleged risks. As amici curiae California Medical Association, California Dental Association, and California Hospital Association observe, medical treatment decisions are

made jointly by the physician and the patient after together discussing and weighing the relevant risks and benefits of treatment. The learned intermediary doctrine itself recognizes that patients are often influenced by their physician's treatment recommendations and that a physician may be able to assuage a patient's fears or persuade the patient that the benefits of treatment outweigh any risks. (See *Brown, supra*, 44 Cal.3d at p. 1061.) For this reason, the causation analysis cannot hinge solely on whether the risk conveyed in a hypothetical warning would have altered the physician's assessment to such a degree that the physician would no longer recommend the treatment for the patient. But it also cannot turn solely on how the patient alone would have responded to the risk disclosed in the hypothetical stronger warning. This is because the risk of any hypothetical stronger warning would not have been conveyed directly to the patient. Instead, it would have been communicated to the patient by his or her physician who would have utilized his or her medical expertise to assess the risk and to recommend a course of treatment for the patient based on that assessed risk. When discussing the recommended treatment, physicians assist the patient by contextualizing any risks based on the patient's medical circumstances and needs; trying to alleviate the patient's fears regarding the risks; describing the risks and benefits of other possible treatments; distilling any studies and medical literature related to the treatment decision; and explaining the reasons why the physician believes the recommended treatment is the best option for the patient despite the risks. This is the physician's function as an intermediary because, as the learned intermediary doctrine recognizes, if the warning were conveyed to the patient directly by the manufacturer, the patient might

be inclined to reject even beneficial treatment. (*Carmichael, supra*, 17 Cal.App.3d at p. 989.) The causation analysis should therefore begin by determining what, if anything, the patient’s physician would have communicated to the patient regarding the relative risks and benefits of the prescription drug or medical device in response to a stronger warning, and should then turn to whether an objectively prudent person in the patient’s position would have declined the treatment even where the evidence shows that the physician’s treatment recommendation would have been unchanged by the stronger warning. In other words, the plaintiff must prove that an objectively prudent person in the patient’s position would have declined treatment *despite* the physician’s assessment that the benefits of the treatment for the patient would still outweigh any risks disclosed by a stronger warning.³

Somatics asks us to find “as a matter of law” that “an objectively prudent person would not refuse last-resort, life-saving treatment because of a small risk of side effects.” Somatics explains that Himes suffered from severe depression and suicidal ideation, her physicians had previously prescribed nine different antipsychotics and antidepressants that failed to alleviate her depression, and Dr. Fidaleo prescribed ECT — a “long-established medical procedure used at the nation’s top hospitals to treat serious mental health issues” — in a “last resort” effort “to save [her] life.” Somatics further asserts that “[n]o objectively prudent person would refuse a prescribed treatment where (1) the patient is facing a serious risk of death,

³ We do not address how a physician’s negligence in reading the manufacturer’s warnings, communicating the risks, or prescribing the treatment to a patient might affect this analysis.

(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.” It is not for us to decide, however, whether Somatics’s view of the facts is correct or whether an objectively prudent person in the patient’s position might reasonably decline the recommended treatment under such circumstances. “Our role here is limited to setting out general principles of California law for the assistance of the Ninth Circuit. The application of these principles of law to the specific facts of [the] case is a matter for the federal judiciary.” (*Vu, supra*, 26 Cal.4th at p. 1153.) Nevertheless, for the purpose of providing guidance, we observe that the facts Somatics raises, if true, will certainly be relevant to the causation analysis. That is, relevant factors that should be considered in determining whether an objectively prudent patient would have declined physician-recommended treatment include, but are not necessarily limited to, whether the physician weighed and assessed the risks and benefits of the treatment and, after discussing those risks and benefits with the patient, continued to recommend the treatment; whether the treatment was novel or was instead an established method for addressing the patient’s condition; the availability and utility of alternative treatments and the degree to which they have previously been tried in an effort to address the patient’s condition; the severity of the patient’s condition; and the likelihood that the treatment would have resulted in more than marginal benefits to the patient.

In addition, personal characteristics of the patient or circumstances unique to the patient should be taken into account when applying the objectively prudent person in the patient’s position standard. Informed consent cases illustrate how such characteristics or circumstances might be considered.

In *Wilson v. Merritt* (2006) 142 Cal.App.4th 1125, for example, the plaintiff was a paraplegic “who had been largely paralyzed by a prior surgery and was dependent upon the use of his arms and shoulders for any mobility at all, and who, at that point, had already achieved about a 20 percent improvement . . . based on physical therapy alone.” (*Id.* at p. 1139.) Given the plaintiff’s unique medical circumstances and prior treatment history, the court found that there was sufficient evidence for a jury to conclude that an objectively prudent person in the patient’s position would have declined the recommended procedure — manipulation of his shoulder under anesthesia — if the patient had known it could result in a torn rotator cuff and a fractured bone. (*Ibid.*) As another example, in *Daum v. SpineCare Medical Group, Inc.* (1997) 52 Cal.App.4th 1285 there was sufficient evidence for a jury to find that an objectively prudent person in the patient’s position would have declined an experimental surgery had the patient been warned of the risks, particularly given that the plaintiff had previously taken a conservative approach to surgery and other treatment options were available. (*Id.* at p. 1312.) Ultimately, we recognize that it may well be a rare case in which an objectively prudent person in the patient’s position would decline treatment even when the physician recommends it and believes it to be a last resort treatment necessary to save the patient’s life. Nevertheless, we do not decide whether this matter presents such a rare case, as this is an issue for the federal courts to resolve.

Himes asserts that causation in this context should not be determined by how an objectively prudent person in the patient’s position would have reacted to a stronger warning communicated by patient’s physician, and that we should instead find that causation is established by the patient’s

subjective testimony that he or she would have declined the treatment in response to the warning. The Ninth Circuit correctly rejected this argument. (*Himes v. Somatics, LLC, supra*, 2022 WL 989469, at p. *3, fn. 3.) As the Ninth Circuit observed, we held in *Cobbs* that “an objective test” — measured by “what would a prudent person in the patient’s position have decided if adequately informed of all significant perils” — “is preferable” in the context of medical treatment decisions because by “the time of trial the uncommunicated hazard has materialized.” (*Cobbs, supra*, 8 Cal.3d at p. 245.) If a subjective test were used, a plaintiff could simply offer self-serving testimony asserting that he or she would have declined the recommended treatment after being informed of the risks. (*Ibid.*) Subjectively, the plaintiff may believe this to be true “with the 20/20 vision of hindsight, but we doubt that justice will be served by placing the [defendant] in jeopardy of the patient’s bitterness and disillusionment.” (*Ibid.*)

Himes urges us to limit the objective standard to medical malpractice claims against patients’ physicians, and to not extend it to failure-to-warn claims against prescription drug or medical device manufacturers. We decline to limit the objective standard in the way Himes suggests. Our observation in *Cobbs* that a subjective standard is prone to hindsight bias applies in failure-to-warn claims against manufacturers of prescription drugs or medical devices, just as it does in informed consent cases against physicians. (See *Cobbs, supra*, 8 Cal.3d at p. 245.) The court in *Canterbury v. Spence* (D.C. Cir. 1972) 464 F.2d 772, which we relied on in *Cobbs* in adopting the objective standard, explained that a subjective standard “places the factfinder in the position of deciding whether a speculative answer to a hypothetical question is to be credited” and “calls for a subjective

determination solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk.” (*Id.* at p. 791.) An objective standard is preferable because, though the plaintiff’s testimony would remain relevant, “it would not threaten to dominate the findings” and would “be appraised congruently with the factfinder’s belief in its reasonableness.” (*Ibid.*) The objective standard thereby “ease[s] the fact-finding process and better assure[s] the truth as its product.” (*Ibid.*) An objective standard is particularly useful in cases in which the plaintiff is unable to testify, perhaps because the patient has passed away or is incompetent.

Moreover, even assuming, as Himes asserts, that a subjective standard of causation applies in other failure-to-warn cases involving consumer products,⁴ the learned intermediary doctrine recognizes that decisions regarding whether to take a prescription drug or medical device are different from decisions regarding whether to buy or use a consumer product. Consumers may reasonably expect consumer products to be safe when used as intended, but “a patient’s expectations regarding the effects of [a prescription] drug [or medical device] are those related to him [or her] by his [or her] physician.” (*Brown, supra*, 44 Cal.3d at p. 1061.) In addition, whereas consumer products are generally used for personal convenience or pleasure, prescription drugs and medical devices are often necessary to ensure the health of the patient. Physicians accordingly do not discuss the risks of treatment in isolation, but rather discuss them alongside the benefits of treatment as well as the risks of

⁴ We herein adopt an objective causation standard only in the context of failure-to-warn claims involving prescription drugs or medical devices, and we express no view on whether it might apply to other failure-to-warn claims.

foregoing treatment altogether. A subjective standard that relies on the plaintiff's postinjury assessment regarding how he or she would have reacted to the warning in isolation would not only be prone to hindsight bias, it would also fail to take into account the context in which the risks of prescription drugs and medical devices are discussed with patients as well as patients' general reliance on the treatment recommendations of their physicians. The objective standard incorporates the physician's role in the treatment decision by asking not whether the plaintiff subjectively believes, in hindsight, that he or she would have declined to use the drug or medical device in light of a stronger warning, but rather whether an objectively prudent person in the patient's position would have refused the treatment even though his or her physician would have still recommended the treatment. We therefore conclude that the Ninth Circuit was right to adopt the objectively prudent person in the patient's position test set forth in *Cobbs*.

III. CONCLUSION

In conclusion, we answer the Ninth Circuit's certified question as follows: A plaintiff is not required to show that a stronger warning would have altered the physician's decision to prescribe the product to establish causation. A plaintiff may instead establish causation by showing that the physician would have communicated the stronger warning to the patient and an objectively prudent person in the patient's position would have thereafter declined the treatment notwithstanding the physician's continued recommendation of the treatment.

HIMES v. SOMATICS, LLC
Opinion of the Court by Groban, J.

GROBAN, J.

We Concur:

GUERRERO, C. J.

CORRIGAN, J.

LIU, J.

KRUGER, J.

JENKINS, J.

EVANS, J.

See next page for addresses and telephone numbers for counsel who argued in Supreme Court.

Name of Opinion Himes v. Somatics, LLC

Procedural Posture (see XX below)

Original Appeal

Original Proceeding XX on request by 9th Circuit (Cal. Rules of Court, rule 8.548)

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