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May 2, 2022

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**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)(2), Plaintiff-Appellant, Michelle Himes ("Himes") submits this letter in response to the letter submitted by Defendant-Appellee Somatics, LLC ("Somatics") addressing 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"). As detailed in Himes' opening letter, the question posed by the Ninth Circuit is properly certified to this Court and presents an unresolved issue of fundamental importance concerning the interplay between the learned intermediary doctrine and a plaintiff's causation burden in a prescription pharmaceutical and medical device products liability case.

Somatics, like Himes, *agrees* the Court should accept the certified question but further requests that the Court reformulate the question presented. For the reasons outlined herein, Himes disagrees that the Ninth Circuit's question should be reformulated as postulated by Somatics. Himes further responds to several misleading representations made in Somatics' opening letter and, pursuant to Rule of Court 8.548(e)(3), takes this opportunity to also propose her own slightly modified question for the Court's consideration.

## Response to Somatics' Letter

In its opening letter, Somatics falsely claims that ECT is a life-saving treatment and argues that the Ninth Circuit's question should be amended to add "can a reasonable juror conclude that a prudent person would refuse prescribed treatment if the undisputed testimony shows that all other treatment options had been exhausted and the patient was facing a risk of death." *See* Somatics' Letter at 6. Somatics' premise for its modified question is factually and legally flawed.

*First*, Somatics' summary judgment motion was not supported by any expert

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testimony and there was nothing to establish that "all other treatment options had been exhausted" for Ms. Himes. There was no testimony provided as to what all the available treatment options were or that they all had been utilized or exhausted in Himes' case.

*Second*, Somatics' summary judgment motion was not even premised on the argument Somatics now advances —namely, that a prudent person in Himes' position would have consented to ECT even if warned about the risk of permanent memory loss and brain damage. The "prudent person" standard was articulated for the first time by the Ninth Circuit on appeal, it was not a theory advanced by Somatics in its summary judgment papers, or in its briefing on appeal in the Ninth Circuit.

*Third*, assuming the prudent person standard applies[1], the Ninth Circuit in this case has already concluded that a reasonable jury could conclude that a prudent person in Himes' position would have declined the treatment if she had been adequately warned about the risk of brain injury and permanent memory loss. *See Himes v. Somatics, LLC*, No. 21-55517, 2022 WL 989469, at *3 (9th Cir. Apr. 1, 2022) ("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.").

*Fourth*, because the Ninth Circuit has already made a finding of fact 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[,]" *see Himes*, 2022 WL 989469 at *3, under this Court's binding precedent, the Court is bound to accept the Ninth Circuit's factual finding, as this Court's role is limited to answer the "question of California law." *Pooshs v. Philip Morris USA, Inc*., 51 Cal. 4th 788, 793, 250 P.3d 181, 184 (2011) ("In addressing the issue presented here, we emphasize that our role is only to answer the "question of California law" that the Ninth Circuit posed to us…We play no role in assessing the merits of plaintiff's factual assertions, which must be determined in the federal court.").

*Fifth*, to accept Somatics' question, the Court must first determine that Somatics' ECT machine is a "life-saving" machine. However, Somatics' summary judgment motion was not supported by any expert testimony, nor was any proof submitted that its ECT machine is a life-saving device. Notably, Somatics has *never* undertaken any clinical trials to assess the safety or efficacy of its device, thus, this assertion is simply unfounded.

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[1] Himes submits that the prudent person standard *does not* apply in prescription failure-to-warn cases because, in such cases, the causation standard for failure to warn claims is the "*substantial factor*" test as outlined in Judicial Council of California Civil Jury Instruction (CACI) 1205 (strict liability) and CACI 1222 (negligence), and California courts have routinely allowed plaintiffs to establish causation by providing "self-serving" testimony as to how they would have altered their conduct in failure to warn cases. *Colombo v. BRP US Inc.,* 230 Cal. App. 4th 1442, 1454, 179 Cal. Rptr. 3d 580, 593 (2014) (collecting cases).

Indeed, in adjudicating Somatics' summary judgment motion, the district court made the following finding of fact and deemed the following facts undisputed:

> The following facts are undisputed unless otherwise noted:
>
> Somatics has never conducted any clinical trials of its Thymatron System IV device to determine its safety and efficacy. Over the years, Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death associated with ECT. Somatics never investigated these complaints, nor did it submit adverse events to the FDA or warn physicians and consumers of these risks.

*Riera v. Mecta Corp.,* No. 2:17-CV-06686-RGK-JC, 2021 WL 2024688, at *1 (C.D. Cal. May 14, 2021) (internal citations omitted). Moreover, while Somatics' summary judgment motion did not contain any expert affidavits or reports, Himes provided *unrefuted* expert reports, expert declarations, and peer reviewed journal articles establishing that, to date, no mechanism of action has been identified as to how ECT purportedly treats depression; and there is no evidence that ECT prevents suicides. *See e.g.*, 2-ER-29-49; 3-ER-441-454; 3-ER-456-479; 4-ER-878-910. Indeed, in the summary judgment proceedings, Somatics stated that the following fact was "*undisputed*:"

> A recently published meta- analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read and Laura McGrath of the University of East London, concluded: "Given the high risk of permanent memory loss and the small mortality risk, this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well designed, randomized, placebo-controlled studies have investigated whether there really are any significant benefits against which the proven significant risk can be weighed."

*See* 2-ER-49; *see also* John Read et al, *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses*, 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019) (4-ER-878). Lastly, it is worth emphasizing that the FDA has *never* approved a single ECT device, and Somatics' ECT device has never been approved because Somatics has never conducted, nor has it submitted any clinical trials to the FDA demonstrating the safety or efficacy of its device.[2] Notably, as of 2018, the FDA has required Somatics to warn patients and physicians that "The long-term safety and effectiveness of ECT treatment has not been demonstrated." 21 C.F.R. § 882.5940. Accordingly, the premise for Somatics' modified question that Himes exhausted all treatment options or that ECT is somehow a life-saving machine is not supported by the

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[2] Rather, Somatics' device received "clearance" meaning that it was grandfathered in because its device was based on technology that predated the passing of the FDA's Medical Device Amendments Act in 1976. The distinction between approval and clearance is significant. The FDA only spends approximately 20 hours clearing a device (as it does not assess safety or efficacy), whereas it spends nearly 1200 hours on approvals. 2-ER-32-36.

evidence submitted in the summary judgment proceedings. Rather, as outlined *supra*, the unrefuted evidence demonstrated that Somatics never tested the safety or efficacy of its ECT machine, its machine has never received FDA approval, no evidence was submitted that ECT prevents suicide and the undisputed evidence submitted by Himes and her experts was that the harms of ECT outweigh any of its purported benefits.

*Finally*, the premise advanced by Somatics in its proposed modified question, that as a matter of law a reasonable jury can never conclude that a prudent person would refuse ECT treatment (even though as outlined *supra*, the Ninth Circuit already made a factual finding that a reasonable jury could so conclude, *see Himes*, 2022 WL 989469 at *3), is at odds with California statutory law which provides that:

> 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. The physician shall indicate in the treatment record that the treatment was refused despite the physician's advice and that he has explained to the patient the patient's responsibility for any untoward consequences of his refusal.

CAL. WELF. & INST. CODE § 5326.85. Thus, California law places the decision of whether a patient like Himes (who was a voluntary patient and had the capacity to give consent) consents to undergo ECT *exclusively* within the province of the patient. Welfare and Institution Code Section 5326.85 is thus another independent basis for why this Court should reject Somatics' invitation to modify the question. California law is clear that a doctor is *not* permitted to perform ECT without the patient's consent and it would be contradictory to Section 5326.85 for this Court to now conclude that the patient's decision to consent can be usurped by a doctor, a judge, or a jury. Simply put, California has done away with the paternalistic doctor knows best approach that Somatics is advocating in its reframed question. Instead, California through its Constitution and statutory laws, in particular as it pertains to procedures such as electroshock therapy, has opted for a legal landscape wherein the self-autonomy of patients and general principles of freedom and personal choice trump the edicts of physicians. CAL. WELF. & INST. CODE § 5326.85; *Riese v. St. Mary's Hosp. & Med. Ctr*., 209 Cal. App. 3d 1303, 1317 (1987).

In sum, Himes respectfully submits that the Court should reject Somatics' invitation to modify the Ninth Circuit's question.

**Himes' Proposed Restated Question**

To the extent the Court is at all inclined to modify the question, pursuant to California Rule of Court 8.548(e)(3), Himes proposes the following modified question for the Court's consideration:

> ***Assuming the learned intermediary doctrine applies in situations where the device manufacturer has failed to provide adequate warnings to the physician intermediary***, 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~~ ***the patient*** would have declined the treatment after receiving the stronger risk warning?

As to the *first modification*, it is Himes' contention that, in cases, like here, where it is admitted and undisputed that the manufacturer has failed to provide adequate warnings to the physician intermediary, then the manufacturer can no longer seek shelter behind the learned intermediary doctrine.

Under established California law, manufacturers have a duty to warn consumers about the hazards inherent in their products. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1003 (1991). In the context of medical products that require a prescription, California has adopted what has often been referred to as the "learned intermediary" doctrine. It provides that, *if* a manufacturer provides adequate warnings to a patient's doctor, then there is no need to warn the patient directly. *Carlin*, 13 Cal. 4th at 1116; *Stevens v. Parke, Davis & Co*., 9 Cal. 3d 51, 65 (1973); *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..."); *Love v. Wolf*, 226 Cal. App. 2d 378, 395 (1964) (same).

This Court, in *Stevens*, adopted the learned intermediary doctrine and held:

> In the case of medical prescriptions, '***if*** adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.'

*Stevens*, 9 Cal. 3d at 65 (*quoting Love*, 226 Cal.App.2d at 395) (emphasis added). Thus, the learned intermediary is an *exception* to the duty, imposed on any seller of a good, to warn *consumers* directly of known or knowable risks, provided those risks were sufficiently disclosed to the learned intermediary. Indeed, by using the word "*if*," this Court specifically and intentionally limited the learned intermediary defense (i.e., to avoid a duty to warn patients directly) to those instances where the manufacturer provided "adequate warnings" to the patients' doctors. And, this makes sense. The purpose of the doctrine is not to eliminate a manufacturer's duty to warn; it is to ensure consumers make informed decisions in conjunction with their physician. This principal was echoed and reiterated by the Supreme Court in *Brown*, which held:

> [A] patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties. The manufacturer cannot be held liable ***if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient*** or if the patient relies on inaccurate information from others regarding side effects of the drug.

*Brown v. Superior Ct*., 44 Cal. 3d 1049, 1061–62 (1988) (emphasis added). Himes contends that these cases, *Love*, *Carmichael, Stevens,* and *Brown* provide that a pharmaceutical and device manufacturer can only invoke the learned intermediary doctrine "***if*** adequate warning of potential dangers of a drug has been given to doctors." *Stevens*, 9 Cal. 3d at 65 (emphasis added). And, *if* adequate warnings were not given to anyone (and the intermediary was not independently informed of the risk), the defense is unavailable; any intermediary is, by definition, no longer "learned."

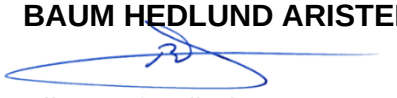
Here, it is *undisputed* that Somatics did not provide *any* warnings to plaintiffs' ECT doctors, much less adequate warnings, concerning brain injury or permanent memory loss. 1-ER-8; 3-ER-386-90; *see also Riera*, 2021 WL 2024688, at *1 ("Somatics never investigated these complaints, nor did it submit adverse events to the FDA or warn physicians and consumers of these risks.") Thus, under California Supreme Court precedent, Somatics cannot invoke the learned intermediary defense. Any other rule would pervert the entire purpose of the learned intermediary doctrine, effectively shielding medical device and pharmaceutical makers from liability even when they clearly did not warn of a known or knowable risk.

Himes' *second modification* to the certified question proposes eliminating of the prudent person standard which the Ninth Circuit adopted *sua sponte* even though Somatics never articulated such a standard in its summary judgment motion. As discussed in footnote 1 supra, the causation standard for products liability failure to warn claims is the "*substantial factor*" test as outlined in CACI 1205 (strict liability) and CACI 1222 (negligence), and California courts have routinely allowed plaintiffs to establish causation by providing "self-serving" testimony as to how they would have altered their conduct in failure to warn cases. *Colombo v. BRP US Inc.,* 230 Cal. App. 4th 1442, 1454 (2014) (collecting cases). Here, given that Himes has testified that, had she been warned of the risk of brain injury and permanent memory loss, she would not have consented to ECT, under the substantial factor test and cases such as *Colombo*, her testimony is sufficient to create a triable issue of fact for the jury to adjudicate.

**Conclusion**

For these reasons, and the reasons explained in Himes' opening letter, this Court should accept the Ninth Circuit's request to answer the certified question either as originally posed by the Ninth Circuit or, if the Court is inclined to modify the question at all, it should do so as herein modified by Himes.

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 May 2, 2022, at Los Angeles, California.

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**STATE OF CALIFORNIA**
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