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

PETITIONER'S CONSOLIDATED ANSWER TO ALL FILED *AMICUS CURIAE* BRIEFS

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INTRODUCTION

A choir of six amici consisting of pharmaceutical trade organizations and various physician organizations joined the docket to, for the most part, lend a supporting voice to respondent, Somatics, LLC ("Somatics"). Many of the amici regurgitate arguments previously advanced by Somatics and which petitioner, Michelle Himes ("Himes"), has already addressed in her opening and reply briefs. Himes takes this opportunity to respond to the overarching arguments advanced by the various amici, all of which seek to curtail an injured plaintiff's ability to bring failure to warn claims against irresponsible manufacturers.

ARGUMENT

The pharmaceutical and device trade organizations worry that adopting a causation analysis that includes the patient (as opposed to one that focuses exclusively on the doctor) would somehow (a) be inconsistent with the learned intermediary doctrine; (b) be speculative; and (c) impact the bottom line of the lucrative pharmaceutical and device industry. The amici's arguments are factually unfounded and legally flawed.

I. The Pharmaceutical Trade Organization Amici Advocate for An Erroneous Causation Standard That Seeks to Abolish the Ultimate Consent of the Patient from the Analysis

The pharmaceutical and device trade organization amici are of the collective opinion that the consent of Himes is irrelevant to the causation issue and that, under the learned intermediary doctrine, the Court should endorse a position that *only* considers the conduct of the physician for purposes of causation *and completely ignores the injured patient*. Indeed, the

Products Liability Advisory Council, Inc. ("PLAC"), advocates that neither the subjective nor objective patient standard test should be applied (*see* Br. at 21-26), and we should instead only view causation through the prism of the physician and whether the physician would have prescribed and administered ECT.[1] Amici further contend a causation standard that

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[1] The Civil Justice Association of California (CJAC) in its brief ***erroneously*** states: "Indeed, when the learned intermediary doctrine was first articulated as such in *Sterling Drug, Inc. v. Cornish* (8th Cir.1966) 370 F.2d 82, the informed consent doctrine had not yet been developed. California did not recognize "informed consent" as an integral part of the physician's overall obligation to patient until years after the learned intermediary doctrine was recognized by numerous courts accross (sic) the country. (*See Cobbs v. Grant* (1972) 8 Cal.3d 229.)." *See* CJAC Br. at 28. Contrary to CJAC's arguments, the doctrine of informed consent was developed in the early 1900s, specifically, as early as 1905 when the Illinois Court of Appeal held:

> [U]nder a free government at least, the free citizen's first and greatest right, which underlies all others--the right to the inviolability of his person, in other words, his right to himself--is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise and prescribe (which are at least necessary first steps in treatment and care), to violate without permission the bodily integrity of his patient by a major or capital operation, placing him under anæsthetics for that purpose, and operating on him without his consent or knowledge.

Pratt v. Davis, 118 Ill. App. 161, 166 (Ill. App. Ct. 1905), aff'd, 224 Ill. 300, 79 N.E. 562 (1906). This principle was reaffirmed by Judge Benjamin Cardozo who, in 1914, held: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon

completely ignores the patient somehow "promotes" patient autonomy (*see* e.g., PLAC Br. at 17-21). Indeed, the proposed causation standard that purports to value human autonomy as advocated by the pharmaceutical trade organization amici actually disregards patient autonomy altogether.

As Himes articulated in her opening and reply briefs, these arguments that seek to eradicate the ultimate consent of the injured patient from the causation inquiry are at odds with established California law which provides that a patient's informed consent is paramount and necessary prior to *any* medical procedure being performed on the patient, *see 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), and in the context of ECT, California has a specific statutory scheme confirming that each patient has

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who performs an operation without his patient's consent, commits an assault, for which he is liable in damages." *Schloendorff v. Soc'y of New York Hosp.*, 211 N.Y. 125, 129–30 (1914). Notably, the very first judicial court to utilize the phrase "informed consent" was a California Court of Appeal in *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 578 (1957); *see also* Bazzano et al., *A Modern History of Informed Consent and the Role of Key Information*, 21 OCHSNER JOURNAL 81 (2021). Thus, CJAC is simply mistaken to the extent it argues the learned intermediary (which was first coined by the Eighth Circuit in 1966) somehow predates principles of informed consent (as informed consent principles have been recognized since the early 1900s); CJAC is also wrong to the extent it argues California did not recognize the principles of informed consent until *after* coinage of the learned intermediary doctrine, since as outlined herein, California recognized informed consent in case law as early as 1957 and the learned intermediary doctrine was not enunciated until 1966 by the Eighth Circuit. Thus, contrary to CJAC's arguments, in American and California jurisprudence, informed consent principles *predate* the learned intermediary doctrine.

a right to be informed of the risks associated with the procedure and has a right to refuse treatment after being informed of the risks. Cal. Welf. & Inst. Code §5326.85. Exclusively to protect their bottom line, the pharmaceutical trade organization amici ask this Court to adopt a causation path that would ignore Himes' absolute right to refuse to consent to treatment (had she been adequately warned) and instead focus exclusively on the intermediary doctor. Of course, to adopt their approach and to determine that no causation exists in this case, the Court would have to presume that, in violation of the aforementioned statutory rules, as well as common law rules governing medical battery, Dr. Raymond Fidaleo would have *administered* ECT to Himes even after she refused to consent (after receiving additional warnings concerning the serious risks of brain damage, permanent memory loss and an inability to formulate new memories associated with ECT). It is troubling that pharmaceutical trade organization amici are asking this Court to *illicitly presume* (in complete contravention of the established evidence, *see e.g.*, 3-ER-340, 344, 345 & 5-ER-948) that Dr. Fidaleo would have committed battery and what would essentially amount to human rights violations, simply to ensure that the bottom line of Somatics and the pharmaceutical industry are protected. The Court should not accept amici's invitation to erase patient consent from the equation at the altar of the pharmaceutical industry's profits.

At least as to the issue of whether the consent of patients remains germane to the causation analysis, the *physician* organization amici (including the American Psychiatric Association ("APA") and the California Medical Association ("CMA")) do at least *implicitly* agree with

Himes that the consent of the patient is *mandatory* prior to a patient being administered any medical procedure. As the APA noted:

> Clinicians make a recommendation for ECT based on an overall assessment of risks and benefits, informed by education, training, and clinical expertise. *Ultimately, however, the judgment about whether to undergo ECT is made by the patient or the patient's authorized legal representative.*

See APA Br. at 15 (emphasis added). Likewise, the CMA agrees, in part, with Himes that the patient plays a crucial and mandatory role in whether a drug is prescribed or if a procedure is administered to her. Specifically, the CMA states, "both physicians and patients decide by weighing the benefits of the treatments against the risks" and provides a sample chronology of events (similar to what Himes outlined in her Reply Brief at 21-23) as to how a doctor's recommendation turns into a prescription or administration of a procedure. And, importantly, a crucial element prior to prescription/administration according to the CMA, is the doctor and patient discuss the risks and benefits of the drug/procedure and ultimately "[*t]he patient* decides either to *consent* or *refuse*." *See* CMA Br. at 11 (some emphasis added).[2] Thus, as the physician organization amici (APA and CMA) appear to appreciate, the consent of the patient is a paramount and

[2] CMA, however, goes on to endorse an "objective" patient standard and further advances other arguments Himes disagrees with as further articulated herein and/or previously outlined in her opening and reply briefs. Likewise, the APA makes certain statements concerning the efficacy and safety of ECT that were not part of the record (and not necessarily germane to the legal issues before this Court), however, Himes will briefly address them *infra*.

necessary element in determining whether the patient would have been administered ECT—and, contrary to the arguments advanced by Somatics and the pharmaceutical industry amici, the Court should *not* ignore the injured patient in its causation analysis.

II. The Learned Intermediary Doctrine Is Only Relevant to the Issue of *Duty* and Cannot be Used by the Negligent Device Manufacturer as a Sword to Challenge Causation

A justification advanced by the pharmaceutical trade organization amici for excluding the patient (whether subjectively or objectively) from the causation analysis is the *mistaken* belief that the learned intermediary doctrine is somehow mandatorily implicated in the *causation* analysis and that, for this reason, the patient's consent is immaterial. Somatics and its pharmaceutical trade organization amici are mistaken.

First, as the Arizona Supreme Court recently explained: "the [learned intermediary doctrine] is based on principles of duty, ***not causation***." *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 23, 365 P.3d 944, 948 (2016) (emphasis added). The Supreme Court of Arizona went on to endorse the court of appeals' legal conclusion that "[i]n its application, the [learned intermediary doctrine] appears to be less a rule of causation and more a standard for determining when a drug manufacturer has satisfied its duty to warn." *Watts*, 239 Ariz. at 23 (citations omitted).

The same is true in California, and under this Court's precedent. Under California law, the learned intermediary doctrine is simply a means by which a prescription pharmaceutical or medical device manufacturer can discharge its duty to warn the patient/user by instead warning the

patient's physician. *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973) ("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.") (emphasis added); *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). And it follows that, when the manufacturer fails to warn the physician (or otherwise fails to establish the physician was independently aware of the risk at issue), then the device manufacturer is no longer able to seek shelter behind the learned intermediary doctrine. *Watts*, 239 Ariz. at 24 ("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."); *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.' Consequently, where a manufacturer provides inadequate warnings, or no warning at all, it 'cannot rely upon the intermediary, even if learned, to pass on or give warnings.'"); *see also Glover v. Bausch & Lomb, Inc.*, 343 Conn. 513, 539, 275 A.3d 168, 183 (2022) ("Although manufacturers may invoke the learned intermediary doctrine as a shield against claims that they failed to provide adequate warnings to users as long as they provided such warnings to healthcare providers…we see nothing in… our case law that would indicate that the doctrine was intended to provide a

shield against liability for foreseeable injuries caused by the *withholding* of information about inherently dangerous medical devices.").

Thus, contrary to the arguments of the pharmaceutical industry amici, as the above authority (including the recent Arizona Supreme Court decision) confirm, the learned intermediary doctrine is *not* a rule of causation, but rather, limited to the issue of duty. Accordingly, having failed in its duty to warn Himes' physician, Somatics is no longer entitled to absolve itself of liability by impermissibly interjecting the intermediary (whom it failed to warn) into the causation inquiry by trying to argue what the *intermediary doctor* should have done or would have done, or didn't do or did. This is confirmed by the first judicial decision to coin the phrase "learned intermediary," *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). In *Sterling*, the drug manufacturer, which failed to warn the doctor, sought to absolve itself of liability by pointing to the purported conduct of the doctor. In rejecting the drug manufacturer's arguments, the Eighth Circuit held:

> The sole issue was whether appellant negligently failed to make reasonable efforts to warn appellee's doctors. *If appellant did so fail, it is liable regardless of anything the doctors may or may not have done*. If it did not so fail, then it is not liable for appellee's injury. The issue was to be resolved by the jury, and we see no error in the court's instruction.

Sterling Drug, 370 F.2d at 85 (emphasis added). This principle was likewise recognized by this Court's seminal *Stevens* decision which held the intervening conduct of the physician cannot absolve a negligent drug manufacturer that has failed to adequately warn. *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 69 (1973) ("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]."); *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.").

Accordingly, this Court should reject Somatics and its amici's invitation to interject the learned intermediary doctrine into the causation inquiry and allow Somatics (which admitted it failed to provide adequate warnings to Dr. Fidaleo) to escape liability for its own negligence and dereliction by pointing to the conduct of Dr. Fidaleo.

Himes pauses to note that, in 1995, the Canadian Supreme Court dealt with a case that implicated the exact issues facing this Honorable Court. *See Hollis v. Dow Corning Corp*., 4 S.C.R. 634 (1995)[3]. *Hollis* was a medical device products liability case wherein a patient was harmed by a breast implant that ruptured and the plaintiff established the implant manufacturer (Dow) was aware of the risk of ruptures but failed to adequately warn her surgeon of the risk. Dow, like Somatics in this case, sought to rely on the learned intermediary doctrine to escape liability. The

[3] A copy of the Canadian Supreme Court's *Hollis* decision is attached to the concurrently filed Motion for Judicial Notice.

Canadian Supreme Court disagreed, and a few passages from its opinion are instructive.

First, as to the issue of whether the manufacturer (which failed to adequately warn the doctor) could seek shelter behind the learned intermediary doctrine, the Canadian Supreme Court likewise held as follows:

> [T]he "learned intermediary" rule is merely an exception to the general manufacturer's duty to warn the consumer. The rule operates to discharge the manufacturer's duty not to the learned intermediary, but to the ultimate consumer, who has a right to full and current information about any risks inherent in the ordinary use of the product. Thus, the rule presumes that the intermediary is "learned," that is to say, fully apprised of the risks associated with the use of the product. Accordingly, the manufacturer can only be said to have discharged its duty to the consumer when the intermediary's knowledge approximates that of the manufacturer. *To allow manufacturers to claim the benefit of the rule where they have not fully warned the physician would undermine the policy rationale for the duty to warn, which is to ensure that the consumer is fully informed of all risks*. Since the manufacturer is in the best position to know the risks attendant upon the use of its product and is also in the best position to ensure that the product is safe for normal use, the primary duty to give a clear, complete, and current warning must fall on its shoulders.

Hollis v. Dow, 4 SCR 634, 660 at ¶29 (1995) (emphasis added).[4] *Second*, similar to: (1) this Court's seminal ruling in *Stevens*; (2) the Eight Circuit's *Sterling* decision (which first implemented the learned intermediary doctrine); and (3) this Court's other decisions governing causation and

[4] The pin citations to the paragraphs refer to the paragraph numbers listed in the left and/or right margins of the *Hollis* opinion.

ensuring the negligent actors are held responsible, including *T.H. v. Novartis Pharms. Corp.*, the Canadian Supreme Court likewise held that, once it is established the drug manufacturer failed to warn the doctor, the manufacturer cannot point to the doctor's hypothetical conduct of whether he or she would have passed on the warning or other purported derelictions to escape its owns negligence:

> Simply put, I do not think a manufacturer should be able to escape liability for failing to give a warning it was under a duty to give, by simply presenting evidence tending to establish that even if the doctor had been given the warning, he or she would not have passed it on to the patient, let alone putting an onus on the plaintiff to do so. Adopting such a rule would, in some cases, run the risk of leaving the plaintiff with no compensation for her injuries. She would not be able to recover against a doctor who had not been negligent with respect to the information that he or she did have; yet she also would not be able to recover against a manufacturer who, despite having failed in its duty to warn, could escape liability on the basis that, had the doctor been appropriately warned, he or she still would not have passed the information on to the plaintiff. Our tort law should not be held to contemplate such an anomalous result.

Hollis, 4 S.C.R. 634, 685 at ¶60.

Finally, the Canadian Supreme Court proceeded to cite to, *inter alia*, the Eighth Circuit's *Sterling* decision as well as the First Circuit's decision in *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033 (1st Cir. 1972), holding:

> [T]he plaintiff's claim against the manufacturer should be dealt with in accordance with the following rationale. The ultimate duty of the manufacturer is to warn the plaintiff adequately. For practical reasons, the law permits it to acquit itself of that duty by warning an informed intermediary. Having failed to warn the intermediary, the manufacturer has failed in its duty to warn the plaintiff who ultimately suffered injury by using the product. The fact that the

> manufacturer would have been absolved had it followed the route of informing the plaintiff through the learned intermediary should not absolve it of its duty to the plaintiff because of the possibility, even the probability, that the learned intermediary would not have advised her had the manufacturer issued it. The learned intermediary rule provides a means by which the manufacturer can discharge its duty to give adequate information of the risks to the plaintiff by informing the intermediary, but if it fails to do so it cannot raise as a defence that the intermediary could have ignored this information. I observe that a number of courts in the United States have reached a similar conclusion.

Hollis, 4 S.C.R. 634, 685 at ¶ 61 (citing to *Sterling* and *McCue*). The Canadian Supreme Court's cogent analysis of the learned intermediary doctrine and refusal to allow the negligent device manufacturer from escaping liability by attempting to point to the physician's conduct is consistent with this Honorable Court's *Stevens* decision, as well as with the holdings of the very first court (*Sterling*) to implement the learned intermediary doctrine. *Stevens*, 9 Cal. 3d at 65; *Sterling Drug*, 370 F.2d at 85.

III. Under Established California Authority in Strict Products Liability Cases, the Subjective Testimony of the Plaintiff is Admissible to Establish Her State of Mind and What She Would Have Done Had She Been Adequately Warned; and an Injured Plaintiff Who Testifies She Would Not Have Consented to the Administration of ECT had She Been Adequately Warned, Has Established a Triable Issue of Fact as to the Issue of Proximate Causation

Several of the amici complain that a causation standard that relies on what the patient would have done had she been warned (either by her doctor or by the manufacturer) would be too *speculative* and subject to "hindsight" bias and, for that reason, we should either: (a) exclusively focus on what the doctor would have done; or (b) focus on what the doctor

would have done (i.e., passed on the warnings) in conjunction with what a reasonable patient would have done (i.e., "objective" patient standard). Both arguments are fundamentally flawed.

As an initial matter, it is unclear to Himes why the "hindsight" testimony of what her administrating doctor (who profits from administering ECT and has his own "hindsight" biases) would have done had he been warned is permissible, admissible, and not speculative according to the *amici*, but Himes' testimony as to what she would have done had she been warned is somehow too speculative and inadmissible? Both Himes' and the doctor's testimony involve "hindsight" testimony and, if amici and Somatics agree the doctor's hindsight testimony is admissible, then they must equally agree that Himes' "hindsight" testimony is also admissible. Let us not forget that it is Somatics' admitted failure to issue any warnings that led to Himes being administered ECT and sustaining ECT-induced injuries. Thus, Somatics' dereliction of refusing to warn is what has created the hypothetical scenario as to what Himes or her doctor would have done had they been adequately warned.

Under these circumstances, this Honorable Court has recognized that causation need not be established with mathematical certainty, but rather can involve some "guesswork" and may even be established by the self-serving testimony of the plaintiff, and that these causation issues should almost always be resolved by the jury. *Campbell v. Gen. Motors Corp*., 32 Cal. 3d 112 (1982). The following quote from this Court's seminal products liability decision in *Campbell* is highly instructive:

> Unless very unusual circumstances exist, this type of claim presents a

factual issue which can only be resolved by the trier of fact. In the ordinary case the question becomes one of what would have happened if the product had been otherwise. This is of course incapable of mathematical proof, and a certain element of guesswork is always involved. Proof of the relation of cause and effect can never be more than the projection of our habit of expecting certain consequents to follow certain antecedents merely because we have observed those sequences on previous occasions. When a child is drowned in a swimming pool, no one can say with certainty that a lifeguard would have saved him; but the experience of the community is that with guards present people are commonly saved, and this affords a sufficient basis for the conclusion that it is more likely than not that the absence of the guard played a significant part in the drowning. *Such questions are peculiarly for the jury*. Whether proper construction of a building would have withstood an earthquake, whether reasonable police precautions would have prevented a boy from shooting the plaintiff in the eye with an airgun, whether a broken flange would have made an electric car leave the rails in the absence of excessive speed, whether a collision would have occurred if the defendant had not partially obstructed the highway, and many similar questions, cannot be decided as a matter of law.

The plaintiff in a strict liability action is not required to disprove every possible alternative explanation of the injury in order to have the case submitted to the jury. It is not incumbent upon a plaintiff to show that an inference in his favor is the only one that may be reasonably drawn from the evidence; he need only show that the material fact to be proved may logically and reasonably be inferred from the circumstantial evidence...The mere fact that other inferences adverse to plaintiff might be drawn does not render the inference favorable to plaintiff too conjectural or speculative for consideration by the jury….

It is particularly appropriate that the jury be allowed to determine the inference to be drawn when the evidence indicates that a safety device, designed to prevent the very injury that occurred, was not

> present. To take the case from the jury simply because the plaintiff could not prove to a certainty that the device would have prevented the accident would enable the manufacturer to prevail on the basis of its failure to provide the safeguard…Such a rule would provide a disincentive to improve the safety features of a product and thereby interfere with one of the major policy goals of strict liability.
>
> Furthermore, whether an inference should be drawn may be properly influenced by a policy which makes the action favored or disfavored.…The paramount policy to be promoted by the rule of strict liability is the protection of otherwise defenseless victims of manufacturing defects and the spreading throughout society of the cost of compensating them. To deny to plaintiff the benefit of the inference of proximate cause would frustrate that policy.
>
> Under these principles, the evidence introduced by plaintiff in the present case was sufficient to withstand the motion for nonsuit. Plaintiff testified that she was injured when thrown from her seat to the floor on the opposite side of the bus. She further testified that before falling she reached out with both arms for something to hold on to, but nothing was there. Given plaintiff's position at the time the bus turned, a jury could reasonably infer from the evidence that a handrail or guardrail within her reach would have prevented the accident. Although this fact may not be capable of mathematical proof, it is nevertheless a reasonable inference that may be drawn from the evidence.

Campbell v. Gen. Motors Corp., 32 Cal. 3d 112, 119–22 (1982) (internal citations, quotations, and brackets omitted); *see also Haft v. Lone Palm Hotel*, 3 Cal. 3d 756, 765 (1970) ("we have concluded that after plaintiffs proved that defendants failed to provide a lifeguard or to post a warning sign, the burden shifted to defendants to show the absence of a lifeguard did not cause the deaths."). Moreover, as outlined in the opening brief, in strict products liability cases, California courts have routinely allowed plaintiffs

to establish causation by providing purported "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); *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 accordance with the warning, which caused him injury, was sufficient evidence to present to the jury); *Georges v. Novartis Pharms. Corp*., 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013) (holding that plaintiff's testimony as to what she would have done had she been warned of the drug's risk "is sufficient for a jury to find that Plaintiff's use of the Treatment Drugs would have changed with adequate warning."); *see also Cope v. Davison*, 30 Cal. 2d 193, 200 (1947) ("The state of mind of a person, like the state or condition of the body, is a fact to be proved like any other fact when it is relevant to an issue in the case*, and the person himself may testify directly thereto.*").

Amici, like Somatics, attempt to argue that, for causation purposes, whether Himes (i.e., the injured plaintiff) would have taken the drug had she been warned should be assessed by the "objective" patient standard used in medical malpractice cases (as espoused by *Cobbs*) and not by the subjective standard which as previously discussed is routinely utilized in strict products liability cases. Curiously, none of the amici have cited to a single precedent from this Court or any *California* appellate court in support of their novel contention that the subjective standard is not appropriate for *products liability* cases. As outlined in Himes' reply brief, the only California cases that have applied the "objective" tests are cases

limited to medical-malpractice claims, and as this Court has previously explained, "[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 (CAL. CIV. CODE § 3333.2); shorter statute of limitations for medical-malpractice claims (i.e., one year after discovery for med-mal claims versus two-years after discovery for products liability claims and placing a three-year statute of limitation cap on med-mal claims from date of injury where no such cap exists in other personal injury claims, *see* CAL. CIV. PROC. CODE §§ 335.1 (personal injury against products manufacturers) & 340.5 (personal injury claims against physicians)); evidentiary limitations to protect physicians (e.g., allowing physicians to present collateral source evidence such as evidence of plaintiff's medical insurance and income-disability insurance to offset damages, *see* CAL. CIV. CODE § 3333.1); mandatory bifurcation of statute of limitations in trials involving physicians if requested by the physician defendant (*see* CAL. CIV. PROC. CODE § 597.5); 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)). The foregoing protections afforded to physicians, however, are not afforded to medical device manufacturers. Indeed, while physicians are not subject to 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.

In advocating for an objective test in a strict products liability case, the California Medical Association ("CMA") erroneously contends that the "substantial factor" test has somehow been "eliminated" or "expelled" and that, purportedly, the only test that applies in products liability cases is the "but for" test. *See* CMA Br. at 55. CMA is mistaken. As the notes accompanying Judicial Council of California Civil Jury (CACI) 430 (Causation: Substantial Factor) make clear, "'substantial factor subsumes the 'but for' test of causation…" *See* CACI 430; *see also Mitchell v. Gonzales*, 54 Cal. 3d 1041, 1052 (1991) (same). Moreover, this Court has long recognized that, in products liability and negligence cases, causation is established under the *substantial factor* test. *Mitchell*, 54 Cal. 3d at 1052-1053; *Rutherford*, 16 Cal. 4th at 968–69 ("California has definitively adopted the substantial factor test of the Restatement Second of Torts for cause-in-fact determinations."); *see also* CACI 1205 (strict liability) and CACI 1222 (negligence)[5]. Moreover, CMA fails to explain why the subjective testimony of the plaintiff as to what she would have done had she been warned would not be sufficient even under a "but for" test. Nor has CMA

[5] Unlike products liability failure to warn cases which implement the substantial factor test (*see* CACI 1205), in med-mal cases involving *a doctor's* failure to obtain informed consent, consistent with *Cobbs*, the jury instructions do not implement a broad substantial factor test but instead implement the objective/reasonable patient standard. *See* CACI 533.

cited to any case law in support of its proposition that the subjective testimony of the plaintiff would not be permissible under the "but for" test of causation. Simply put, the same way Somatics and amici contend the self-serving subjective testimony of Dr. Fidaleo is necessary and sufficient for causation inquiry, they must concede (as recognized by established California case law) the subjective testimony of Himes as to what she would have done had she been adequately warned by her doctor (or the manufacturer) is likewise permissible and admissible to establish causation. *Campbell*, 32 Cal. 3d at 122 (plaintiff's testimony sufficient to establish that defendant's product defect was the cause of her injury); *Dimond*, 65 Cal. App. 3d 173; *Georges*, 988 F. Supp. 2d at 1158; *Cope*, 30 Cal. 2d at 200 ("The state of mind of a person, like the state or condition of the body, is a fact to be proved like any other fact when it is relevant to an issue in the case, *and the person himself may testify directly thereto.*") (emphasis added).

Interestingly, the Canadian Supreme Court in the *Hollis* decision also wrestled with the question of whether the subjective or objective test should apply for establishing causation. In Canada, as in California, for medical malpractice cases, Canadian courts apply the "objective" test in medical malpractice cases, but the Supreme Court held that, in failure to warn products liability cases against medical product manufacturers, the plaintiff may rely upon the "subjective" test to establish causation (i.e., about what she would have done had she been adequately warned of the risks). In addressing why the subjective test was appropriate in products liability cases, *Hollis* quoted approvingly from another Canadian case and

held: [6]

> The considerations applicable to and the responsibilities involved in a doctor-patient relationship differ markedly from those of a manufacturer-consumer relationship. As between doctor and patient, there is a direct and intimate relationship in which the relative advantages and disadvantages of a proposed medical treatment, including the taking of a drug, can be considered, discussed and evaluated. As between drug manufacturer and consumer, the manufacturer is a distant commercial entity that, like manufacturers of other products, promotes its products directly or indirectly to gain consumer sales, sometimes, as in this case, accentuating value while under-emphasizing risks. Manufacturers hold an enormous informational advantage over consumers and, indeed, over most physicians. The information they provide often establishes the boundaries within which a physician determines the risks of possible harm and the benefits to be gained by a patient's use of a drug. Manufacturers, unlike doctors, are not called upon to tailor their warnings to the needs and abilities of the individual patient; and, unlike doctors, they are not required to make the type of judgment call that becomes subject to scrutiny in informed consent actions.
>
> When a manufacturer's breach of the duty to warn is found to have influenced a physician's opinion as to the safety of a drug thereby contributing to the physician's non-disclosure of a material risk and the consumer's ingestion of the drug, the manufacturer is not entitled to require the injured consumer to prove that a reasonable consumer in her position would not have taken the drug if properly warned. At this juncture, the case stands on no different footing than the usual products liability case in which there is no question of the intervention of an intermediary, and should be treated as such. The manufacturer has put a product on the market without proper warning. The likelihood that the consumer will take the drug without knowledge of its potential risks is a foreseeable consequence of the breach of the duty to warn. Whether the particular consumer would

[6] *Buchan v. Ortho Pharmaceutical Ltd.*, 12 O.A.C. 361 (1986).

> have taken the drug even with a proper warning is a matter to be decided by the trier of fact on all of the relevant evidence.

Hollis, 4 S.C.R. 637, 672 at ¶44 (*quoting Buchan v. Ortho Pharmaceutical Ltd.*, 12 O.A.C. 361 (1986)). *Hollis* went on to address the very same concerns of "hindsight" involved in the subjective testimony of the injured patients as advanced by the amici in this case. In dispelling with these objections to the subjective test and explaining why different tests should be applied to a med-mal case against a doctor versus a products liability case against a manufacturer, *Hollis* held:

> …in a suit against a manufacturer for failure to warn this concern [hindsight bias] can be adequately addressed at the trial level through cross-examination and through a proper weighing by the trial judge of the relevant testimony. While this difference between the type of proof required in the two kinds of actions may seem anomalous, it is amply justified having regard to the different circumstances in which the relevant duties arise, and the consequent difference in the nature of these duties. As Robins J.A. intimated in *Buchan*, the duty of the doctor is to give the best medical advice and service he or she can give to a particular patient in a specific context. It is by no means coterminous with that of the manufacturer of products used in rendering that service. The manufacturer, on the other hand, can be expected to act in a more self-interested manner. In the case of a manufacturer, therefore, there is a greater likelihood that the value of a product will be overemphasized and the risk underemphasized. It is, therefore, highly desirable from a policy perspective to hold the manufacturer to a strict standard of warning consumers of dangerous side effects to these products. There is no reason, as in the case of a doctor, to modify the usual approach to causation followed in other tortious actions. Indeed the imbalance of resources and information between the manufacturer and the patient, and even the doctor, weighs in the opposite direction. Moreover, it is important to remember that many product liability cases of this

> nature will arise in a context where no negligence can be attributed to a doctor. It would appear ill-advised, then, to distort the rule that is appropriate for claims against a manufacturer simply because of an apparent anomaly that results in cases where a doctor is also alleged to have been negligent.

Hollis, 4 S.C.R. 635, 675 at ¶46. The foregoing California authorities, as well as the cogent decision from the Canadian Supreme Court, confirms that, for strict products liability cases against manufacturers, this Court should continue to apply the substantial factor test for causation and, as part of that test, should continue to allow plaintiffs to testify as to what they would have done had they been adequately warned.

Finally, the "objective" test is particularly improper in the instant products liability case concerning ECT treatment. California law specifically provides that a doctor may not administer ECT without the express consent of the patient. 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."). Given the decision to undergo ECT treatment is a personal choice (and one person may have greater risk tolerance than another), to suddenly apply an objective "prudent person" standard to whether a patient would have undergone ECT had she been adequately warned, runs afoul of Welfare & Institution Code Section 5326.85, which places consent *exclusively* in the hands of the patient.

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IV. The Pharmaceutical Trade Organizations' Lament That Adopting a Traditional Causation Analysis Would Somehow Impact Their Bottom Line and Harm Scientific Innovation Is Factually Baseless and Has Already Been Rejected By This Honorable Court in *Carlin*

Some of the pharmaceutical trade organizations, in particular California Life Sciences ("CLS"), argue that adopting Himes' argument as to causation would somehow cripple the pharmaceutical industry. *See* CLS Br. at 23-25. Yet, the doom and gloom painted by CLS and the laments concerning the impact on the pharmaceutical industry's bottom line, are not supported by any evidence or the case law. Indeed, these specious arguments have already been rejected by this Court. *Carlin v. Superior Ct.*, 13 Cal. 4th 1104, 1117 (1996); *see also Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1003 (1991). In rejecting the identical argument advanced by CLS, this Honorable Court when it adopted the strict liability doctrine in failure to warn cases for pharmaceuticals held:

> Upjohn offers no clear or sufficient basis for concluding that research and development will inevitably decrease as a result of imposing strict liability for failure to warn of known or reasonably scientifically knowable risks; indeed, requiring manufacturers to internalize the costs of failing to determine such risks may instead increase the level of research into safe and effective drugs. In any event, 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. Simply put, Somatics could easily have *and very cheaply* prevented the serious life-altering injury Himes and numerous other ECT patients sustained if it had simply issued timely and proper warnings. As the record reflects, when probed about the cost and means through which Somatics could have issued warnings, Somatics' co-owner testified there would be no substantial expense to Somatics and that it could have, among other avenues, used Dear Doctor letters, product updates, and other means used to promote its device to issue warnings to physicians and customers:

> 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, 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 because to do so would cause Somatics to lose customers (i.e., "alienate psychiatrists"). 2-ER-44-45; 4-ER-874-876.

V. Response to Other Red Herring Arguments Raised by Certain Amici

In addition to the overarching arguments raised by amici, there were several additional arguments raised by some of the individual amici that serve no purpose other than to distract the Court from the pertinent issues on appeal.

A. California Life Sciences' Reference to A Prior Unpassed Legislation is Factually Irrelevant and Not Worthy of Any Evidentiary Weight

California Life Sciences ("CLS") refers to an unpassed legislation from 2008 wherein the California legislature was contemplating modifying the learned intermediary doctrine to apply an exception for pharmaceutical products that are advertised directly to consumers. According to CLS, the California State Assembly did not take the bill up for a vote. *See* CLS Br. at 21. It is unclear to Himes what relevance, legally or factually, the unvoted prior legislation has on the merits of this case. Factually, Himes is not seeking to create a direct-to-consumer exception to the learned intermediary doctrine, rather, she is simply contending that the learned intermediary doctrine as adopted by California is a rule governing *duty* (not causation), which permits device manufacturers to warn doctors in lieu of the patients about their product's risks. However, if the manufacturer fails to comply with its duties of warning the doctor, then it

can no longer seek shelter behind the learned intermediary doctrine as the various authorities cited herein and in Himes's opening and reply briefs support. Thus, a prior unpassed legislation concerning a proposed direct-to-consumer exception to the learned intermediary rule has no relevance to this action whatsoever. Indeed, California has long held that evidence of "unpassed bills" have little if any evidentiary value. *See Miles v. Workers' Comp. Appeals Bd.*, 67 Cal. App. 3d 243, 248 (1977) ("we recently examined this subject of 'unpassed bills' and concluded that 'as evidence of legislative intent they have little value.'"); *Troy Gold Indus., Ltd. v. Occupational Safety & Health Appeals Bd.*, 187 Cal. App. 3d 379, 391, n.6 (1986) ("a single unenacted bill….is meaningless as an expression of legislative intent…"); *Ambrose v. Cranston*, 261 Cal. App. 2d 137, 143 (1968) ("admission in evidence of an unenacted Senate bill….was erroneous. Although it is arguable that the introduction of the bill created an inference that some members of the Legislature thought a change in the law necessary in order to give retired judges increased retirement benefits, it is also arguable that the failure to pass the bill raised an inference that members of the Legislature thought the bill unnecessary because increased benefits were already provided by existing law. We have disregarded both these inferences in reaching our own conclusion on a question which solely involves an interpretation of statutory law."); *Sacramento Newspaper Guild v. Sacramento Cnty. Bd. of Sup'rs*, 263 Cal. App. 2d 41, 58 (1968) ("The light shed by such unadopted proposals is too dim to pierce statutory obscurities. As evidences of legislative intent they have little value.")

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B. The Amicus Brief Filed By PhRMA Contains a Number of Arguments That are Factually and Legally Flawed

The Pharmaceutical Research and Manufacturers of America's (PhRMA) brief raises certain misleading and erroneous arguments that warrant a brief response. *First*, PhRMA claims that a ruling in Himes' favor would result in over-warning that would harm patients. Yet its arguments are at odds with the facts of the case and this Court's precedent. Here, it is undisputed that Somatics did not provide *any* warnings to Dr. Fidaleo during the relevant period. Notably Somatics' president, Conrad Swartz, M.D., testified that the manual Dr. Fidaleo and his hospital (Sharp Hospital) received did not contain any warnings concerning the risks associated with Somatics' ECT device:

> 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, *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). It is curious that

PhRMA as an *amici* would argue that a finding of liability against Somatics in this case would create the risk of "over-warning" when the facts reveal that Somatics did not provide *any* warnings during the relevant time period. Moreover, the facts reveal that, in 2006, Somatics contemplated adding a warning concerning cognitive injuries but chose not to do so to protect its bottom line and not to alienate is customers. 2-ER-44-45; 4-ER-874. It was not until October 2018 when, through its website and other means, including letters to select physicians, Somatics finally added warnings, including warnings concerning the risk of permanent memory loss and brain damage. See 4-ER-653 ("ECT may result in anterograde or retrograde amnesia" and "in rare cases, patients may experience permanent memory loss or permanent brain damage."); see also 2-ER-48; 3-ER-410-420; 4-ER-653; 4-ER-658. And, subsequently the FDA also promulgated rules ordering Somatics to add additional information concerning the cognitive injuries as well information to both doctors and patients (i.e., patient labeling) that informed patients: "The long-term safety and effectiveness of ECT treatment has not been demonstrated." 21 C.F.R. § 882.5940(b)(1)(ix)(G). Thus, factually, PhRMA's over-warning arguments are baseless. Likewise, legally, California for decades has implemented and extended strict liability principles to products including prescription pharmaceuticals so as to ensure manufacturers issue timely and adequate warnings concerning the risks associated with their products. Indeed, contrary to keeping consumers in the dark regarding risks associated with products they consume, the tort system encourages warnings and safety measures (so as to prevent injuries) and the adoption

and application of strict products liability laws fosters those goals. *See e.g., Greenman v. Yuba Power Products, Inc*., 59 Cal.2d 57, 63–64 (1963); *Campbell*, 32 Cal. 3d at 121–22; *Anderson*, 53 Cal. 3d at 1003; *Carlin*, 13 Cal. 4th at 1117.[7]

Second, PhRMA contends the label is the *sole* means through which a drug/device manufacturer warns and that whether a doctor read the label is a litmus test to causation. This Court's precedent as well as other applicable case law provide otherwise. As to the first issue, that the label is the sole means through which a manufacturer must warn, this Court has already held 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 ("Many prescribing physicians would not come into contact with package inserts or warning labels attached to the drug when the pharmacist filed the prescription. 'Dear Doctor' letters might have been easily disregarded in the bulk of everyday mail received by the physician. It was within reason for the jury to find

[7] Importantly, in this case, we are dealing with a lack of warning concerning serious and disabling risks and, as outlined in the *undisputed* peer-reviewed journal publications supporting Himes' opposition to the summary judgment motion, the risk of such cognitive injury is as high as 12% according to one of the few prospective studies performed on this issue. 4-ER-912 (a large-scale prospective study of cognitive outcomes in 2007 found that months after ECT, autobiographical memory of patients were significantly worse and that 12% of ECT patients were deemed to have suffered "marked and persistent retrograde amnesia"). Thus, this is not a case about a speculative or non-serious risk as PhRMA attempts to imply in its amicus brief. See e.g. PRMA Br. at 39.

such warnings inadequate and to hold Parke, Davis liable for failing to reasonably warn of the drug's danger."); *see also Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 84-85 (8th Cir. 1966) (a jury could find that sending product cards to doctors was unreasonable, whereas sending a letter to doctors specifically calling their attention to side effects of a drug would be reasonable);[8]. Moreover, device companies, including Somatics,

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[8] *Stevens* on multiple occasions also approvingly cited to another Eight Circuit' decision *Sterling Drug, Inc. v. Yarrow* which likewise held:

> On the issue of breach of appellant's duty to use reasonable efforts to warn, there is no overwhelming proof of discharge of this duty. On the contrary a reasoning trier of the facts could find, on substantial evidence, that the methods of warning chosen by the appellant, including the product cards, the Physicians' Desk Reference, the 'Dear Doctor' letter, and the willingness to answer inquiries were not reasonable efforts to warn under the circumstances of this case.
>
> The 'Dear Doctor' letter could have been reasonably found to be lacking in emphasis, timeliness and attention inviting qualities. A reasoning mind could find that appellant's warning actions were unduly delayed, reluctant and lacking in a sense of urgency, and therefore unreasonable under the circumstances. While a warning in February 1963 in an attention inviting letter would probably have been timely in this case if promptly received and heeded by appellee's physician, it could be inferred that a reasonably earlier warning, with greater intensity could well have reached appellee's physician directly, or indirectly through other professional channels such as conversations with other doctors and discussions at conventions. The delay in issuance of the 'Dear Doctor' letter from August 1962 to February 1963, its wording, and the manner of its circulation could be found unreasonable considering the magnitude of the risk involved…. The trier of the fact could reasonably conclude

communicate with doctors through a myriad of means, including, promotional literature, sales representatives, 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 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 manufacturer took reasonable steps to warn the doctor in a reasonable manner as warranted under the facts and circumstances. *Stevens*, 9 Cal.3d at 67; *Sterling Drug, Inc.*, 408 F.2d at 994 (8th Cir. 1969); *see also Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 406-407, 421 N.Y.S.2d 81 (1979) ("it is incumbent upon the manufacturer to bring the warning home
to the doctor. The greater the potential hazard of the drug, the more extensive must be the manufacturer's efforts to make that hazard known to the medical profession…[¶]…In view of the seriousness of these hazards, we decline to hold that, as a matter of law, Lilly's decision to limit its warning to its package inserts was reasonable and therefore sufficient.").

Third, PhRMA contends that California has not adopted a heeding presumption – i.e., a presumption that, if a warning is given, it will be

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> that the urgency of the circumstances reasonably required more than the relatively slow action and relative lack of emphasis employed in composing and circulating the 'Dear Doctor' letter. The longer the warning was delayed the greater the risk became.

Sterling Drug, Inc. v. Yarrow, 408 F.2d 978, 994 (8th Cir. 1969).

heeded. Contrary to amici's contention California Court of Appeals on multiple occasions in pharmaceutical products liability actions have recognized a heeding presumption. See e.g., *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). PhRMA responds that *Grinnell* was a breach of warranty case and *Toole* a fraud claim, and thus not applicable. To the contrary, *Grinnell,* like this case, was a case where a patient was injured by a prescription pharmaceutical product and sued the manufacturer and the Court of Appeal specifically recognized the breach of implied warranty claims upon which the case was tried was the same as a strict products liability claim, that the two theories had the same basic elements, and the court proceeded to address the case "with the rules involving strict liability rather than the superseded implied warranty concept." *Grinnell*, 274 Cal. App. 2d at 433. In finding liability under the various causes of action, the court recognized the heeding presumption and held: "*the jury could infer that the language of the insert was read by the doctors…and that they relied upon it*…" *Grinnell*, 274 Cal. App. 2d at 441. Similarly, *Toole* was a products liability case wherein the plaintiff sued a drug manufacturer as a result of personal injuries he sustained from the defendant's drug and his causes of action included, inter alia, negligence, breach of warranty and fraud, and the court there too recognized a heeding presumption (i.e., that the doctor was presented with

the product literature and an inference that he relied upon the information). *Toole*, 251 Cal. App. 2d at 707–08. PhRMA does not make any viable arguments as to why these cases are not applicable authority. Moreover, even assuming the heeding presumptions were only done in the contexts of fraud or warranty claims (which they were not), PhRMA does not explain why California would allow a presumption in a fraud or warranty claim, which have more heightened burdens of proof than in strict products liability cases wherein the plaintiff's burden of proof is intended to be relaxed and lessened. *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 431 (1978) ("One of the principal purposes behind the strict product liability doctrine is to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action.")[9]

Fourth, to the extent PhRMA or any amici argue that Dr. Fidaleo did not rely on Somatics' inadequate warnings and information, the facts as outlined in the opening and reply brief tell a different tale. See Himes' Opening Br. at 17-21 & n. 5 & 6. Moreover, the Ninth Circuit has likewise confirmed that:

> Dr. Fidaleo testified that he pays attention to "dear physician" letters from manufacturers alerting him to new safety risks. From this

[9] *See also Haft v. Lone Palm Hotel*, 3 Cal. 3d 756, 765 (1970) ("we have concluded that after plaintiffs proved that defendants failed to provide a lifeguard or to post a warning sign, the burden shifted to defendants to show the absence of a lifeguard did not cause the deaths."); *see also Dimond v. Caterpillar Tractor Co.*, 65 Cal. App. 3d 173, 183 (1976) ("the law has stood ready to come to the aid of a hapless plaintiff who, through no fault of his own, is unable to provide direct evidence that defendant's breach of duty was a proximate cause of his injuries.")

> 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.
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> 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). This Honorable Court should reject amici's implied invitation to revisit a factual finding of fact made by the Ninth Circuit.

Lastly, PhRMA and other amici cite to a recent California Court of Appeal decision which affirmed a demurrer in a products liability case involving several hundred plaintiffs arising out of allegations that nearly a dozen manufacturers had engaged in off-label promotion, i.e., promotion for uses not approved by the FDA. *Amiodarone Cases*, 84 Cal. App. 5th 1091, 300 Cal.Rptr.3d 881 (2022), review filed (Dec. 13, 2022). The Court of Appeal affirmed the granting of a demurrer of the failure to warn claims on *preemption* grounds, i.e., finding that plaintiffs were impermissibly seeking to enforce the FDA regulations. *See Amiodarone Cases*, 300 Cal. Rptr. 3d at 892 ("We conclude that because plaintiffs seek to enforce FDA regulations, the claims are preempted as attempts to privately enforce the Federal Food, Drug, and Cosmetic Act." Having found the claims preempted, the court further proceeded to undertake an analysis concerning the interplay between the preemption doctrine and the learned intermediary doctrine. *Id*. at 893. The court then proceeded to make statements that are

admittedly supportive of the arguments advanced by Somatics and its amici as to the learned intermediary doctrine (i.e., that the doctrine apparently continues to apply even when the plaintiffs have implicitly alleged in their master complaint that their physicians were not adequately warned). *See Id.* at 894-895. For reasons outlined previously in this brief as well as Himes' opening and reply brief, Himes respectfully contends the *Amiodarone* court's analysis of the learned intermediary issue on this point is erroneous and, as Himes has articulated in her briefs, the learned intermediary doctrine *only* pertains to the issue of duty and does not apply to causation, and once it has been shown that the manufacturer failed to adequately warn the physician (and the physician was not independently aware of the unwarned risks), the manufacturer is no longer entitled to rely upon the learned intermediary doctrine. *See e.g.*, *Stevens*, 9 Cal. 3d at 51 & 65; *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, 954 (E.D. Cal. 2013); *see also Glover*, 343 Conn. at 539; *Watts*, 239 Ariz. at 24 ("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."); *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1195 (D.N.M. 2008) ("The learned-intermediary doctrine is inapplicable where there has been a failure to warn.").[10]

[10] Himes questions how much the Court of Appeal's decision in *Amiodarone* on the learned intermediary issue was colored by the Court's overarching rulings on preemption and the unique allegations in the case pertaining to

C. The APA's Brief Raises Issues that Are Irrelevant and Paints a Misleading Depiction of ECT that Reads More Like an Advertisement Than a Truthful Unbiased View of the Facts – Facts and Data Which, When Fully Examined, Reveal the Efficacy of ECT is Dubious and it is Associated with a Number of Serious and Life-Threatening Risks

The APA spends the bulk of its brief advocating for the safety and efficacy of ECT. Of course, none of its arguments are relevant to the issues in this appeal given that, in the trial court below, Somatics *conceded* that ECT causes permanent memory loss and brain injury and *conceded* that it failed to provide adequate warnings concerning these risks to physicians, including Dr. Fidaleo. Notably, while Himes supported her summary judgment opposition with unrefuted and undisputed expert reports and testimony (4-ER-44—487, 855-865 & 877-918), Somatics marshalled no expert reports or declarations on the issue of the safety and efficacy of ECT. *See e.g.*, 2-ER-28-76. Indeed, in the trial court, Somatics agreed that the following salient facts concerning the safety of ECT 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).

"medication guides." Notably, in this appeal, Somatics has never raised a preemption defense nor is Himes (unlike the *Amiodarone* plaintiffs) seeking to enforce FDA laws concerning medication guides. Suffice it to say that Himes contends *Amiodarone* was erroneously decided on the learned intermediary issue and, even from a procedural posture, Himes respectfully questions the appropriateness of the trial court and the Court of Appeal dismissing and adjudicating such fact-intensive claims on a demurrer.

- … 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."[11] 2-ER-49 (**Undisputed** Fact No. 49).

Kirsch and Read's peer-reviewed study and meta-analysis, which was contained in the record (4-ER-877-918), cited to numerous other studies that likewise found that ECT is linked to permanent memory loss, including a large 2007 prospective study that found 12% of ECT patients suffered "marked and persistent retrograde amnesia." 5-ER-912. Considering Somatics' concession and the record presented to the trial court, not surprisingly, the trial 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

[11] 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).

> adverse events to the FDA *or warn physicians and consumers of these risks*"

1-ER-4 (emphasis added). Seeking a mulligan on behalf of Somatics, the APA has filed an irrelevant amicus brief advocating for the safety and efficacy of ECT (on issues the trial court has already factually adjudicated and/or which otherwise are not germane to this appeal). In section A of its brief, the APA hails the efficacy of ECT and cites to select journal publications. However, the APA fails to identify a single placebo-controlled study, an essential requirement for establishing the efficacy of a device in the modern era of evidence-based medicine. Rather, the APA primarily cites articles written by well-known ECT advocates, including paid consultants of ECT manufacturers.[12] It is worth reemphasizing that,

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[12] Although the APA attempts to paint "modern ECT" as having "little resemblance" to original methods of ECT treatment, Himes presented evidence in the lower court showing otherwise. (APA Br. at 16). As Himes' expert psychiatrist explained:

> The "newer" and allegedly "modified" forms of ECT are not different or less harmful than the original form, as both apply enough electricity to the head of a patient to induce a major motor seizure. It is impossible to induce a major motor seizure through application of electricity to the cranium without causing traumatic brain injury. Indeed, contemporary ECT is more damaging to the brain because it requires much higher energy doses in order to produce a seizure in patients who [sic] given prior sedatives for sleep or anxiety, and then anesthesia during the ECT treatments. Sedatives and anesthesia increase the seizure threshold, requiring these more traumatic doses of electricity. In previous years 200 milliamps of electrical current

notwithstanding the APA's proclamations concerning the safety and efficacy of ECT, despite the fact that ECT has been in existence for 80-years, the FDA in its most recent 2018 analysis concluded that the long-term safety and efficacy of ECT *has not been established* and issued regulations that now require ECT manufacturers to warn both the doctor *and the patient*, that: "**The long-term safety and effectiveness of ECT treatment has not been demonstrated**" 21 C.F.R. § 882.5940(b)(1)(viii)(J) (physician labeling); & 882.5940(b)(1)(ix)(G) (patient labeling). The fact that, after 80 years, the long-term safety and efficacy of this device has not been established is grist for the mill that its safety and efficacy is not as promising as the APA proselytizes and APA's select members who earn their income by selling and administering ECT.

Similarly, the APA's brief does not paint a completely accurate picture of the articles it cites. As way of example, APA in footnote 6 cites to the Kucuker article for the proposition that "[m]ost studies show suicidal ideas or behaviors decrease with ECT treatment." APA Br. at 12. Yet what APA fails to mention is that, in this same study, the author admitted the following limitations:

> The ECT studies had limitations. Information regarding the difference in illness severity between patients who underwent ECT and control patients was not available for most studies we reviewed. Control patients were also poorly characterized in most studies, and

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> were commonly used in humans as well as in animal experiments to produce seizures as a part of ECT, while today the doses produced by the machines are over 1,000 milliamps.

3-ER-446 (Peter Breggin, M.D. Decl.).

> the definition of control groups was not clear, making the comparisons vague…The number of ECT courses and the ECT parameters also varied across studies, making it challenging to synthesize information and draw definitive conclusions.

Mehmet Utku Kcuker, *A Systematic Review of Neuromodulation Treatment Effects on Suicidality*, FRONTIERS IN HUMAN NEUROSCIENCE (June 2021). Notably, even in the Kcuker article, the author noted that certain studies "showed higher rates of completed suicides associated with ECT." *Id.* And tellingly, a meta-analysis conducted by the United Kingdom ECT Review Group found: "Although ECT is sometimes thought to be a lifesaving treatment, there is no direct evidence that ECT prevents suicide..." UK ECT Review Group, *Efficacy and Safety of ECT in Depressive Disorders,* 361 LANCET 806 (2003).

The APA further proclaims that severe cardiovascular complications or death are rare, see APA Br. at 13, however a 2019 review of 82 studies found that about **1 in 50** people suffer "major adverse cardiac events" after ECT. *See* Andreas Duma, M.D., *Major Averse Cardiac Events and Mortality Associated with Electroconvulsive Therapy: A Systematic Review and Meta Analysis*, 130 ANESTHESIOLOGY 83 (2019).[13]

[13] While in its brief the APA seeks to equate the mortality of ECT to being no different than surgery or child birth, what the APA fails to mention is that the usual course of ECT consists of at least 12 sessions done over the course of a few months and indeed most patients (like Himes) tend to have at least two courses which can be more than 24 separate ECT treatments and, in each session, they are exposed to the risks of ECT as well as the attenuated risks associated with the anesthesia and other adjuvants. When

As to the issue of permanent memory loss, the APA's brief neglects to mention that the first ever large-scale prospective study of cognitive outcomes, in 2007, found that six-months after ECT, autobiographical memory was significantly worse than pre-ECT levels; and that **1 in 8** patients (approximately 12%) were deemed to have suffered "marked and persistent retrograde amnesia." Harold Sackheim et al., *The Cognitive Effects of Electroconvulsive Therapy in Community Settings*, 32 NEUROPSYCHOPHARMACOLOGY 244 (2007).[14] In sum, the APA's brief, which seeks to supplement the record Somatics chose to leave vacant, and seeks to raise factual issues which conflict with the trial court's findings of fact (and conflict with issues Somatics itself deemed undisputed concerning the risks of ECT), is irrelevant, misleading, and does not paint a complete picture concerning the safety and unproven efficacy of ECT—again, the FDA most recently concluded that the long-term safety and efficacy of ECT has "not been demonstrated." 21 C.F.R. § 882.5940(b)(1)(ix)(G).

CONCLUSION

It has been said that "One voice speaking truth is a greater force than fleets and armies." While six amici submitted several hundred combined

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it comes to surgery, most people may go through life with perhaps a couple of surgical procedures in their entire life – few people have 24 surgeries in the span of a single year.

[14] In addition, in light of the cognitive injuries that have been reported following ECT, the FDA now requires Somatics' ECT label to warn physicians of the need to provide cognitive monitoring for patients both prior to and during the course of ECT treatment via neuropsychological assessment. See 21 C.F.R. § 882.5940(b)(1)(viii)(B)(7).

pages of briefing to come to the aid of Somatics and support its preposterous claim that the consent of the patient in a products liability failure to warn case is *irrelevant*, their collective arguments, which largely parrot Somatics' arguments, do not alter the merits of Himes' position, which is supported by common sense, principles of justice and importantly the case law. The Court's ultimate ruling should protect the virtues of informed consent and freedom of bodily integrity and not sacrifice them at the altar of the pharmaceutical industry's bottom line and their proposed misapplication of legal doctrines.

In answering the certified question, the 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: December 28, 2022

Respectfully submitted,

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Dated: December 28, 2022

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Date

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