No. S273887

In the Supreme Court

of the

State of California

MICHELLE HIMES

Plaintiff-Petitioner,

vs.

SOMATICS, LLC,

Defendant-Opposing Party.

On Request from the US Court of Appeals for the Ninth Circuit
For Answer to Certified Questions of California Law

REPLY BRIEF

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The overshadowing theme underlying Somatics' brief is a desire to create precedent which sacrifices patient autonomy and proclaims the wants of a physician are paramount to the choice and consent of the patient.

The right to be free of undesired physical contact traces its origins to English common law of the thirteenth century, is an integral part of our constitutional freedoms -- the "right to refuse medical treatment has been specifically recognized as a subject of constitutional protection." *United States v. Charters*, 829 F.2d 479, 490–92 (4th Cir. 1987); *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) ("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'"). Courts have recognized that no right is more sacred, or more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person. *Charters*, 829 F.2d at 491 (citing cases). This constitutional right to avoid unwanted touching forms the basis of the doctrine of informed consent – a doctrine that provides "a patient has a right to be informed of the value and

possible consequences of a treatment and to refuse or consent to that treatment." *Id.*; *see also Cobbs*, 8 Cal. 3d at 243 ("the decision whether or not to undertake treatment is vested in the party most directly affected: *the patient*.") (emphasis added).

Indeed, so highly does California value patient consent and autonomy that, with respect to the procedure at issue in this case – electroshock or electroconvulsive therapy ("ECT") – the California legislature passed specific legislation stating *both* voluntarily admitted patients and *even patients who have been admitted in a hospital against their will* (i.e., involuntary patients) must provide informed consent prior to being administered ECT and no ECT may be administered without the informed consent of the patient:

> 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.

CAL. WELF. & INST. CODE § 5326.85[1]. While this statute was cited in Himes' opening brief, it is curiously absent in Somatics' brief. Simply put,

[1] Himes was *not* an involuntary patient.

Somatics' arguments that the ultimate consent of the patient should be disregarded by this Court for purposes of products liability law involving pharmaceuticals and medical devices, is not only an affront to our moral and constitutional principles as espoused above, but a disregard of common sense and the law.

* * * *

In her opening brief, Himes established Somatics failed to warn her doctor about the risks of permanent memory loss and brain damage associated with ECT and that, as a result of its failure to comply with its warning obligations, it could not seek shelter behind the learned intermediary defense. *See e.g.*, *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973); *Hill v. Novartis Pharms. Corp*., 944 F. Supp. 2d 943, 954 (E.D. Cal. 2013). *Second,* Himes established that, under California precedent, once it is determined that Somatics was negligent for failing to issue required warnings, Somatics could not then point to the dereliction or negligence of the doctor to absolve itself of liability. *Stevens*, 9 Cal.3d at 69; *see also T.H. v. Novartis Pharm Corp*., 4 Cal.5th 145, 184 (2017); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). *Third*, Himes argued that, even if the learned intermediary defense continued to apply to a manufacturer that failed to

provide warnings to the intermediary/doctor, then the injured plaintiff may establish causation by showing that, had the doctor been adequately warned, he would have relayed the warnings to the patient and the patient testified that, armed with the enhanced warning, she would not have consented to the procedure and hence would have avoided the injuries caused by the medical device. Such a fact pattern (as in this case) demonstrates that the manufacturer's failure to warn the intermediary was a proximate cause of the plaintiff being exposed to the harms associated with the medical device. *Georges v. Novartis Pharms. Corp.*, 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013); *Stanley v. Novartis Pharm. Corp.*, 11 F.Supp.3d 987, 1003 (C.D. Cal. 2014); *see also Riera v. Somatics, LLC*, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018)(5-ER-1148). *Fourth*, Himes argued that, under established California products liability law governing failure to warn cases, the subjective attestation of the plaintiff as to what she would have done had she been adequately warned are sufficient to establish causation, *see Colombo v. BRP US Inc.*, 230 Cal. App. 4th 1442, 1454 (2014) (collecting cases), and this Court should not adopt the Ninth Circuit's newly crafted "objective test" which is a test exclusively reserved for medical malpractice cases and is not applicable to products liability cases.

Realizing that it cannot prevail on the facts and the law, Somatics resorts to making a number of statements that are inconsistent with the record, citations to material outside of the record, false, irrelevant and disparaging characterizations, and arguments that conflict with established California laws and policies -- to attempt to unpack all of them in this reply would not only be a waste of the Court's time, but also an unproductive endeavor. Rather, Himes will focus her reply on the substantive issues but will point out any misrepresentations and transgressions in Somatics' brief to the extent they impact the substantive arguments.

I. Under California Law All Patients, Including Patients in Himes' Condition and Even Involuntary Admitted Patients, Are Afforded the Constitution and Statutory Right to Grant Informed Consent Prior to Undergoing a Surgical Procedure, Including Electroshock Therapy

Somatics begins its brief with painting a disparaging and misleading picture of Michelle Himes (Himes), which is neither appropriate nor relevant to the questions to be addressed by this Court. Somatics' goal appears to be to cast Himes in such a light to convince this Court that she somehow is not worthy of her bodily autonomy and the rights and protections afforded to all persons and patients in California. CAL. WELF. & INST. CODE § 5326.85 (both voluntary and involuntary committed patients

must provide informed consent before ECT is administered); *Riese v. St. Mary's Hosp. & Med. Ctr.*, 209 Cal. App. 3d 1303, 1317 (1987); see also *Cobbs v. Grant*, 8 Cal. 3d 229, 243–44 (1972).

Whether Himes was an appropriate candidate for ECT treatment is irrelevant to the questions presented and was never at issue in the motion for summary judgment.[2] Now, on appeal, without the benefit of a fully developed record, Somatics seeks to paint Himes as an unhinged, dangerous person who was at risk of death, and saved by ECT. In fact, the record and Himes' current condition shows otherwise.

Himes is presently a mother of five children who, unfortunately, faced a difficult childhood and struggled with depression throughout most of her young adult life. 2-ER-269 & 5-ER-949. In 2009, Himes and her husband moved from Nevada to California, where she began treatment with a new doctor. 5-ER-949. From 2009 to 2011, she tried several different antipsychotics and antidepressants that did not relieve her symptoms of depression, and instead worsened her condition. *Id*. Prior to then, she had

[2] Somatics' lofty proclamations concerning the efficacy and benefits of ECT are unsupported. See 3-ER-444. Indeed, the FDA currently requires that *patients and doctors* be warned that: "The long-term safety and effectiveness of ECT treatment has not been demonstrated." 21 C.F.R. § 882.5940. Moreover, a number of studies have found no evidence that ECT prevents suicide. See e.g., 5-ER-906.

never been hospitalized, but in this three-year period, she was hospitalized numerous times. SER 3.

As her symptoms from her depression worsened, Himes ***voluntarily*** enrolled in an inpatient psychiatry program at Sharp Mesa Vista Medical Center ("Sharp Hospital") in San Diego, California. 3-ER-328. Himes and her husband met with Raymond Fidaleo, M.D. ("Dr. Fidaleo") to discuss ECT treatment as a potential treatment for her depression. 5-ER-949. At the time, Himes was only 25 years old and was experiencing "postpartum psychosis," as she had recently given birth to her six-week-old infant. SER 3.[3]

After watching an informational video at Sharp Hospital that explained "how great ECT was," receiving informational pamphlets that touted the benefits of ECT, and being informed by Dr. Fidaleo that short-term memory loss was a side effect of ECT, Himes consented to receive

[3] Somatics' brief also refers to a incident at the hospital contacting child services, however, as this issue was never relevant to summary judgment (nor relevant to this appeal), the record on this issue was never fully developed. When this case proceeds to trial, the record will reveal that when Dr. Fidaleo learned of the incident, he vehemently disagreed with the decision to contact child services, as Himes was not a threat to her children and never harmed her children.

ECT. 2-ER-309-10 & 3-ER-342 & 502. Neither the informational material she received, nor Dr. Fidaleo or the consent form, ever advised Himes that brain damage or permanent memory loss was a risk of ECT. 3-ER 310-313 & 5-ER-949.

After undergoing 26 sessions of ECT at Sharp from April 2011 to June 2012, Himes never returned for her next ECT sessions, and Dr. Fidaleo never followed up with Himes after her last ECT visit. 5-ER-949-950. Himes and her husband moved back to Nevada so that she and her daughter could live with family while her husband was stationed overseas with the Navy. *Id*. ECT did not prove to be therapeutic, as she was again hospitalized in April 2013, and she continued taking psychiatric medications until December 2015, when she became pregnant with her third child. *Id*. Since then, Himes learned more about the side effects of psychiatric drugs and recognized that medication she took was more harmful to her at the time than it was helpful. *Id*.

Aside from being ineffective, Himes' 26 ECT procedures caused brain damage and permanent memory loss. These are side effects which Somatics knew about for years prior to her ECT procedure but failed to warn doctors about. 2-ER-39-47. Dr. Fidaleo has testified that had he been

warned of these risks they would have been included in his informed consent documents which he gives to patients, and Himes in turn has testified that had she been warned by Dr. Fidaleo of these serious permanent risks, she would not have consented to ECT. 3-ER-337-345 & 5-ER-948.

II. Himes Supported Her Claims Concerning ECT Causing Brain Damage and Permanent Memory Loss with Expert Testimony and Peer Reviewed Studies and it Was Somatics Who Failed to Marshall in Any Expert Reports or Scientific Literature

Next, Somatics refers to Himes as a "crusader" simply because she, like many other patients injured by defective pharmaceutical and medical devices, had the gall to file a products liability action for the serious injuries she has sustained as a result of Somatics' concealment of the serious risks associated with its ECT. If this were not enough, Somatics proceeds to state that "she's anti-science." Res. Br. at 2. It is unclear what Somatics seeks to purchase with these unfounded, disparaging remarks, however, they are baseless, and fall short of the professionalism expected of litigants in the highest court of this great state.

Continuing its disparaging and false narrative, Somatics dedicates part of its brief *falsely* claiming that "Plaintiff makes no meaningful effort to

engage with scientific literature" and that "[t]he critical piece missing from Plaintiff's attack on ECT is, of course, science." Res. Br. at 10-11. To the contrary, Himes supported her arguments with peer reviewed journal articles (4-ER-855-865 & 877-918) and expert reports/declarations (4-ER-440-487), all of which were unrefuted and *undisputed* by Somatics. *See e.g.*, 2-ER-28-76. For example, in the district court, Somatics stated that, *inter alia*, the following expert supported facts were **undisputed:**

- Prior to Plaintiffs' ECT treatments, Somatics was aware, or should have been aware, of numerous articles published in the peer reviewed medical literature and in numerous textbooks concerning the risk of permanent memory loss, severe cognitive impairment and brain damage. See 2-ER-39-40 (**Undisputed** Fact No. 28).

- Somatics manufactures an ECT machine that administers electric current to a patient's head that is approximately one hundred times what tasers use, approximately the same current used to stun pigs prior to slaughter, roughly one-fifth as much current as the electric chair, and applies voltage that is more than one hundred times what is required to damage brain cells, and yet Somatics chose not to provide any warnings to plaintiffs' medical providers concerning any risks or adverse events associated with its ECT device. 2-ER-47 (**Undisputed** Fact No. 47).

- 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."[4] 2-ER-49 (**Undisputed** Fact No. 49).

Indeed Dr. Read's peer reviewed study and meta-analysis which was contained in the record (4-ER-877-918), cited to numerous other studies that had likewise found that ECT is linked to permanent memory loss, including a large 2007 prospective study that found 12% of ECT patients had "marked and persistent retrograde amnesia." 5-ER-912. Dr. Read's study further cited to a 2004 New Zealand Government report that stated "ECT may permanently affect memory and sometimes this can be of major personal significance," and noted the "slowness in acceptance by some professional groups that such outcomes are real and significant in people's lives." 5-ER-913.

Although Himes supported her opposition with expert reports and peer reviewed journal articles concerning the risks and limited efficacy of ECT, it was Somatics that failed to cite any medical literature. Indeed as revealed above and in the Separate Statement, Somatics **did not dispute**

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[4] John Read, Ph.D. et al, *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses*, 21 Ethical Human Psychology & Psychiatry 64 (2019)

that its ECT device is linked to serious risks of brain injury and permanent memory loss and that it failed to issue any warnings concerning these risks. 2-ER-37-49; see also 1-ER-4 & 9. To now fill in the hole, Somatics impermissibly resorts to citing *promotional* material from the websites of various hospitals (none of which were in the record) and none of which are supported by peer-reviewed citations. *See* Res. Br. at 9-10. Indeed, a cursory review reveals that these promotional websites actually contain inaccurate information. For example, the promotional website from the Mayo Clinic provides that in ECT "small electric currents are passed through the brain"; however, in this case, Somatics has agreed with Himes' Biomedical and Electrical Engineering expert, Kenneth Castleman, Ph.D. (a former Senior Scientist at NASA's Jet Propulsion Laboratory), that Somatics' ECT machine "administers electric current to a patient's head that is approximately one hundred times what tasers use . . . roughly one-fifth as much current as the electric chair, and applies voltage that is more than one hundred times what is required to damage brain cells." 2-ER-47.

III. It is Undisputed That Somatics Failed to Provide Adequate Warnings Concerning Permanent Memory Loss to Dr. Fidaleo

In its Brief, Somatics contends it "has consistently disputed Plaintiff's accusations of warning inadequacy . . ." See Res. Br. at 8. Yet the record and the undisputed facts reveal otherwise. In opposing Somatics' motion for summary judgment, Plaintiffs' Separate Statement of Uncontroverted Facts No. 47 stated, in part, that "Somatics chose not to provide ***any warnings*** to plaintiffs' medical providers concerning ***any*** risks or adverse events associated with its ECT device." 2-ER-47–48 (emphasis added). Somatics responded to this factual contention as "**undisputed**." *Id*. (emphasis in original). Considering Somatics' concession, not surprisingly, the district court in the section of its order outlining the "undisputed facts," made the following findings of fact:

> Over the years, Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia [and] cognitive impairment…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*"

1-ER-4. After making this finding of fact, the district court, in its discussion section of the Order, went on to conclude that Somatics "did not provide any warnings to . . . Dr. Fidaleo concerning the risk of brain injury or

permanent memory loss." 1-ER-9.

Moreover, Somatics' eleventh-hour contention that it somehow provided adequate warnings is factually inaccurate. The sole manual for the Thymatron IV ECT device Somatics provided to Sharp Hospital at the time Himes received ECT was the 6th Edition (issued in 2001), and even Somatics' owner, Conrad Swartz, M.D., testified this manual did not contain *any* warnings:

> Q. My question was different. The manual that accompanied the ECT device for the Thymatron IV, did that manual contain any warning about the risks associated with the Thymatron IV device?
>
> A. I believe it did not.

See 3-ER-387. During his deposition (3-ER-387–390), Swartz further elaborated that the 6th Edition of the Thymatron IV manual, which is the sole version that Sharp Hospital received prior to Himes' ECT procedures (and which is the device used in Himes' ECT procedures), *did not* contain *any* warnings:

> Q. …But version six, Doctor, if I asked you to point me to the page that contains the warnings and adverse events associated with

the use of ECT, what page would I have to go to in this manual, Exhibit 3?

A. There is no such page.

3-ER-390; *see also* 3-ER-510-564 (6th Edition Manual). The foregoing facts confirm that Somatics' representation in its brief that "Somatics has consistently disputed Plaintiff's accusations of warning inadequacy…" is a gross misrepresentation, as Somatics has already admitted that it never provided *any* warnings concerning the risks of ECT to Himes' doctor, or to the hospital where Himes received her ECT.

IV. Having Failed to Issue Any Adequate Warnings to Dr. Fidaleo and Having Failed to Show Dr. Fidaleo was Independently Aware of the Risks of Brain Injury and Permanent Memory Loss, Somatics Cannot Seek Shelter Behind the Learned Intermediary Defense

The undisputed fact that Somatics never provided any warnings concerning risks, including risks of permanent memory loss to Dr. Fidaleo and Sharp Hospital, is highly germane to the learned intermediary issue that is to be addressed by this Honorable Court.

As outlined in Himes' opening brief, under 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). However, in the context of medical products that require a prescription, California has adopted what has been referred to as the "learned intermediary" defense, which provides that, *if* a manufacturer provides adequate warnings to a patient's doctor, then there is no need to warn the patient directly. *Stevens*, 9 Cal. 3d at 65. In *Stevens* this Court 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. Thus, the learned intermediary defense 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.

Contrary to implications in Somatics' brief, the purpose of the learned intermediary defense is *not* to eliminate a manufacturer's duty to warn; it is to ensure that manufacturers provide necessary warnings to allow patients in consultation with their doctors to make informed decisions. *See e.g.*, *Brown v. Superior Ct.*, 44 Cal. 3d 1049, 1061–62 (1988). Indeed, so highly does California law value the principles of encouraging

manufacturers to issue warnings that this Court has extended the principles of strict liability in failure to warn cases to govern prescription medications. *Carlin v. Superior Ct.*, 13 Cal. 4th 1104, 1117 (1996) (citing *Anderson*, 53 Cal.3d at 1003). In sum, contrary to Somatics' implications that the learned intermediary should somehow be treated as a form of immunity, the law as espoused by this Court in *Stevens* and further elaborated by *Carlin* is clear that the purpose of the learned intermediary (and strict liability doctrine) is for the manufacturer to warn doctors so that doctors could undertake their roles as "learned" intermediaries and pass those warnings to patients. And it follows that when a manufacturer has failed to issue the required warnings to doctors, and fails to establish that the doctors were independently informed of the risks, then the manufacturer cannot invoke the learned intermediary defense. Aside from being supported by this Court's enunciations in *Stevens* and the other cases cited in the opening brief (see Himes Br. at 29-43), this principle finds support from other courts, including, recently, the Supreme Court of Arizona. *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 24, 365 P.3d 944, 949 (2016) ("the [learned intermediary doctrine] does not create a blanket immunity for pharmaceutical manufacturers. The doctrine does not apply, for

instance, if the manufacturer fails to provide adequate warnings to the learned intermediary."); *see also Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) ("However, physicians can be learned intermediaries only when they have received adequate warnings…Thus, the learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician."); *Garner v. Boehringer Ingelheim Pharms., Inc.*, 888 F. Supp. 2d 911, 922–23 (S.D. Ill. 2012) (same); *Proctor v. Davis*, 291 Ill. App. 3d 265, 283 (1997) ("Doctors who have not been sufficiently warned of the harmful effects of a drug cannot be considered 'learned intermediaries'...")

Somatics disagrees and argues a manufacturer may be excused from a duty to warn the intermediary if the intermediary is already aware of the risk. Resp. Br. at 22.[5] Himes had a detailed discussion of this very issue, as it was a crucial point in this Court's seminal case in *Webb*, which addressed the issue in the context of the sophisticated intermediary defense. Himes Br. at 33 -36. However, as outlined in the opening brief, in this case Somatics has *never* established that Dr. Fidaleo was already aware of the

[5] It is worth noting that Somatics' proposition is not universally endorsed and indeed has even been previously rejected by this very court. *Stevens*, 9 Cal. 3d at 69 ("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].")

risk of permanent memory loss and brain damage. To the contrary, the undisputed evidence demonstrates that Somatics never issued any warnings about these serious risks to Dr. Fidaleo, his deposition confirms he was not independently aware of these risks—indeed he testified that had he been warned of these risks by Somatics, he would have warned Himes and would have included the risks in his informed consent paperwork. 2-ER-47–48 & 3-ER-337, 340 & 444-45. Thus, Somatics cannot seek shelter behind the *Webb* or *Carlin* "intermediary already knew" exception.

V. Somatics' Proposed Causation Path Which Only Focuses on if the Doctor Would Have Prescribed Is at Odds with the Precedent of Multiple Courts and Fails to Take Into Account that the Patient Plays a Seminal and Mandatory Role in Determining if She Ultimately Agrees to Ingest a Drug or Consent to Undergo A Surgical Procedure

Somatics' next major point of contention is its *misconception* that Himes is attempting to skirt her causation burden.[6] Somatics misapprehends Himes' arguments and the applicable jurisprudence. Himes fully appreciates and embraces her causation burden, which she has established regardless of whether or not the learned intermediary defense

[6] *See*, *e.g.*, Res. Br. at 24.

applies.

Himes agrees that California has adopted the learned intermediary doctrine, but disagrees with Somatics' proposed application of the doctrine and its impact on her causation burden. As articulated in the opening brief, under the facts of this case wherein the manufacturer has failed to warn the intermediary doctor, the learned intermediary doctrine is inapplicable. *Hill v. Novartis Pharms. Corp*., 944 F. Supp. 2d 943 (E.D. Cal. 2013) ("the doctrine, 'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.'"); *Stevens*, 9 Cal. 3d at 65 & 69.

Moreover, even if the learned intermediary doctrine did apply, Himes has established that Somatics' failure to warn her doctor was a proximate cause of her ECT induced injuries. Specifically, she has established that, had her doctor been adequately warned, he *would have relayed the warnings to her*, and she in turn testified that armed with the enhanced warning she would not have consented to the ECT procedure, and thus would not have suffered the injuries induced by ECT. Under established California law as well as the precedent cited *infra* and in the opening brief, this is more than sufficient to establish proximate causation.

Somatics, however, argues that the only way plaintiffs can establish

causation, is to show that the doctors would not have *prescribed* ECT. However, that is not the law. The injury here was not caused by the prescription of ECT, rather, it was caused by the *administration* of ECT. Thus, if all that had occurred in this case was that Dr. Fidaleo prescribed ECT, but Himes decided not to consent to ECT and thus was not administered ECT, then no tort would have occurred, and no injury would have been caused by ECT. Accordingly, Somatics is incorrect to the extent it seeks to limit the inquiry to the issue of prescription without any regard to the more important question of *administration*.

Himes pauses to note that although some cases focus on prescription and Somatics seeks to have this court embrace the "would not have prescribed" theory of causation, neither Somatics nor the cases it has relied upon ever really explain what it means to "prescribe." In the context of drugs, a doctor may initially recommend a specific drug to alleviate an ailment but in the course of the consultation and as part of the recommendation there is routinely a back and forth wherein doctors outline some of the potential side effects and counsel on instructions for taking the mediation (e.g.., drug may cause dizziness, don't drive while taking this drug). Once the recommendation is made and the back and

forth of risks and benefits occur, a patient then may decide that the benefits of the drug outweigh the risks and decide to take it; or maybe after hearing the risks, the patient may either refuse the recommendation or prescription. It is for this reason that focusing *exclusively* on whether the doctor would have "prescribed" is inappropriate. Certainly, yes if the doctor would not have prescribed or recommended the drug had he been warned then causation is established. However, because the patient plays a central and mandatory role in deciding if she will accept a doctor's recommendation /prescription to take and ingest a drug after being warned of the risks and potential benefits, any causation question in these cases *must* take into account what the patient would have done after being warned of the risks by her doctor. And, if it is established that the doctor would have relayed the warnings to the patient, and the patient—armed with knowledge of those side effects—would have rejected the recommendation/prescription, then those facts likewise establish proximate causation.

With respect to a medical device procedure such as ECT that requires anesthesia and the *written* informed consent of a patient, there is even more justification for ensuring that the consent of the patient is part of the causation calculus. Somatics' contention that only the "prescription" or

recommendation matters, fails to take into account that with respect to any surgical procedure (in particular ECT), the law requires the informed consent of a patient prior to administration. Thus a "prescription" is nothing more than a recommendation by the doctor, whereas the ultimate injury causing act is the "administration" of ECT. Accordingly, in the context of medical devices such as ECT, the focus must be on if the ECT would have been "administered," and here it is beyond dispute that had Somatics issued warnings to Dr. Fidaleo, he would have relayed those warnings to Himes, and Himes has established that armed with the warnings regarding the risk of permanent memory loss, she would not have consented to ECT. Thus, causation is established.

Rather than focusing exclusively on the prescription, courts have focused more broadly on whether the enhanced warning would have "altered the conduct" of the doctor (and the patient). *See Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004) (holding the analysis in a *wrongful death* case is whether stronger warnings would have "*altered the conduct* of the prescribing physician") (emphasis added); *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017) (same). *Changed conduct* would include the fact that, having received enhanced warnings,

the doctor would have passed on those warnings to the patients, and armed with stronger warnings, the patient would have refused to consent to the treatment. *Georges v. Novartis Pharms. Corp.*, 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013); *Stanley v. Novartis Pharm. Corp.*, 11 F. Supp. 3d 987, 1003 (C.D. Cal. 2014) (same); *Riera v. Somatics, LLC*, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018) (same); *see also* out of state cases cited in Himes' Brief at 51-52. Of the out of state cases previously cited, the following block quote from the Fifth Circuit is instructive:

> Moreover, because [Dr.] Wilkinson testified that he was never informed of the significant risk of tardive dyskinesia associated with long-term Reglan use and that such information certainly would have changed the "risk/benefit analysis" and the conversation he would have had with McNeil about the risks, the inadequate labeling could be a producing cause of the injury even if [Dr.] Wilkinson had never testified that he would not have prescribed Reglan had a contraindication been inserted. Sworn testimony from McNeil establishes that she was never told of the significantly increased risk of tardive dyskinesia with use of Reglan for greater than twelve weeks and that, if she had known of such a risk, she would not have taken Reglan for longer than that.
>
> The doctrine of the "learned intermediary" presupposes that the physician will act as an intermediary. This function includes discussing the cost-benefit ratio with the patient if necessary. Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a "producing" cause of the injury, because it effectively sabotages the function of the intermediary.

McNeil v. Wyeth, 462 F.3d 364, 372–73 (5th Cir. 2006). Somatics in its brief cites to other cases it contends support its argument that the sole inquiry is if the doctor would have prescribed as opposed to if the doctor would have relayed the stronger warnings. However, an examination of the cases cited by Somatics reveals they are in many respects factually distinguishable. For, unlike the facts of our case, the very first case cited by Somatics on this issue, *Thompson v. Janssen Pharms., Inc*., the physician was independently aware of the risk associated with the medication. 2017 WL 5135548, at *8 (C.D. Cal. Oct. 23, 2017) ("Here, the record shows that all of Thompson's prescribing physicians were aware of gynecomastia and other risks associated with Risperdal."). Likewise in *Guillen v. Eli Lilly & Co*., the doctor was independently aware of the risk. 394 F. App'x 814, 816 (2d Cir. 2010). In *Gall v. Smith & Nephew, Inc*., the treater testified he was independently aware of the risk at issue. 71 Cal. App. 5th 117, 123 (2021) ("[Dr.] Hernandez testified he did know of the ion risk..."). In *Carnes v. Eli Lilly & Co*., the doctor had independent knowledge of the risk at issue. 2013 WL 6622915, at *5 (D.S.C. Dec. 16, 2013). Likewise, in *Gaghan v. Hoffman-La Roche Inc*., unlike the facts of our case, the doctor testified he would *not* have warned the patient concerning the risk at issue. 2014 WL 3798338, at *17 (N.J. Super. Ct. App. Div. Aug. 4, 2014) ("[Dr.] did not believe it was necessary to warn the patient about its potential occurrence.").

VI. Somatics' Public Policy Arguments that Its Bottom Line Should Be Protected at the Expense of the Rights of the Innocent Patients It Has Severely Injured, Has Already Been Rejected By This Court

Somatics also argues that a standard which incorporates the consent of the patient in the causation calculus somehow "threatens patients' rights." Res. Br. at 50-53. But as outlined in the Opening Brief and *supra*, patient consent is a bedrock of our constitutional and legal principles, especially in cases involving medical procedures like ECT. Somatics' policy arguments that California tort law and policy somehow is more interested in preserving the bottom line of negligent device manufacturers at the expense of severely-injured patients is at odds with California law and this Court's precedent which, *inter alia*, has endorsed *strict liability* in failure to warn cases against pharmaceutical manufacturers so as to incentivize the timely issuance of adequate warnings.

In 1944, Justice Roger Traynor explained tort doctrine must aim to minimize the social costs of accidents. *Escola v. Coca Cola Bottling Co*., 24 Cal.2d 453, 462 (1944) (Traynor, J., concurring) ("public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products"). Two decades later this Court in *Greenman v. Yuba Power Products, Inc*., 59 Cal.2d 57, 63–64 (1963), unanimously adopted Judges Traynor's concurring *Escola* opinion, and

California became one of the first states in the United States to adopt the theory of strict products liability.

In 1991, this Court in *Anderson* extended strict liability *failure to warn* claims to asbestos cases under the theory that as between the injured user and the manufacturer who places the product on the market the latter should bear the loss. *Anderson*, 53 Cal. 3d at 998. *Anderson's* holding concerning the policy and applicability of strict liability failure to warn claims was subsequently extended by this Court in 1996 to prescription drug products wherein the Court held:

> we see no reason to depart from our conclusion in *Anderson* that the manufacturer should bear the costs, in terms of preventable injury or death, of its own failure to provide adequate warnings of known or reasonably scientifically knowable risks. As we observed: 'Whatever may be reasonable from the point of view of the manufacturer, the user of the product must be given the option either to refrain from using the product at all or to use it in such a way as to minimize the degree of danger.' Although *Anderson* itself involved a nondrug, asbestos, our conclusion therein applies with equal force to prescription drugs.

Carlin, 13 Cal. 4th at 1117. Somatics now resurrects the same financial concerns of insurance costs and increased prices that were specifically rejected in *Anderson* and *Carlin* for failure to warn cases (and curiously cites to and relies upon the *dissenting* opinion in *Carlin* to support its misplaced argument). The simple fact is that Somatics could have easily prevented the injury that Himes and the numerous other ECT patients sustained if it simply issued timely and proper warnings. Somatics has neither argued nor

established that there would be any significant costs associated with issuing Dear Doctor letters and updated warnings to its customers and psychiatrists who use ECT. To the contrary, the record reflects Somatics could have issued enhanced warnings without any substantial expense and could have, among other avenues, used the same means in which it promotes its device to issue such warnings:

Q. What is the expense to Somatics for issuing enhanced warnings if you chose to issue enhanced warnings?

A. **It's not a substantial expense**, whatever it is.

Q. …Doctor, what modes of communication do you utilize to communicate with your current customers, as well as potential customers? And let me place this in the time frame of, let's say, between 2002 and 2012? What were the modes of communication?

A. There were mass mailings. There were meetings at trade shows, specifically the American Psychiatric Association and the Association of Convulsive Therapy. That – and there may have been a number of e-mails.

See 3-ER-395. A warning that Somatics *admits* would not have caused it to incur a substantial expense would have prevented Himes' serious injuries. However, as the record further reflects, even though Somatics knew (or at least should have known) about the risks of brain damage and permanent

memory loss, and even though in 2006 (years prior to Himes' ECT), Somatics' owners contemplated issuing a warning, Somatics chose to *not* issue any such warnings. In internal communications, the Somatics owners appear to express concern that adding a warning about permanent memory loss would cause Somatics to lose customers (i.e., "alienate psychiatrists"). 2-ER-44-45; 4-ER-874-876.

In a similar breath, Somatics argues that adopting a causation standard that incorporates patient consent would somehow "dramatically reduce a plaintiff's evidentiary burden on causation." See Res. Br. at 50. Yet there is nothing about the learned intermediary doctrine or strict products liability that is aimed to *increase* plaintiff's burdens. To the contrary, California courts adopted strict products liability (including in prescription drug failure to warn cases, see e.g., *Carlin*), and "one of the principal purposes behind the strict product liability doctrine is to relieve an injured plaintiff of many of the onerous evidentiary burdens…"*Barker*, 20 Cal. 3d at 431; *see also Anderson*, 53 Cal. 3d at 994.

Second, adopting Himes' causation approach which respects and incorporates the consent of the patient is consistent with other strict products liability cases wherein plaintiffs are allowed to establish causation

by demonstrating had they been warned they would have not agreed to the procedure and/or not taken or used the product and thus would have avoided its harms. This too is consistent with this Court's precedent and the principles of strict liability. *Anderson*, 53 Cal.3d at 1003.

Third, Somatics' arguments that Plaintiffs' burdens will be softened because "most physicians will say they would've passed on a stronger warning…" is buttressed by the cases it had cited wherein plaintiff's claims against the drug manufacturer were dismissed because the physician testified that he would not have passed enhanced warnings to his patients.[7] Furthermore in the context of serious risks, like here, it is certainly reasonable and expected that doctors testify (as did Dr. Fidaleo) that they would pass such warnings to their patients, had the doctors been adequately warned by Somatics. *See Riera*, 2018 WL 6242154, at *11.

VII. Somatics' Misplaced Contention that Dr. Fidaleo Was Somehow Not Exposed to Somatics Manual and Would Not have Heeded Enhanced Warnings (Had One Been Issued) Has Already Been *Factually* Rejected By the Ninth Circuit

Somatics argues that Dr. Fidaleo would not have been exposed to and

[7] *See e.g.*, *Gaghan*, 2014 WL 3798338, at *17 ("[Dr.] did not believe it was necessary to warn the patient about its potential occurrence.").

would not have read an enhanced warning had one been issued. However, the Ninth Circuit *factually* disagreed with Somatics and made the following findings of fact:

> 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.

Himes v. Somatics, LLC, 2022 WL 989469, at *2–3 (9th Cir. Apr. 1, 2022). At this procedural posture wherein this Court is being asked to answer a question of California *law*, it is inappropriate for Somatics to ask this Honorable Court to second guess the *finding of fact* made by the Ninth Circuit. Moreover, under California law, there is an inference that if a warning had been provided by the manufacturer, it would have been read and heeded by the doctor. *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 441 (1969) (while no testimony was provided as to whether doctors had read the manufacturers label, the California Court of Appeal held that "*the jury could infer that the language of the insert was read by the doctors…and*

that they relied upon it…") (emphasis added); *see also Toole v. Richardson-Merrell Inc.*, 251 Cal. App. 2d 689, 707–08 (1967). Finally, the facts reveal Dr. Fidaleo both through Somatics *as well as his ECT technician* was exposed to the Somatics label and trained by Somatics personnel on the use of the device. 3-ER-326; *see also* 3-ER-333 & 335. *See American T. Co. v. California etc. Ins. Co.* 15 Cal.2d 42, 67 (1940) (reliance can be established through evidence of *indirect* reliance); *see also Georges v. Novartis Pharms. Corp*., 2013 WL 5217198, at *9 (C.D. Cal. Apr. 4, 2013) (under California law the manufacturers duty to warn runs not only to the prescribing physician but also to *other* medical providers who are in a position to reduce the risk of harm in accordance with instructions and warnings).[8]

[8] The law in other jurisdictions is in accord. *See Holley v. Burroughs Wellcome Co*., 74 N.C. App. 736, 746 (1985) (collecting cases); see also *Knipe v. SmithKline Beecham*, 583 F.Supp.2d 602, 621 (E.D.Pa. 2008). Somatics also relies upon *Ramirez v. Plough, Inc*., 6 Cal. 4th 539 (1993), but *Ramirez* actually confirms that Dr. Fidaleo's second-hand reliance on the label sufficiently links the chain of causation. *Ramirez* dealt with an over-the-counter drug manufacturer that failed to issue warnings in Spanish. *Id*. at 555-56. The court determined causation was lacking because the minor-plaintiff's mother, who was literate only in Spanish, did not read the label, and importantly, she did not have the English-language label translated to her. *Id.* Thus, implicit in the Court's analysis is that causation could have been established if the information in the label was relayed to her by someone else. Here, plaintiffs have presented evidence of this form of reliance, and more.

Lastly, contrary to Somatics' argument, this Court has already held that the manual or label is not the sole, nor even the most effective, means that medical device and pharmaceutical companies communicate with physicians. *Stevens*, 9 Cal. 3d at 67. Moreover, device companies, including Somatics, communicate with doctors through a myriad of means, including, promotional literature, sales representatives, "Dear Doctor" letters, seminars, and medical journal articles. *Stevens*, 9 Cal.3d at 67-69 (sales representatives are "a highly effective means of promoting the use" and "to disseminate information as to the drug's hazard"); see also 3-ER-395(avenues through which Somatics communicates with customers/psychiatrists who perform ECT). Thus, whether or not a doctor read a package insert does not serve as a litmus test for causation, rather, the key question is whether the doctor relies upon the device manufacturer's safety and risk representations, irrespective of the venue in which those representations occurred. *Stevens*, 9 Cal.3d at 67. Here, as already factually determined by the Ninth Circuit, Dr. Fidaleo testified he relies upon safety alerts that he obtains from manufacturers and that he would have relied upon and heeded had Somatics issued warnings. 3-ER-336-344; *Himes*, 2022 WL 989469, at *2–3.

To the extent that this Court accepts Somatics' invitation to address a factual finding of fact that has already been determined by the Ninth Circuit, this Court should (a) consistent with its past precedent as espoused in *Stevens* conclude that in such pharmaceutical and medical device products liability cases, reading the label is not the litmus test for establishing if the doctor would have relied on a warning but that instead reliance can be shown through the myriad of more effective means of communications including sales representatives, medical literature, dear doctor letters, conferences and other modes that doctors rely upon to learn of risks, including new safety risks associated with drugs and devices; (b) consisted with prior California appellate decisions in *Grinnell* and *Toole* this Court should conclude California law provides an inference that doctors would have read and heeded a warning had one been provided, see e.g., *Grinnell*, 274 Cal. App. 2d at 441; and (c) that consistent with the decision of this Court in other context as well as other federal court decisions in pharmaceutical cases, the doctor's reliance can be established through evidence of *indirect* reliance. *American T. Co.,* 15 Cal.2d at 67; *see also Georges*, 2013 WL 5217198, at *9; *Knipe*, 583 F.Supp.2d at 621.

VIII. This Court Should Continue to Apply the Substantial Factor Test for Causation in Strict Products Liability Cases Which Allows Plaintiff's Subjective Testimony to Establish Causation

Lastly, this Court should reject Somatics' request that the "objective" patient standard applies to products liability cases for purposes of establishing if a patient or consumer would have acted differently had they been warned. Prior to the Ninth Circuit's announcement in this case, to counsel's knowledge, no California court had required an objective person test in a strict products liability case when the plaintiff was alive to testify as to how she would have reacted had she been warned. Rather, the objective person standard espoused in *Cobbs* is limited to medical malpractice cases wherein the Court wanted to protect *physicians* from liability. As this Court subsequently explained in *Truman*, "[t]he prudent person test for causation was established *to protect defendant physicians…*" *Truman v. Thomas*, 27 Cal.3d 285, 294, n.5 (1980) (citing to *Cobbs*, 8 Cal.3d at 245). California has consistently afforded various exclusive protections to physicians, including, for example, placing limits on non-economic damages in claims against physicians as espoused in the Medical Injury Compensation Reform Act (MICRA), shorter statute of limitations for medical-malpractice claims, evidentiary limitations to protect physicians,

bifurcation of statute of limitations in trials involving physicians, and refusal to apply strict products liability to claims against physicians and hospitals (see e.g., *San Diego Hosp. Assn. v. Superior Ct.*, 30 Cal. App. 4th 8, 13 (1994) ("California courts have repeatedly held that strict liability may not be imposed against health care providers for injuries suffered by their patient.") The foregoing protections afforded to physicians, however, are not afforded to medical device manufacturers. Indeed, while physicians are not subject strict products liability, pharmaceutical and device manufacturers *are* subject to such liability. Accordingly, one cannot take a protection that is provided exclusively for the benefit of physicians and suddenly apply it to device manufacturers in *strict products* liability cases, which are governed by the substantial factor standard and routinely permit plaintiffs' subjective testimony to establish causation.[9] *Colombo v. BRP US Inc.*, 230 Cal. App. 4th 1442, 1454 (2014) (collecting cases); *see also Dimond v. Caterpillar Tractor Co.*, 65 Cal. App. 3d 173 (1976) (in a products liability case, the plaintiff's testimony that he read a warning, and acted in

[9] Tellingly, all of the cases that Somatics has marshalled in support of its "objective" standard argument are cases involving *medical-malpractice*; they are not products liability cases.

accordance with a warning, which caused him injury, was sufficient evidence to present to the jury); *see also Hrymoc v. Ethicon, Inc.*, 467 N.J. Super. 42, 90 (App. Div. 2021); *Mongeon v. Ethicon, Inc.*, 456 F. Supp. 3d 298, 301-03 (D. Mass. 2020).

Consistent with the above authority, this Court should continue to hold that a plaintiff in a products liability failure to warn case may establish causation by her testimony that, had she been warned of the risks either from the intermediary or the manufacturer, she would not have agreed to the ECT procedure, and any credibility issues should be resolved by the jury.

CONCLUSION

In answering the certified question, this Court should conclude that, when a device manufacturer *fails* to warn the intermediary, then (a) the manufacturer loses the protections afforded by the learned intermediary defense; (b) the manufacturer may not point to any conduct of the doctor to absolve itself of its own negligence; and (c) an injured plaintiff may meet her causation burden by establishing that, had she been warned of the true risks of the device by her doctor or the manufacturer, she would not have

consented to the medical procedure.

Dated: October 19, 2022

Respectfully submitted,
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Dated: October 19, 2022

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