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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MICHELLE HIMES; et al., Plaintiffs-Appellants, and JOSE RIERA; et al., Plaintiffs, v. SOMATICS, LLC, Defendant-Appellee, and MECTA CORPORATION, Defendant.	No. 21-55517 D.C. No. 2:17-cv-06686-RGK-JC MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
R. Gary Klausner, District Judge, Presiding

Argued and Submitted March 7, 2022
Pasadena, California

Before: IKUTA, LEE, and FORREST, Circuit Judges.

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

Appellants Michelle Himes, Marcia Benjamin, and Daniel Benjamin appeal the district court's order granting summary judgment for appellee, Somatics, LLC. We have jurisdiction under 8 U.S.C. § 1291. We affirm as to the Benjamins' claims. For Himes's claims, we certify a question of law to the Supreme Court of California in a separate order filed concurrently with this memorandum disposition.

Himes and the Benjamins sued Somatics in diversity for negligence, strict liability, and loss of consortium arising from injuries that Himes and M. Benjamin allegedly sustained from Somatics's electroconvulsive therapy ("ECT") product, Thymatron ECT Machine ("Thymatron"). In essence, the appellants claim that Somatics's misbranding and failure to warn about certain risks of ECT—specifically, the risks of permanent memory loss, inability to formulate new memories, and brain damage—caused Himes and M. Benjamin their injuries. The appellants relied on the testimony of the prescribing physicians that—had Somatics given them warnings about these risks—they would have communicated those warnings to the appellants who, in turn, claim they would not have consented to the procedures.

The district court granted Somatics's motion for summary judgment after concluding that the appellants presented no evidence to create a genuine issue of material fact as to causation. In particular, the district court held that absent evidence that the stronger warnings would have affected the physicians' decision to prescribe

ECT, the claims fail as a matter of law.

On appeal, the appellants contend that (1) the district court erred in applying the learned intermediary doctrine to analyze the claims and (2) the district court applied an incorrect causation standard to the appellants' claims.

1. To start, we reject the appellants' argument that the learned intermediary doctrine does not apply whenever the manufacturer has not provided sufficient warnings to a physician.

Under California law,[1] when drugs or medical devices are supplied in the context of the physician-patient relationship, the learned intermediary doctrine applies. *See Webb v. Special Elec. Co., Inc.*, 370 P.3d 1022, 1034 n.10 (Cal. 2016). Under this doctrine, "manufacturers have a duty to warn physicians of risks that are known or scientifically knowable at the time of the drug's distribution." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017) (citing *Carlin v. Superior Court*, 920 P.2d 1347, 1349–54 (Cal. 1996)). Thus, "the duty to warn runs *to the physician*, not to the patient." *Carlin*, 920 P.2d at 1354.

As cases from our court and the Supreme Court of California make plain, even when warnings are assumed to be deficient, in the context of prescription products, the analysis always relies on the impact of a hypothetical stronger warning on the

[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)).

physician. *See Motus*, 358 F.3d at 661; *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661–63 (Cal. 1973). After all, because the adequacy of warnings is always challenged in failure-to-warn claims, "[i]f the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California." *Sanchez v. Bos. Sci. Corp.*, 38 F. Supp. 3d 727, 734 (S.D. W. Va. 2014) (applying California law).

We thus conclude that the district court correctly relied on the learned intermediary doctrine to analyze the claims. Accordingly, a "product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." *Motus*, 358 F.3d at 661.

2. The parties dispute the appropriate causation standard for the learned intermediary doctrine. The appellants argue that it is enough to show that the physicians would have passed along to the patients the stronger warnings, which would have led the patients to refuse the procedure. In contrast, the appellee argues that there must be evidence to show that the stronger warnings would have altered the physicians' decision to prescribe ECT treatment.

The Benjamins' claims fail, regardless of the causation standard applied, because a reasonable jury could not find that M. Benjamin's treating physician, Dr. Michael Frankel, would have known about any stronger warnings issued by

Somatics.

Dr. Frankel testified that he has not relied on any disclosure from Somatics to inform him of the risks of ECT. He further testified that he does not "pay terribly much attention" to literature from manufacturers informing him of updated safety information associated with their products, and he did not recall ever "specifically receiving" a "dear physician" letter informing the medical community about new risks.[2] No reasonable juror could conclude from this testimony that Dr. Frankel would have become aware of any stronger warnings issued by Somatics. And as we have explained in a similar situation in *Motus*, when a plaintiff cannot show that the prescribing physician would have learned about a stronger warning in the first instance, there cannot be a causal nexus between the allegedly inadequate warning and the plaintiff's injury. 358 F.3d at 661.

We thus affirm the district court's grant of summary judgment for Somatics with respect to the Benjamins' claims.

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[2] At oral argument, appellants' counsel drew our attention to the part of the deposition in which Dr. Frankel's responded affirmatively to the following questions: "And *if you are alerted* to new risks concerning . . . a device that you utilize, you would pay attention to that[] . . .? And if the manufacturer warned of a new serious risk, you would relay that risk to patients; correct?" (emphasis added). But that hypothetical assumes that Dr. Frankel would first be alerted to new risks, which the rest of Dr. Frankel's testimony showed was implausible since he did not read disclosures from Somatics, does not pay attention to literature from manufacturers, and does not remember receiving, let alone reading, a "dear physician" letter warning about new risks.

3. For Himes's claims, we conclude that evidence in the record shows that Himes's treating physician, Dr. Raymond Fidaleo, would have learned about stronger warnings and passed them along to Himes, but there is no evidence that these warnings would have altered his prescribing conduct.

Dr. Fidaleo testified that he pays attention to "dear physician" letters from manufacturers alerting him to new safety risks. From this testimony, a reasonable jury could conclude that if Somatics had issued a stronger warning about the risks of ECT, Dr. Fidaleo would have become aware of them.

Further, Dr. Fidaleo testified that if he were presented with warnings about these risks, he would include them in his patient consent forms and discuss them with his patients. From this testimony, a reasonable jury could conclude that, through Dr. Fidaleo, Himes would have become aware of the stronger risk warnings. We also hold that a reasonable jury could conclude that a prudent patient in Himes's position would have declined the treatment after receiving warnings about the risk of permanent memory loss, inability to formulate new memories, and brain damage.[3]

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[3] We disagree with the appellants' contention that in establishing causation through warnings, the effect of a stronger warning on a patient could be determined through the patient's subjective post-hoc declaration. As the Supreme Court of California has explained in the physician failure-to-inform context,

> [s]ince 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

Dr. Fidaleo's testimony, however, does not establish that he would have altered his prescribing conduct. On the contrary: (i) as to the risk of permanent memory loss, had Dr. Fidaleo been told about the risk, he testified that it "wouldn't stop" him from using ECT because "[a]ll drugs and all things have memory loss," (ii) as to the risk of inability to formulate new memories, Dr. Fidaleo testified that it would be a "significant" concern but that he "would have to see it also [him]self" and that he is "not seeing that with [his] patients," and (iii) as to the risk of brain injury, Dr. Fidaleo testified that he would be reluctant to use ECT *if* that were a risk but that he does not believe that this is an actual risk "[b]ecause people go back and function normally after ECT." (emphasis added). In sum, Dr. Fidaleo's testimony demonstrated that warnings about these risks would not have altered his decision to prescribe ECT either because such risks are not unique to ECT or because he simply would not credit those warnings based on his own experience with the therapy. No reasonable jury could conclude from this testimony that warnings about these risks

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> we doubt that justice will be served by placing the physician in jeopardy of the patient's bitterness and disillusionment. Thus an objective test is preferable: i.e., what would a prudent person in the patient's position have decided if adequately informed of all significant perils.

Cobbs v. Grant, 502 P.2d 1, 11-12 (Cal. 1972). We thus conclude that if it were possible to establish causation through warnings communicated to the patient by the physician, the effect on the patient must be determined based on what a prudent person in the patient's position would have done with the benefit of stronger warnings.

would affect Dr. Fidaleo's decision to prescribe and use ECT.

The resolution of this appeal turns on the proper causation standard applied to Himes's claim. 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. As further explained in the accompanying certification order, because there is no controlling state precedent on this question, and the question implicates important policy concerns, we conclude that it warrants certification 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).

AFFIRMED IN PART.