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VIA CM/ECF

April 21, 2022

Supreme Court of California
350 McAllister Street
San Francisco, CA 94102-4797

Re: *Himes v. Somatics, LLC,* No. S273887*,* On Certification from the U.S. Court of Appeals for the Ninth Circuit

LETTER RE: CERTIFIED QUESTION PER RULE OF COURT 8.548(e)

To the Honorable Justices of the Supreme Court of California:

Somatics, LLC ("Somatics") is the Defendant-Appellee in the above-referenced case pending before the United States Court of Appeals for the Ninth Circuit. On April 1, 2022, the Ninth Circuit issued an Order requesting that this Court decide a question of California law that could determine the outcome of the case. In accordance with California Rule of Court 8.548(e), Somatics writes in support of the Ninth Circuit's request but urges this Court to slightly restate the certified question in order to ensure that the answer will fully resolve this case and provide clear guidance to future litigants.

I. Background

This appeal addresses the scope of a plaintiff's burden of proof under California's learned intermediary doctrine, which "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship." *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187 n.10 (2016). The doctrine recognizes that a healthcare patient relies on the medical judgment of a learned intermediary—a physician—in deciding whether to use a prescribed medical product. In light of this reliance, a manufacturer's "duty to warn runs *to the physician,* not to the patient," as the "patient's expectations regarding the effects of [the prescribed medical product] are those related to him by his physician." *Carlin v. Superior Ct.*, 13 Cal. 4th 1104, 1116, 1118 (1996) (internal quotation marks omitted). Under California law, the physician "in reality stands in the shoes of the ordinary consumer," i.e., the patient, for purposes of the duty to warn. *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 n.6 (1992); *see Carlin*, 13 Cal. 4th at 1116.

As the Ninth Circuit has long recognized, under California's learned intermediary doctrine, "[a] plaintiff asserting causes of action based on a failure to warn must prove *not only* that [(1)] no warning was provided or the warning was inadequate, *but also* that [(2)] the inadequacy or absence of the warning caused the plaintiff's injury." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227,

1238 (9th Cir. 2017) (emphasis added) (internal quotation marks omitted).[1] This appeal requires a determination of how a plaintiff may satisfy that second requirement—which federal courts traditionally call the "proximate causation" requirement.

Many federal courts have held that, to prove proximate causation under California's learned intermediary doctrine, a plaintiff must "demonstrate that the inclusion of an adequate warning would have altered [the physician's] *decision to prescribe*." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004) (emphasis added); *see 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) ("Plaintiffs have provided no evidence that a different warning would have *altered the physicians' decisions to prescribe* . . . . Therefore, they cannot demonstrate the causation required to survive summary judgment under California's learned intermediary doctrine." (emphasis added)).[2]

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[1] *Cf. Ramirez v. Plough, Inc*., 6 Cal. 4th 539, 556 (1993) (requiring a "causal connection between the representations or omissions that accompanied the product and plaintiff's injury"); *Smith v. Lockheed Propulsion Co*., 247 Cal. App. 2d 774, 780 (1967) ("It is axiomatic that an essential element of a plaintiff's cause of action, whether based on negligence or strict liability, is the existence of a causal connection between defendant's act and the injury which plaintiff suffered.").

[2] *See also Guillen v. Eli Lilly & Co.*, 394 F. App'x 814, 816 (2d Cir. 2010) (under California law, summary judgment appropriate where plaintiff "has failed to demonstrate that her treating physicians would have altered their *decision to prescribe* [the drug at issue] had a different warning been provided by [the manufacturer]") (emphasis added); *Neal v. Eli Lilly & Co.*, 394 F. App'x 823, 825 (2d Cir. 2010) (same); *Misouria v. Eli Lilly & Co*., 394 F. App'x 825, 827 (2d Cir. 2010) (same); *Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1144 (S.D. Cal. 2016) ("In order to prove causation, a plaintiff must allege that the inadequate warning or lack of warning about the medical device risk would have *altered the prescribing physician's decision to use the product*." (emphasis added)); *In re Zyprexa Prods. Liab. Litig.*, 2009 WL 3596982, at *11 (E.D.N.Y. Oct. 20, 2009) (granting summary judgment where plaintiff "offered no evidence suggesting that his physicians would have *altered their prescription decisions* had [the defendant's] warning been different, as required under California's learned intermediary doctrine" (emphasis added)); *Brown v. Johnson & Johnson,* 2019 WL 2577296, at *8 (E.D. Cal. June 24, 2019), *report and recommendation adopted sub nom. Brown v. Johnson & Johnson, Inc*., 2019 WL 3943980 (E.D. Cal. Aug. 21, 2019) ("To demonstrate that the inadequate warning caused the plaintiff's injuries, the plaintiff must show a causal link between the warning label and *the physician's decision to prescribe the drug.*" (emphasis added)); *cf. Galinis v. Bayer Corp.*, 2019 WL 2716480, at *11 (N.D. Cal. June 28, 2019) (proximate causation established by physician's testimony that, had she been warned about a risk

In the instant case, Plaintiff-Appellant Michelle Himes ("Himes") brought California failure to warn claims against Somatics, a manufacturer of a medical device used to perform electroconvulsive therapy ("ECT") for individuals with severe mental illness. Himes claims that Somatics injured her by failing to provide an adequate warning that ECT carried a risk of brain injury including permanent memory loss and inability to form new memories. Himes claims that she suffered such an injury after receiving ECT as prescribed and administered by her physician Dr. Raymond Fidaleo.[3] 5-ER-1001; 6-ER-1212.[4]

During discovery in the District Court for the Central District of California, Dr. Fidaleo gave undisputed testimony that (1) he would have prescribed ECT to Ms. Himes even if he had received a warning of a risk of brain injury because (2) ECT was a last-resort measure to treat Himes's imminently life-threatening medical condition [redacted], as all other treatment options had failed and Himes [redacted]

Dr. Fidaleo was unequivocal that, because of Ms. Himes's otherwise-untreatable, life-threatening condition, which left her unable to function in daily life, a heightened warning of brain injury would not have stopped him from prescribing ECT and from urging Himes to undergo the treatment. *See* 5-ER-1013 ("It wouldn't stop me. You have to take the whole thing. All drugs and all things have memory loss. If you forgot your wedding date, but you knew how to function, I wouldn't consider that a reason not to give treatment.").

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of blood clots, she "'would not prescribe" the drug at issue and indeed stopped prescribing it to other patients "'as soon as [she] got this information'").

[3] The parties dispute whether ECT is capable of causing Himes's claimed injury, and this factual dispute precludes any determination of warning inadequacy as a matter of law. *See Carlin*, 13 Cal. 4th at 1116 (a key element of the warning adequacy inquiry is "whether any warning should have been given," as a manufacturer need not warn of a risk that is "merely speculative or conjectural, or so remote and insignificant as to be negligible"); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 932 (2004) ("a warning is not necessarily appropriate" for every risk, since "overwarning" of "very remote" risks can "crowd[] out necessary warnings") (internal quotation marks omitted)).

[4] This letter refers to Himes's excerpts of record as "ER" and refers to Somatics's supplemental excerpts of record as "SER."

Unable to offer evidence to dispute Dr. Fidaleo's testimony regarding his prescription decision, Himes offered her own testimony that, had Dr. Fidaleo mentioned the heightened warning of brain injury to her, she would have refused ECT when he prescribed it. She pointed to a portion of Dr. Fidaleo's testimony in which he stated that, had he been aware of a heightened warning, he would have mentioned it to Himes while still prescribing the treatment.

The District Court granted Somatics's motion for summary judgment, reasoning that Himes had failed to meet her proximate causation burden. The District Court agreed with other courts that, under California law, a plaintiff must offer evidence that a heightened warning would have *changed her physician's prescription decision* in order to prove that a failure to provide the physician with a heightened warning proximately caused the plaintiff's injury. Here, as it was undisputed that Dr. Fidaleo would have prescribed ECT even if provided with a heightened warning, Himes failed to meet her burden. 1-ER-3-10.

Himes appealed to the Ninth Circuit.

II. The Certified Question

On appeal to the Ninth Circuit, Somatics argued in support of the District Court's conclusion that, because the learned intermediary doctrine puts the physician in the shoes of the consumer for purposes of the failure to warn doctrine, relying on the physician as the learned intermediary who can interpret the complex risks and benefits of treatment, the proximate causation inquiry turns on whether a heightened warning would alter *the physician's decision to prescribe*. Himes, in contrast, argued that, even where it is undisputed that a heightened warning would have had no impact on the physician's decision to prescribe a medical product, a plaintiff may establish proximate causation solely through her own testimony, offered after the fact, that she would have refused prescribed treatment if the physician had relayed the warning to her.

The Ninth Circuit agreed with Somatics that the effect of a stronger warning could not be determined by a plaintiff's *subjective* post-hoc declaration. But the Ninth Circuit also recognized that the California Supreme Court had not issued a decision squarely addressing whether a plaintiff could establish proximate causation through evidence that, under an *objective* standard, a *prudent person in the plaintiff's position* would have refused prescribed treatment if informed of the risk. Accordingly, the Ninth Circuit certified 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?

III. Request for Acceptance and Restatement of the Certified Question

Somatics requests that this Court answer the certified question because the scope of a plaintiff's proximate causation burden under California's learned intermediary doctrine is an important question of law, impacting numerous litigants in failure to warn claims. *See* Cal. R. Ct. 8.548(f)(1) (in exercising its discretion as to whether to answer a certified question, the Court "may consider whether resolution of the question is necessary . . . to settle an important question of law").

However, Somatics also requests a slight restatement of the certified question. The Ninth Circuit's statement of the question is incomplete because one of two possible answers will leave an important ambiguity for future litigants and could, in the instant case, fail to fully clarify whether Dr. Fidaleo's undisputed testimony prevents Himes from meeting her proximate causation burden.

If this Court accepts the question and answers that the proximate causation inquiry turns only on the physician's decision to prescribe, then that answer will fully resolve this appeal. Somatics believes that that is the correct answer under California law. But if this Court accepts the question and answers it in favor of the plaintiff—holding that the learned intermediary acts more like a messenger than a learned intermediary, so that a plaintiff may establish proximate causation merely by showing that if a physician would have relayed a manufacturer's warning, and a prudent person in her position might refuse treatment prescribed by her physician—then California law will remain unclear as to whether undisputed evidence that the prescribed treatment is a *last-resort life-saving measure* precludes a reasonable juror from concluding that a prudent person in the plaintiff's position would refuse prescribed treatment.

As discussed below, Somatics respectfully urges this Court, if it chooses to accept the certified question, to adopt a proximate causation standard based on the physician's prescription decision alone. But if the Court accepts the certified question and instead endorses the "prudent person" approach, then Somatics requests that the Court clarify whether, as a matter of California law, a reasonable juror can conclude that a "prudent" person would refuse a prescribed last-resort life-saving treatment. It will be useful to future litigants to understand not just *whether* a plaintiff must show prudent refusal of prescribed treatment but also *how* the plaintiff must show prudent

refusal of prescribed treatment. Thus, Somatics asks this Court to restate the certified question as follows:

> 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? And, if the latter prudent person approach is acceptable, can a reasonable juror conclude that a prudent person would refuse prescribed treatment if the undisputed testimony shows that all other treatment options had been exhausted and the patient was facing a risk of death?

Any answer to this restated certified question will be dispositive in this case. The answer will clarify whether Himes has created a triable issue on proximate causation notwithstanding *both* (1) Dr. Fidaleo's undisputed testimony that he still would have prescribed ECT even if provided with a heightened warning *and* (2) Dr. Fidaleo's undisputed testimony that the treatment was a last-resort option for a health condition placing Himes at risk of death. By contrast, an answer to the original question as posed by the Ninth Circuit would be dispositive if this Court concludes that causation in a failure to warn case under the learned intermediary doctrine turns on whether the physician would have changed his prescribing decision on the basis of a heightened warning, but would *not* be dispositive if this Court concludes that causation in a failure to warn case under the learned intermediary doctrine can also turn on whether the patient would have refused treatment if a heightened warning was relayed by a physician.

IV. Request for Adoption of Proximate Causation Standard Focused on the Learned Intermediary's Prescription Decision

If the Court chooses to accept the certified question, Somatics respectfully urges the Court to adopt a proximate causation standard that focuses on the prescription decision of the learned intermediary, rather than on the patient's response to the prescription decision. A standard that focuses only on the prescription decision of the learned intermediary *already* incorporates the element of prudence because such a standard recognizes that a prudent patient will rely on a learned intermediary's judgment in deciding whether to use a medical treatment.

California courts have repeatedly stressed that physicians, rather than patients, are best suited to interpret warnings provided by the manufacturers of prescription medications and devices, and to balance the complex risks and benefits of treatment in the context of the particular patient. The physician, as the learned intermediary, uses highly specialized training and experience to make informed prescription decisions in the patient's best interest. The patient, by contrast, is vulnerable to uneducated fear-based decisions regarding prescription warnings, and may refuse treatment unwisely if attempting to interpret manufacturers' warnings without reliance on the physician's judgment. A *prudent* patient, therefore, relies on a physician's greater ability to weigh the risks and benefits of prescription treatments. *See, e.g.*, *Plenger*, 11 Cal. App. 4th at 362 n.6 ("The doctor is intended to be an intervening party in the full sense of the word. . . . . Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the [manufacturer's product], he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the [manufacturer's product], thereby jeopardizing his life." (internal quotation marks omitted)); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989 (Ct. App. 1971) (it is physicians who "in the exercise of their medical judgments decide to use" a manufacturer's product; patients have a "limited understanding" and "no way to evaluate" complex medical warnings (internal quotation marks omitted)); *see also Carlin*, 13 Cal. 4th at 1118 ("A patient's expectations regarding the effects of [a medical product] are those related to him by his physician." (internal quotation marks omitted)).

The Ninth Circuit has not expressly stated that a plaintiff bringing a California failure to warn claim against the manufacturer of a prescribed medical product can only show proximate causation through evidence that a heightened warning would alter the physician's decision to prescribe. However, every time the Ninth Circuit has previously analyzed whether a plaintiff has shown proximate causation, the analysis has focused *exclusively* on the absence or presence of evidence that medical professionals would have changed their prescribing decisions. *See Wendell*, 858 F.3d at 1238 (focusing the proximate causation inquiry on evidence that the physician would have changed his "prescribing decisions" by prescribing an alternative medication that lacked the same adverse health risks); *Latiolais v. Merck & Co.*, 302 F. App'x 756, 757 (9th Cir. 2008) (district court properly granted summary judgment where a physician testified that the manufacturer's warnings "did not play a role in his *decision to prescribe* that medication" (emphasis added); *see also Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004) (where the discovery record included evidence that a heightened warning of suicide risk would not have altered a physician's decision to prescribe, reasoning that, "[o]n the record adduced during discovery, [the plaintiff] failed to establish proof that stronger warnings would have changed her husband's medical treatment or averted his suicide").

The Ninth Circuit's prior approach of focusing on prescription decisions is workable and aligns with California case law recognizing that a prudent patient relies on a physician's

prescribing judgment because the physician, not the patient, is best suited to determine whether the health benefits of a treatment outweigh the risks. Accordingly, Somatics requests that this Court agree with the federal courts that have held that a plaintiff bringing a California failure to warn claim against a medical manufacturer must offer evidence that a heightened warning would have changed the *physician's decision to prescribe* the manufacturer's product.[5]

V. Request for, in the Alternative, Adoption of a Standard Recognizing that a Prudent Person Will Not Refuse Last-Resort Life-Saving Treatment

If this Court holds that a plaintiff may alternately establish proximate causation through evidence that a prudent person would refuse prescribed treatment, then Somatics respectfully requests that the Court also hold that, under California law, a reasonable juror cannot find that a prudent person would refuse a prescribed treatment that is a last-resort, life-saving measure. Where (1) all other treatment options have been exhausted, (2) the patient is facing a risk of death, and (3) a physician prescribes and urges the use of a medical treatment after concluding that its health benefits outweigh its risks, a prudent patient would follow the physician's guidance.

In the instant case, the record is clear that Himes was facing a risk of death [redacted], that she had exhausted all other treatment options, and that—even if Dr. Fidaleo had known of a risk of brain injury—he still would have prescribed ECT and urged Himes to engage in ECT in order to save her life. Specifically, Dr. Fidaleo's unrebutted testimony stated that, when he prescribed ECT to Ms. Himes, she was suffering from [redacted] Dr. Fidaleo noted that he had never previously seen a brain injury of Himes's

[5] As noted above, the Second Circuit, interpreting California law, has come to the same conclusion. *See Guillen*, 394 F. App'x at 816 (under California law, summary judgment appropriate where plaintiff "has failed to demonstrate that her treating physicians would have altered their *decision to prescribe* [the drug at issue] had a different warning been provided by [the manufacturer]") (emphasis added); *Neal*, 394 F. App'x at 825 (same); *Misouria*, 394 F. App'x at 827 (same).

claimed severity occur in his years of practice. *See* 5-ER-1014-1015 ("I would have to see it also myself. . . . [Y]ou go by what you see clinically. . . . I don't see that. . . . I would be seeing that myself and I'm not seeing that with my patients.").

To assess whether a prudent person in Himes's position would refuse prescribed treatment, a juror would need to consider these full factual circumstances of Himes's "position":

- the prior exhaustion of other treatment options;
- the clear risk of imminent death, as evidenced by [redacted];
- the clear risk of [redacted];
- a loss of daily functionality, resulting in dire personal consequences including [redacted];
- Dr. Fidaleo's urging and recommendation of the treatment based on an educated and experience-driven analysis of the healthcare benefits and risks; and
- Dr. Fidaleo's assurance that no other patient of his had ever experienced the brain injury described in the heightened warning.

Even if some irrationally fear-driven patients would refuse prescribed treatment under such circumstances due to their "limited understanding," *Plenger*, 11 Cal. App. 4th at 362 n.6, no reasonable juror could find that a *prudent* patient—i.e., one not affected by [redacted]—would refuse prescribed treatment under such circumstances.

Accordingly, if this Court elects to answer the certified question, and if it concludes that failure-to-warn causation in the learned intermediary prescription context can be satisfied merely by a physician's testimony that he would have conveyed a heightened warning while still recommending the prescription, combined with evidence that a prudent person in the patient's position would refuse prescribed treatment, then Somatics respectfully urges this Court to determine whether, as a matter of law, a reasonable juror could conclude that a prudent person would refuse prescribed treatment that is a last-resort, life-saving measure.

VI. Conclusion

For these reasons, Somatics supports the Ninth Circuit's request for guidance on whether a plaintiff in a failure to warn claim against a medical manufacturer must prove that a heightened warning would have changed her physician's decision to prescribe, or whether she may alternatively offer proof that a prudent person in her position would have refused prescribed treatment. Somatics believes that this Court should answer the question by finding that causation in this context can be established only through proof that a heightened warning would have led the physician to alter his prescribing conduct. But if this Court chooses to answer the certified question and concludes that causation in this context can also be established merely through proof that the physician would have passed on a heightened warning alongside a recommendation to take the prescribed treatment and that a "prudent person" would have refused treatment, Somatics urges this Court to restate the certified question so that, if this Court were to endorse the "prudent person" approach, the Court's answer to the certified question would *also* clarify the legal effect of evidence that the treatment at issue was a last-resort life-saving measure.

In answering the certified question, Somatics urges this Court to hold that, under California's learned intermediary doctrine, either (1) the proximate causation inquiry must focus exclusively on the prescription decision of the physician or, (2) even if the proximate causation inquiry may alternately focus on the conduct of a prudent person in the patient's position, no reasonable juror could find that a prudent person would refuse a last-resort life-saving treatment.

Respectfully submitted,

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