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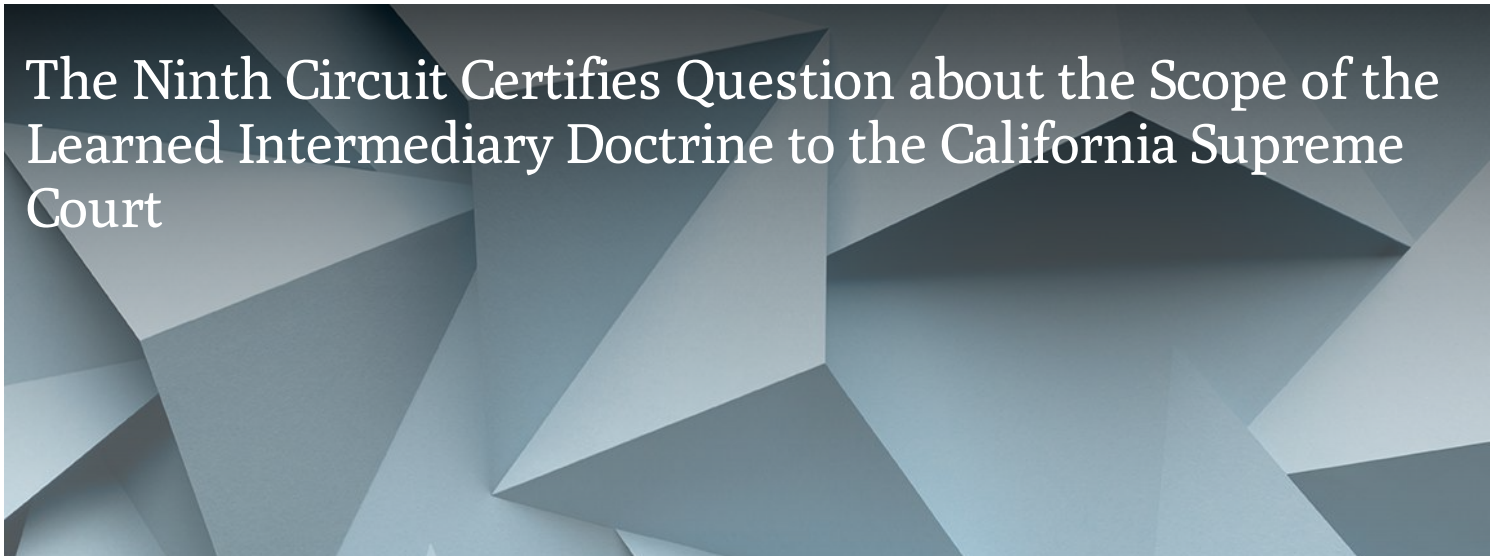
BLOG

The Ninth Circuit Certifies Question about the Scope of the Learned Intermediary Doctrine to the California Supreme Court



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A few weeks ago, the Ninth Circuit certified a significant legal question to the California Supreme Court, the resolution of which may have lasting impact on the learned intermediary doctrine under California law. The question posed: is a plaintiff required to show that stronger warnings would have changed the doctor's conduct in prescribing the product (the common view on causation in the failure-to-warn context), or does it suffice to show that the doctor would have communicated those stronger warnings to the patient, and a reasonable patient would have declined the treatment after receiving them?

The case is *Himes v. Somatics, LLC*, 2022 U.S. App. LEXIS 8793 (9th Cir. Apr. 1, 2022). Two plaintiffs—Michelle Himes and Marcia Benjamin—alleged that the manufacturer of electroconvulsive therapy ("ECT") products, Somatics LLC, failed to warn them about the risks of product use, including memory loss and brain injury. At the district court level, the evidence produced by both plaintiffs was deemed insufficient to create a triable issue of fact as to causation: specifically, the plaintiffs failed to show that stronger warnings would have affected their individual doctors' decision to prescribe ECT. *Id.* at *2-3. As a result, the district court granted summary judgment in favor of Somatics.

The Ninth Circuit appeal raised two issues. First, the plaintiffs argued that the learned intermediary doctrine does not apply, as a matter of law, whenever the manufacturer has not provided adequate warnings to a physician. The Ninth Circuit easily rejected this argument, reasoning that "if the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California." *Id.* at *4.

The second issue, related to causation, was more complex. The Ninth Circuit first acknowledged the established principle 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." *Id.* *4 (citing *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004)). Fair enough, but what does "altered conduct" mean?

For Benjamin, the question did not matter: her claim failed because her doctor testified that he never received any warnings ("stronger" or not) in the first instance: he never read the safety literature or product disclosures, and he never received the "dear physician" letter warning about product risks. *Id.* at *5. As the Ninth Circuit observed, "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." *Id.* As a result, the Ninth Circuit affirmed summary judgment in favor of Somatics on Benjamin's claim.

Himes presented a different story. In contrast to Benjamin's doctor, Himes's doctor testified that he *did* review "dear physician" letters, and that if he had seen warnings in those letters about new safety risks, he would have discussed those risks with his patients. *Id.* at *6. However, his testimony also 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." *Id.* at *8. In other words, the record showed that Himes's doctor "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." *Id.* at *5-6.

This brings us back to *Motus*. In the hypothetical scenario where "stronger warnings" are available, is the inquiry whether the physician would have altered his or her *prescription* plan? Or is the "altered conduct" standard more nuanced, encompassing the decision to communicate those stronger warnings to the patient, which in turn would lead a reasonable person in the patient's position to decline treatment? (And the patient perspective is, of course, an objective standard: the Ninth Circuit expressly rejected the notion that "the effect of a stronger warning on a patient could be determined through the patient's subjective post-hoc declaration." *Id.* at *6 n.3.)

Finding no controlling state precedent on this causation question, the Ninth Circuit took the rare step of certifying it to the California Supreme Court. The panel's certified question is reproduced below. Time will tell how this important causation framework unfolds.

> 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?

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