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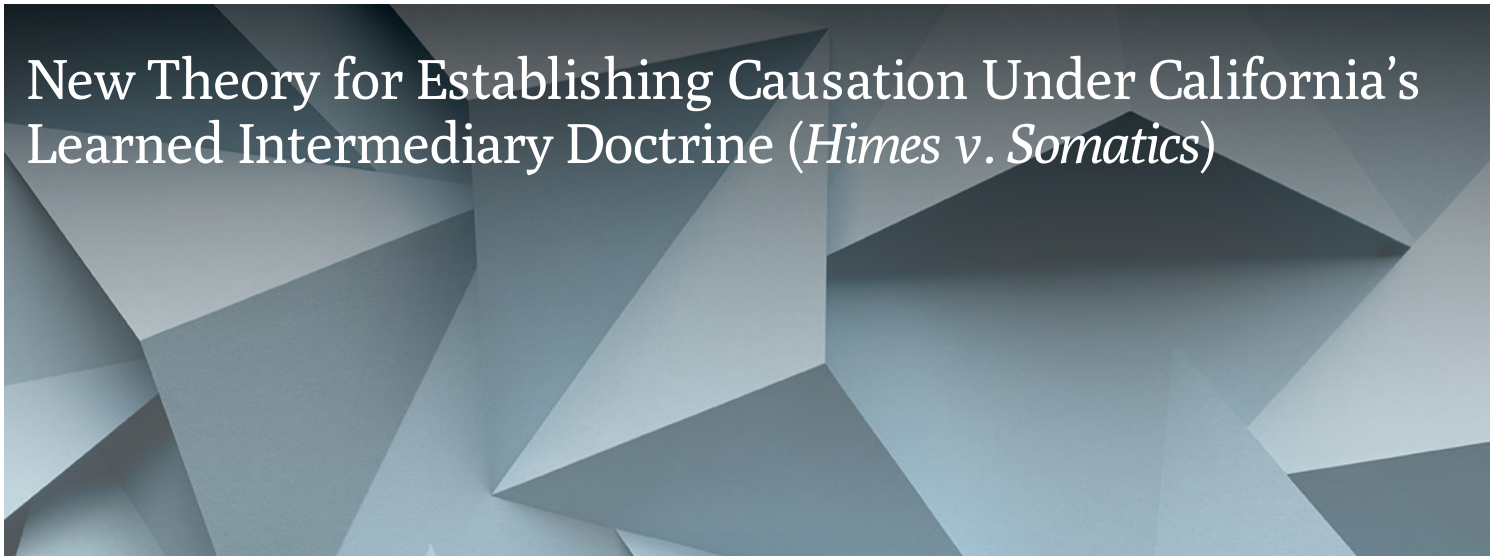
BLOG

New Theory for Establishing Causation Under California's Learned Intermediary Doctrine (*Himes v. Somatics*)



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The California Supreme Court has recognized a new path for plaintiffs to prove causation in failure-to-warn cases against manufacturers of prescription drugs and medical devices. Under the learned intermediary doctrine, such manufacturers have a duty to warn physicians of the risks associated with their products, but do not have a duty to warn patients. Instead, physicians act as intermediaries between manufacturers and patients, using their training to identify, provide, and explain the information that each patient needs under his or her specific circumstances to make an informed choice as to a course of treatment. *Carlin v. Super Ct.*, 13 Cal. 4th 1104 (1996); *accord T.H. v. Novartis Pharms. Corp.*, 4 Cal. 5th 145 (2017).

Defendants in failure-to-warn cases often argue that a stronger or different warning from the manufacturer to the physician would not have altered the physician's decision to prescribe the product. But in *Himes v. Somatics, LLC*, the Court held that 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. 2024 WL 3059637, at *1 (Cal. Sup. Ct. June 20, 2024). Instead, where the evidence shows the physician would have continued to recommend the treatment even with a stronger warning, the plaintiff may still establish causation by proving that the physician would have relayed the warning to the patient and that an "objectively prudent person" in the patient's position would have declined the treatment.[1] *Id*. The Court emphasized that, as in the informed consent context, this objective test is not determined by the plaintiff's subjective belief as to what he or she might have done if provided a stronger warning. *Id.*

ILLUSTRATION OF A NEW CAUSATION THEORY

In *Himes*, the plaintiff alleged that defendant, Somatics, LLC, failed to warn her physician adequately about the risk that electroconvulsive therapy (ECT) could cause her permanent brain damage and memory loss. *Id.* at *2. Somatics won summary judgment, arguing that the deposition testimony of plaintiff's physician that "he still would have recommended ECT even if he had been informed of the risk of permanent brain damage and memory loss" rendered plaintiff unable to establish causation under the learned intermediary doctrine. *Id*. (cleaned up).

While the Ninth Circuit agreed that the plaintiff had "failed to present evidence tending to show [the physician] would have altered his decision to prescribe ECT" if Somatics "had issued a stronger warning about its ECT device," it noted there was a genuine issue of material fact as to whether the physician would have been alerted to a stronger warning and passed that warning on to plaintiff, concluding that the disposition of the appeal hinged on the

applicable causation standard. *Id.* As the Ninth Circuit framed it, the issue was whether a plaintiff is required to show that stronger warnings would have altered the physician's conduct, or 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." *Id.* That was an unresolved question of California law which the Ninth Circuit certified to the California Supreme Court.

Somatics asked the California Supreme Court to hold that a plaintiff cannot establish causation without showing that a stronger warning would have changed the physician's treatment plans. *Id.* at *6. It argued that the patient's decision whether to accept the physician's recommendation is "irrelevant" because the learned intermediary doctrine recognizes that physicians are better equipped to decipher "highly technical information" related to treatment risks and benefits. *Id*. However the Court rejected this position as inconsistent with "the essential role of patient choice in medical treatment decisions" and held that this role does not "disappear in the context of the learned intermediary doctrine." *Id.* To the contrary, "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." *Id.* at *7. Because the doctrine's purpose is "to enable patients to make informed and intelligent decisions," patient autonomy and choice must be treated as relevant. *Id.*

On the other hand, the Court also made clear that the standard is one of what an objectively prudent person would do in the plaintiff's position when presented with the physician's recommendation. Causation cannot be established by the patient's subjective testimony that he or she would have declined the treatment in response to the warning, and although the patient's testimony is relevant, the Court warned that it could also be "self-serving" and is "prone to hindsight bias." *Id.* at *9-10.

The Court answered the certified question by holding that in order to show causation a plaintiff is not required to show that a stronger warning would have altered the physician's decision. Instead, causation may be established by showing that (1) "the physician would have communicated the stronger warning to the patient" and (2) "an objectively prudent person in the patient's position would have thereafter declined the treatment notwithstanding the physician's continued recommendation of the treatment." *Id.* at *10.

IMPLICATIONS FOR MANUFACTURERS OF PRESCRIPTION DRUGS AND MEDICAL DEVICES

Himes opens the door for a new causation theory in failure-to-warn cases. The new causation analysis should "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." *Id.* at *8. If a plaintiff has sufficient evidence to show that a stronger warning from the manufacturer would have prompted his or her physician to relay a stronger warning to the patient, the analysis "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." *Id.*

In evaluating whether a plaintiff has provided evidence that "an objectively prudent patient" would have followed the physician's treatment recommendation, defendants should keep the following guidance from the *Himes* Court in mind:

- Although the plaintiff's testimony is "relevant," it must not "dominate the findings" but must instead "be appraised congruently with the factfinder's belief in its reasonableness." at *10.
- Factors that can guide the appraisal of objective reasonableness include, but are not 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." at *9.
- Litigants and courts can look to informed consent cases to illustrate how a patient's personal characteristics and unique circumstances should be considered. For example, "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." *Id.*

Now that a plaintiff can pursue a fact-intensive causation theory that involves a multifactor reasonableness evaluation, it may become harder to prevail under the learned intermediary doctrine on summary judgment. But this goes only to "whether the manufacturer's failure to warn caused the patient to use the product," and as the *Himes* Court noted, a plaintiff cannot establish causation without also providing evidence that the product is "capable of causing the injury" and caused "the patient's injury in particular." *Id.* at *3. It is therefore more important than ever for defendants to scrutinize plaintiffs' evidence to develop potential lines of attack against both general and specific causation.[2]

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[1] The Court also expressly declined to decide "whether a plaintiff may establish causation through other means." *Himes*, 2024 WL 3059637, *4. In other words, there may be additional alternative avenues for a plaintiff to prove causation in the future, but the Court has not yet decided whether such avenues exist.

[2] For recent discussion of successful challenges to plaintiffs' evidence on general and specific causation, see "Sixth Circuit Confirms Experts Cannot Infer Causation from Association Based on Single Study to Exclusion of Contrary Studies Without Explanation" and "Beyond the Obvious: Does the Failure to Rule Out Idiopathic Causes Survive a Rule 702 Challenge?"

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