FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MICHELLE HIMES; MARCIA BENJAMIN; DANIEL BENJAMIN, individually, and on behalf of all others similarly situated, *Plaintiffs-Appellants*, and JOSE RIERA; DEBORAH CHASE; DIANE SCURRAH, *Plaintiffs*, v. SOMATICS, LLC, *Defendant-Appellee*, and MECTA CORPORATION, *Defendant.*	No. 21-55517 D.C. No. 2:17-cv-06686-RGK-JC ORDER CERTIFYING QUESTION TO THE SUPREME COURT OF CALIFORNIA

Filed April 1, 2022

Before: Sandra S. Ikuta, Kenneth K. Lee, and Danielle J. Forrest, Circuit Judges.

Order

SUMMARY*

California Law

The panel certified to the Supreme Court of California 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?

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

ORDER

The key legal question in the surviving claims in this case revolves around the causation element in a failure-to-warn case against a medical product manufacturer: Can a plaintiff meet the causation requirement by showing that the physician (if informed of the potential dangers in using the product) would have relayed stronger warnings to the patient such that a prudent person would have declined using the medical product? Or does the plaintiff have to prove that a manufacturer's stronger risk warning would have altered the physician's decision to prescribe the product?

The outcome of this case depends on this state law question, and there is no controlling precedent in the California Supreme Court's decisions. Cal. R. Ct. 8.548(a). We thus respectfully certify this question of law to the California Supreme Court under California Rule of Court 8.548.

I. Background

Appellants Michelle Himes, Marcia Benjamin, and Daniel Benjamin sued Appellee Somatics, LLC in diversity[1] for negligence, strict liability, and loss of consortium, alleging that Somatics's misbranding and failure to warn about certain risks of its electroconvulsive therapy ("ECT") device caused Himes and M. Benjamin their injuries. The district court granted summary judgment in favor Somatics after concluding that the appellants failed to establish causation due to an absence of evidence that stronger

[1] Because this is a diversity action, the court applies California substantive law and federal rules of procedure. *See Motus v. Pfizer Inc.*, 358 F.3d 659, 660 (9th Cir. 2004) (citing *Bank of California v. Opie*, 663 F.2d 977, 979 (9th Cir. 1981)).

warnings would have affected their physicians' decision to prescribe ECT.

On appeal, the appellants contend that the district court erred in applying an unduly demanding causation standard and that they established causation through testimony of the prescribing physicians that, had Somatics given them stronger warnings, they would have communicated those warnings to the appellants who, in turn, claimed they would not have consented to the procedures. In contrast, the appellee argues that the district court correctly concluded that there must be evidence to show that the stronger warnings would have altered the physicians' decision to prescribe the product.

As further explained in an accompanying memorandum disposition, we affirmed the district court's grant of summary judgment in favor of Somatics with respect to the Benjamins' claims after we concluded that there is no genuine issue of material fact that M. Benjamin's treating physician would not have learned about any stronger warnings issued by Somatics in the first instance. Accordingly, we held that under either causation standard, the claims would fail.

However, with respect to Himes's claims, we held that while there was a genuine issue of fact as to whether her treating physician would have learned of stronger warnings and communicated them to Himes, no reasonable juror could find that the physician would have altered his decision to prescribe the treatment. Accordingly, we concluded that the disposition of the appeal with respect to Himes's claims hinges on the resolution of the causation standard. If the district court and Somatics are correct that, in failure-to-warn claims, 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.

II. Explanation of Certification

This court has previously concluded that, under California law, "[a] plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017) (quoting *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004)). Further, in *Motus*, we held that "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." 358 F.3d at 661.

But our cases do not resolve the question of *how* a hypothetical stronger warning must alter the conduct of the prescribing physician. In *Wendell*, which the appellee seeks to rely on, we found that the physician's testimony created "questions of material fact as to whether warnings would have changed [the physician's] prescribing practice." 858 F.3d at 1239. But the fact that a change in prescribing conduct established causation does not resolve whether anything less would have. And in *Motus*, the prescribing physician testified that he did not read the label, or any other information provided by the manufacturer, thus making the strength of the warnings irrelevant. 358 F.3d at 661. Because

the causation chain was severed at an earlier stage—like in the Benjamins' case discussed above—it did not require us to determine whether a stronger warning would need to alter the physician's decision to prescribe or merely to provide stronger warnings to the patient.

The question of the proper causation standard for failure-to-warn claims for prescription products is dispositive in this case. There is no controlling state precedent, and the question implicates important policy concerns. Thus, after careful consideration, we exercise our discretion to certify this question to the California Supreme Court. *See* Cal. R. Ct. 8.548(a); *see also Kremen v. Cohen*, 325 F.3d 1035, 1037–38 (9th Cir. 2003) (listing the factors considered when determining whether certification is appropriate).

III. Certified Question

We respectfully certify the following question to the California Supreme Court:

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

We will accept the decision of the California Supreme Court. Cal. R. Ct. 8.548(b)(2). We acknowledge that, as the receiving court, the California Supreme Court may restate the certified question. *Id.* 8.548(f)(5).

IV. Counsel Information

The names and addresses of counsel or the parties, as required by Cal. R. Ct. 8.548(b)(1) are as follows:

Monique Amanda Alarcon, Bijan Esfandiari, R. Brent Wisner, Baum Hedlund Aristei & Goldman, 10940 Wilshire Boulevard, Suite 1600, Los Angeles, CA 90024, for Plaintiffs-Appellants Michelle Himes, Marcia Benjamin, and Daniel Benjamin;

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V. Conclusion

The Clerk shall forward an original and ten certified copies of this certification order, under official seal, to the California Supreme Court. Cal. R. Ct. 8.548(d). The Clerk is also ordered to transmit copies of all relevant briefs, as well as any additional record materials requested by the California Supreme Court. Cal. R. Ct. 8.548(c).

Submission of this appeal for decision is vacated and deferred pending the California Supreme Court's final

response to this certification order. The Clerk is directed to administratively close this docket, pending further order. The parties shall notify the Clerk of this court within fourteen days of the California Supreme Court's acceptance or rejection of certification, and again, if certification is accepted, within fourteen days of the California Supreme Court's issuance of a decision.

QUESTION CERTIFIED; PROCEEDINGS STAYED.