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April 21, 2022

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Office of the Clerk
California Supreme Court
350 McAllister Street
San Francisco, California 94102

Re: *Himes v. Somatics*
CA Supreme Court Case No: S273887
Ninth Circuit Court of Appeals Case No.: 21-55517

To the Honorable Justices of the Supreme Court of California:

Introduction

Pursuant to California Rule of Court 8.548(e), Plaintiff-Appellant, Michelle Himes ("Himes") submits this letter ***in support*** of the United States Court of Appeals for the Ninth Circuit's April 1, 2022 Order Certifying a Question to the Supreme Court of California. *See Himes v. Somatics*, LLC, 29 F.4th 1125 (9th Cir. 2022) (hereinafter, "Order"). Himes respectfully requests that this Honorable Court accept the Ninth Circuit's request.

Background

This case concerns an important and recurring issue in pharmaceutical and medical device products liability cases to which there is no controlling precedent – namely, the interplay between the learned intermediary doctrine and establishing causation in failure to warn cases under California law. The lack of precedent from this Court has resulted in conflicting rulings from district courts attempting to interpret and apply California law.

Michelle Himes was 25 years old when, during a nine-month period, she received a total of 26 Electroshock Therapy (ECT) sessions administered by her doctor, Raymond Fidaleo, M.D. at Sharp Mesa Vista Medical Center in San Diego, California. ECT is the practice of inducing a grand mal seizure through application of electricity to the brain, with the hope of treating depression. The amount of electricity administered in each ECT session is roughly one-fifth the current used in the electric chair for executions and more than a hundred times what is required to damage brain cells.

As a result of her repeated exposures to ECT, Himes alleges she sustained brain injury, including permanent memory loss and severe cognitive dysfunction. Defendant, Somatics LLC, the manufacturer of the ECT machine used on Himes, never warned Dr. Fidaleo or his staff (who were trained by Somatics) that ECT can cause brain injury or permanent memory loss. Likewise, despite having an ongoing duty to issue warnings prior

to Himes' ECT sessions, Somatics never issued any warnings to Dr. Fidaleo or the medical community concerning these risks. It was not until years *after* Himes' ECT sessions, and after the FDA mandated that Somatics issue warnings concerning permanent cognitive injuries, that Somatics issued warnings concerning brain injury and permanent memory loss associated with its ECT device. These after-the-fact warnings came too late for Himes.

Dr. Fidaleo testified that the risk of brain injury is a serious risk and if he knew that a drug or device has the potential to cause brain injury, he "would be reluctant to use it …." Dr. Fidaleo further testified that "had Somatics provided [him] warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories[,]" he would have relayed those warnings to his patients and such warnings "would be in the informed consent" form that he gave to patients. Himes, in turn, testified that, had she been warned of these risks by Dr. Fidaleo, she would not have consented to ECT (and thus would not have been injured by that ECT).

Question Certified by the Ninth Circuit

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?

The Question is Properly Certified

A.

This Court may decide a question of California law on the request of a United States Court of Appeals if "[t]he decision could determine the outcome of a matter pending in the requesting court" and "[t]here is no controlling precedent." CAL. R. CT. 8.548(a). Because these requirements are met in this case, and because of the overriding importance of the issue presented not only to the parties, but also to current and future litigants in prescription drug and medical device products liability cases, this Court should accept the Ninth Circuit's request to answer the certified question.

Pharmaceutical and medical device products liability litigation form a substantial portion of the civil docket. Because there usually is diversity amongst the parties in such cases, they usually are litigated in federal courts and, in many instances, such cases are centralized in federal multi-district litigations (MDLs). It is estimated that at least 20% of the MDL docket in federal courts consist of pharmaceutical and medical-device products liability cases. As federal courts must apply the substantive law of the state where the plaintiff was injured, in cases, like here, where the plaintiff takes a prescription medication or undergoes a medical procedure in California, federal courts sitting in diversity apply California substantive law. *See Himes,* 29 F.4th 1125, n.1 ("Because this is a diversity action, the

court applies California substantive law…").

In California, it is well established that the learned intermediary doctrine applies to failure to warn claims against manufacturers of prescription drugs or medical devices, which provides that a manufacturer may "discharge" its duty to warn the patient directly by warning the patient's doctor. *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 994 (1971) ("the manufacturer of an ethical drug *discharges* its duty of warning if it adequately warns the doctor..") (emphasis added); *Love v. Wolf*, 226 Cal. App. 2d 378, 395 (1964) (same); see also *Stevens v. Parke, Davis & Co*., 9 Cal. 3d 51, 65 (1973).

However, there is confusion and a lack of consensus as to how, under California law, an injured plaintiff must show causation in a prescription product failure to warn case. Somatics argues that, in light of the learned intermediary doctrine, the *only* way to establish causation is for the plaintiff to show that, had the manufacturer issued an adequate warning to the plaintiff's doctor, the doctor would not have prescribed/administered the treatment. Whereas Himes contends that, even if the learned intermediary doctrine were to apply in cases where the manufacturer failed to issue adequate warnings to the intermediary/doctor, a plaintiff can establish causation by showing that, had her doctor been adequately warned by the manufacturer, the doctor would have relayed the warnings to the patient and the patient, armed with enhanced warnings, would not have consented to the procedure (or would not have taken the drug) and thus would have avoided the harms associated with the drug or device.

Cases that support Somatics' position include for example the district court below and *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"). Whereas cases that support Himes' position include for example: *Georges v. Novartis Pharms. Corp*., 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013) (proximate causation established since doctor would have passed on stronger warnings to patient and the patient testified that, with the enhanced warnings, her use of the drug would have altered); *Hill v. Novartis Pharms. Corp*., 2012 WL 6004161, at *4 (E.D. Cal. Nov. 30, 2012); (proximate causation burden met since, even though doctors testified they still would have prescribed the drug had they received enhanced warnings, they also testified they would have relayed those warnings to patients and plaintiff testified, had she been so warned, she would not have consented to the drug's use); *Stanley v. Novartis Pharm. Corp*., 11 F.Supp.3d 987, 1003 (C.D. Cal. 2014) (same); *see also Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1239 (9th Cir. 2017) (quoting *Stanley* that "[c]hanges to treatment and prescription procedures created a triable question of fact on specific causation.").

The lack of controlling precedent resulting in conflicting decisions from lower courts on this crucial outcome-determinative issue is exactly the reason this Honorable Court should accept the Ninth Circuit's certified question. Indeed, even the trial judge overseeing Himes' case issued conflicting rulings on this exact causation issue. In previously denying

Somatics' summary judgment motion with respect to two *other* ECT plaintiffs who, like Himes, had sustained brain injury as a result of ECT, the trial judge held summary judgment on causation grounds was not appropriate because plaintiffs had presented evidence that, had their doctors been adequately warned, they would have relayed those warnings to plaintiffs. *Riera v. Somatics, LLC*, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018) ("Moreover, Plaintiffs present evidence that had doctors known of the risk of permanent memory loss or brain damage, they would have told their patients. Therefore, there is a genuine dispute of fact on this issue, and summary judgment is not appropriate.") Yet, perplexingly, in granting Somatics' summary judgment in Himes' case, the very same trial judge issued a conflicting ruling and held that Himes must establish that her doctor would not have prescribed/administered ECT. *See Riera v. Mecta Corp*., 2021 WL 2024688, at *5 (C.D. Cal. May 14, 2021).

The lack of controlling precedent from this Court has resulted in diverging decisions, which is now at issue in the Ninth Circuit. Obtaining clarity from this Court will not only result in a proper determination of the outcome in Himes' case but will also benefit all other current and future litigants who are litigating pharmaceutical and medical device products liability cases. Accordingly, pursuant to Rule 8.548, the Court should accept the certified questions for adjudication.

B.

This Court's precedent lends support for answering the issue presented by the certified question in the affirmative.

While the California Supreme Court has recognized the learned intermediary doctrine since at least 1973 (*Stevens*), in the intervening 48 years, *not a single* published California Appellate or Supreme Court case has ever endorsed Somatics' argument that the only way to establish causation is for the plaintiff to show that the doctor would not have prescribed the product. Rather, Himes contends that causation can equally be established by showing that, even if the doctor would have *prescribed* the device or drug, so long as the doctor would have relayed enhanced warnings to the patient (had the defendant manufacturer adequately warned the doctor) and the patient testified that, in light of those enhanced warnings, she would not have consented to the procedure or would not have taken the drug. *See e.g., Georges*, 988 F. Supp. 2d at 1158; *Stanley*, 11 F.Supp.3d at 1003. Himes contends that, if enhanced warnings would have altered the prescribing doctor's conduct in this meaningful way, causation is established.

California law has long recognized that each patient has a right to refuse treatment. *Cobbs v. Grant*, 8 Cal. 3d 229, 243–44 (1972); *Riese v. St. Mary's Hosp. & Med. Ctr*., 209 Cal. App. 3d 1303, 1317 (1987). Himes was a competent adult who went to her doctor voluntarily and only agreed to undergo ECT after having the risks and benefits explained to her by her doctor. Her doctor, however, did not know, or appreciate the full extent of the serious harms associated with ECT (including the harm of permanent memory loss and brain damage), because Somatics failed to warn of these risks, thus, her doctor was not

able to relay these important warnings to Himes. Her doctor testified that, had Somatics issued such warnings, he would have relayed them to his patients, and Himes testified that, had she been so warned, she would have refused to consent to ECT, as is her right under California law. *Cobbs*, 8 Cal. 3d at 243 ("the decision whether or not to undertake treatment is vested in the party most directly affected: the patient."); *see also* CAL. WELF. & INST. CODE § 5326.85. As one California court cogently held:

> [T]he right to give or withhold consent to medical treatment is protected by the common law of this state…and by the constitutional right to privacy...The right to refuse treatment with these drugs clearly falls within the recognized right to refuse medical treatment… this right is among those 'guaranteed all other persons by the ... Constitution and laws of the State of California'…

Riese, 209 Cal. App. 3d at 1317–18 (internal citations and brackets omitted). Furthermore, this Court has held that "the patient's right of self-decision is the measure of the physician's duty to reveal. That right can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice." *Cobbs*, 8 Cal. 3d at 244–45. Here, Himes was robbed of that fundamental "right of self-decision" because Somatics concealed the risks of brain damage and permanent memory loss from her doctor and thus she was never informed of these risks by her doctor. To accept Somatics' argument and eliminate the patient's consent from the inquiry of causation in a failure to warn claim would be an affront to the California Constitution, to the principles of self-autonomy as this Court espoused in *Cobbs*, and in violation of California statutory laws that specifically provide that ECT cannot be administered to a patient without the patient's express consent. CAL. WELF. & INST. CODE § 5326.85 ("No convulsive treatment shall be performed if the patient, whether admitted to the facility as a voluntary or involuntary patient, is deemed to be able to give informed consent and refuses to do so.")

An alternative reason this Court's precedent warrants answering the issue presented in the affirmative is that California law is clear that, once it has been established that a defendant has breached its duties (i.e., duty to warn the intermediary), the intervening conduct of a third party (including the intermediary doctor) does not allow the manufacturer to escape liability. *See e.g.*, *Stevens*, 9 Cal. 3d at 69.

Stevens was a wrongful death case wherein it was alleged the decedent died as a result of an antibiotic she was prescribed. *Stevens*, 9 Cal. 3d at 56. The decedent's family sued the prescribing doctor and the drug manufacturer and prevailed against both defendants at trial. On appeal, the drug manufacturer argued that it had issued adequate warnings to the doctor and that the doctor was already aware of the risk of fatality associated with the antibiotic. This Court held that any warning the manufacturer may have issued in its label was watered down by its overpromotion. The Court found that the overpromotion led to the warnings being "nullified," i.e., as if the manufacturer had never warned. *Stevens*, 9 Cal. 3d at 67.

Moreover, and germane to this case, this Court went on to hold that "even assuming

for the sake of argument that the jury accepted [the doctor's] testimony that he was cognizant of the dangers of the drug, nevertheless his negligence was not, as a matter of law, an intervening cause which exonerated [the drug manufacturer]." *Stevens*, 9 Cal. 3d at 69. This Court confirmed that, under California law, the intervening acts of a third person (i.e., the doctor) do not absolve the liability of the original negligent actor (i.e., the negligent drug manufacturer). *Stevens*, 9 Cal. 3d at 69 ("Parke, Davis cannot be relieved of liability because of the intervening act of Dr. Beland in prescribing the drug while cognizant of its dangers. If there is room for reasonable men to differ as to whether the intervening act was reasonably foreseeable, then the question is properly left to the jury.") This Court's language from *Stevens* is an indication that California law would not allow the intervening conduct of Himes' doctor (i.e., whether he still would have prescribed or administered ECT ***if*** he had been warned by Somatics) to allow Somatics (which failed to provide warnings to the doctor) from escaping liability. At a minimum, this is an issue that should be resolved by the trier of fact. *Stevens*, 9 Cal. 3d at 69; *see also T.H. v. Novartis Pharms. Corp*., 4 Cal. 5th 145, 184 (2017) ("we have never allowed a defendant to excuse its own negligence as a matter of law simply by asserting that someone else should have picked up the slack and discharged the duty at issue…Nor have we permitted a negligent actor to evade liability simply because another party may also be liable for a similar tort."); *Stewart v. Cox*, 55 Cal. 2d 857, 864 (1961) ("The fact that a third person does not perform his duty to protect the plaintiff from harm, either because he makes no effort or through his negligence does not succeed, is not a superseding cause.")

C.

The certified question is of overriding importance and this Court should exercise its discretion to resolve it. As this Court has emphasized "a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment." *Cobbs*, 8 Cal. 3d at 242. Yet manufacturers such as Somatics contend the consent of the patient has no place in an injured plaintiff's failure to warn claim and that, notwithstanding the emphasis California law (WELF. & INST. CODE § 5326.85) and this Court's precedent (*Cobbs*), have placed upon patient consent, patient autonomy, and patient self-determination, the only decision that matters is the doctor's decision to prescribe a treatment, without regard to the ultimate consent of the patient.

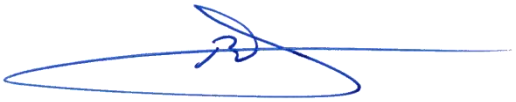
The people of California who take prescription drugs or undergo procedures involving medical devices, as well as the medical device and drug companies who sell these products in California, are entitled to a clear answer to the certified question. If the patient's ultimate consent still plays a role in tort suits involving pharmaceutical and medical device products – as the Court's precedent suggests and as Himes contends – the people of California can rest secure in the knowledge that their self-autonomy and decision to consent to dangerous medical treatments are not just idle words or lofty goals, but rather are rights that are enshrined and protected by this Court under California's tort laws.

Conclusion

For these reasons, this Court should accept the Ninth Circuit's request to answer the certified question.

Respectfully submitted,

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.



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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on April 21, 2022, at Los Angeles, California.

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STATE OF CALIFORNIA
Supreme Court of California

PROOF OF SERVICE

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4/21/2022
Date

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