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Supreme Court of California
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No. S273887

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

MICHELLE HIMES,

Plaintiff–Appellant,

v.

SOMATICS, LLC,

Defendant–Respondent.

On Request from the U.S. Court of Appeals for the Ninth Circuit for Answer to Certified Questions of California Law

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RESPONDENT'S CONSOLIDATED ANSWER TO AMICUS BRIEFS

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INTRODUCTION

Defendant-Appellee Somatics LLC ("Somatics") submits this response to the six amicus briefs filed in this matter. Five amici filed briefs in support of Somatics: The Civil Justice Association of California ("CJAC"); California Life Sciences ("CLS"); the California Medical Association, California Dental Association, and California Hospital Association ("CMA/CDA/CHA"); The Pharmaceutical Research and Manufacturers of America ("PhRMA"); and The Product Liability Advisory Council, Inc. ("PLAC"). A sixth amicus brief—prepared by the American Psychiatric Association ("APA")—was formally filed in support of neither party but provides strong support for Somatics' position; APA's brief identifies, as its sole purpose, the need to correct "inaccurate and unscientific" information in the briefing of Plaintiff-Appellant Michelle Himes ("Plaintiff"). *See* APA Br. at 9.[1] No amici filed briefs in support of Plaintiff's arguments.

As all amici agree, Plaintiff's proposed physicians-as-messengers causation standard rests on a harmful anti-science perspective that demeans medical professionals and endangers healthcare patients. By contrast, the workable, reliable causation standard already used by courts across the country—which focuses exclusively on a physician's decision to prescribe—properly accounts for the role of a learned intermediary in

[1] Unless otherwise noted, this brief adds emphasis and removes internal citations, quotations, footnotes, and alterations.

assessing the risks and benefits of prescription-only treatments like ECT.

ARGUMENT

I. Amici expose Plaintiff's false statements about ECT, illustrating the importance of scientific expertise in the causation inquiry.

Plaintiff's primary strategy in this case is to distract from her failure to satisfy her burden to show causation with arguments that she has satisfied her burden to show inadequate warning. She devotes large swaths of her briefing to disparaging ECT as a dangerous, ineffective treatment administered without adequate warnings. *See* Opening Brief ("OB") 6-16, 21; Reply Brief ("RB") 11-17. Her false statements about ECT have now compelled the nation's leading organization of psychiatrists, the APA, to step into this case and cry foul. The APA warns that "Plaintiff's briefing provides an *inaccurate and unscientific* description of ECT and its potential risks and benefits, while also *distorting the role of treating physicians* in obtaining the informed consent of patients to the administration of ECT." APA Br. at 9. The APA therefore offers this Court "accurate information about these issues," including "the latest scientific and medical consensus." *Id.*

To be sure, as explained in Somatics' answering brief, the certified question doesn't require this Court to assess the relevant scientific evidence regarding ECT and to determine based on that evidence whether Somatics' disclosures contained inadequate warnings. *See* Answering Brief ("AB") 8. Neither party has ever moved for, let alone obtained, summary judgment

on warning inadequacy. Plaintiff was unable to move for summary judgment on that issue below because a warning is only inadequate when it fails to mention *an actual risk* of a medical treatment, *see Carlin v. Superior Court*, 13 Cal. 4th 1104, 1115-16 (1996), and medical professionals including Plaintiff's own physician have testified unequivocally that Plaintiff's claimed injury is *not an actual risk* of ECT, *see* 3-ER-337; 3-ER-341. The sole issue on which Somatics sought and obtained summary judgment—and the sole issue on which the Ninth Circuit has requested clarification from this Court—is whether, *even if* Plaintiff has satisfied her burden to offer evidence that her physician received inadequate warnings, her claims *still fail* because she has not satisfied her burden to offer evidence that the inadequacy caused her claimed injury.[2]

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[2] *Solely* for purposes of its motion on causation, Somatics did not challenge Plaintiff's factual assertions on warning inadequacy. *See, e.g.*, 2-ER-39-40, 47-49 (Somatics' statements that such facts were "[n]ot relevant to issues raised in [the] underlying motion regarding . . . causation" and therefore "[s]olely for purposes of this motion, undisputed"). Accordingly, the district court stated that it "*assumes for purposes of this Order* that Defendant did not provide any warnings to . . . Dr. Fidaleo concerning the risk of brain injury or permanent memory loss." 1-ER-9. Plaintiff's briefs delete the first part of that sentence, falsely telling this Court that the district court "*concluded* that 'Defendant did not provide any warnings to . . . Dr. Fidaleo concerning the risk of brain injury or permanent memory loss.'" OB24 (quoting 1-ER-9); *see* RB16 (same). That deceptive alteration to the language—appearing again in the reply brief, *after* Somatics identified the discrepancy in its answering brief, *see* AB13—contravenes Plaintiff's counsel's professional ethics.

The APA's brief confirms that Plaintiff's attacks on ECT, in addition to being irrelevant, have no basis in medical science. Most importantly, the APA confirms that ECT is *not capable* of causing Plaintiff's claimed injury. Plaintiff has claimed that ECT left her with a brain injury so severe she was unable to form new memories. *See, e.g.*, 5-ER-949. The APA explains that this is *not an actual side effect* of ECT: while ECT can cause some memory loss that "generally does not last for more than a few weeks after treatment, . . . ECT does not appear to result in lasting impairment of other cognitive functions." APA Br. at 14.

The APA explains that "[a] large body of scientific evidence demonstrates that ECT is a *safe and effective* treatment for certain serious mental illnesses" and that "'[t]he majority of published studies reported the safe use of ECT with *minimal and reversible* adverse events.'" *Id*. at 8, 18 (quoting 83 Fed. Reg. 66,103); *accord* AB8-10; CJAC Br. at 16. The Food and Drug Administration ("FDA") is so confident in ECT's safety and efficacy that it recently reclassified ECT devices as a *less* risky medical product. *See* APA Br. at 17-18.

The APA specifically verifies that ECT is a safe and effective treatment for patients with Plaintiff's exact mental health diagnoses: "Extensive scientific evidence," including "a substantial body of research" dating back decades, shows that ECT is "an effective treatment for major depression," leading to lower mortality rates following hospitalization than the rates amongst patients receiving treatments other than ECT. APA Br. at 9-10, 13. Studies show a "significant superiority of ECT in

comparison with trials of antidepressant drugs," particularly because ECT works so much faster. *Id*. at 10-11. Further, ECT "shows particular efficacy in individuals with severe depression that is accompanied by psychosis." APA Br. at 11; *see* AB5.[3] Moreover, "[b]ecause of its swiftness and efficacy," ECT is a particularly critical treatment tool in cases that "involv[e] acute suicide risks." *Id*. at 12; *see* AB5-6.

The APA clarifies that negative media portrayals of ECT are inaccurate and unfairly stigmatizing because they ignore "modern advances" in treatment. APA Br. at 15-17; *accord* AB10. The APA particularly criticizes the movie "One Flew Over the Cuckoo's Nest," APA Br. at 16-17, which Plaintiff shamelessly cites in support of her scientifically-unsupportable arguments regarding ECT, *see* OB8. Unlike the ECT portrayed by a 50-year-old Hollywood movie, modern ECT utilizes "general anesthesia, precisely controlled electrical stimulation, and physiological monitoring," incorporates "[m]ajor technical advances . . . in instrumentation," and "bear[s] little resemblance" to the early-development treatments on which negative media portrayals rely. APA Br. at 16-17.

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[3] In a citation-free footnote to the reply brief, Plaintiff's counsel claims to be aware of new facts, outside the record, bearing on Child Protective Services' decision to remove Plaintiff's infant child from her care. *See* RB 10 n.3; *see also* AB5-6; 3-ER-332. As Plaintiff's counsel failed to introduce any such facts into the record of this appeal, this Court should disregard their improper efforts to alter the existing factual record through unsworn representations.

The inaccuracy of Plaintiff's assertions regarding the side effects of her prescribed treatment, and the Hollywood movie she cites in support of those assertions, only highlight the importance of healthcare patients' reliance on *trained professionals* to make treatment decisions. The APA's members, unlike Plaintiff, have expertise in psychiatry. *Compare* APA Br. at 8 (APA's statement that its members "engage in psychiatric treatment, education, research, and forensic activities, and . . . regularly treat patients with serious mental illness") *with* 5-ER-951 (Plaintiff's declaration that she "suspected" ECT caused her claimed injury after she "looked at websites"). State and federal restrictions on prescription treatments like ECT recognize that *only* a physician can accurately assess of the safety and efficacy of such treatments. *See* 21 U.S.C. § 353(b)(1)(A); 21 C.F.R. § 801.109; Cal. Health & Safety Code §§ 110010.1, 111470.[4]

We live in the age of armchair experts. The internet is chockfull of opinions on medical issues offered by people with no medical training whatsoever, opinions that often mislead

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[4] Plaintiff claims to have evidence from outlier experts who disagree with the medical community's consensus on ECT. *See* RB12-14. She falsely states that "Somatics stated that" facts related to these outlier opinions were "undisputed." *Id*. at 12. Again, Plaintiff improperly deletes words when pretending to quote Somatics. *See supra* note 2. Somatics actually stated only that such facts were "[n]ot relevant to issues raised in [the] underlying motion regarding . . . causation" and thus "*[s]olely for purposes of this [causation] motion*, undisputed." 2-ER-39-40, 47-49. Try as she might, Plaintiff cannot conceal from this Court the fact that Somatics introduced evidence that ECT was *not capable* of causing her claimed injury, including testimony of her own physician. *See* 3-ER-337; 3-ER-341.

laypersons like Plaintiff. The APA's brief exposes the dangers of framing a causation inquiry around the perspective of such armchair experts. That approach would flood the courts with scientifically meritless claims like Plaintiff's, claims based on "look[ing] at websites." 5-ER-951.

II. Amici demonstrate the logical flaws in Plaintiff's causation arguments.

A. Amici recognize that Plaintiff's purported "interpretation" of the learned intermediary doctrine would in fact abolish the doctrine.

The certified question asks only *how*— not *whether*— Plaintiff must satisfy her causation burden under the learned intermediary doctrine. Nonetheless, seeking to bypass that burden altogether, Plaintiff asks this Court to hold that "the protections of the learned intermediary defense are not afforded to manufacturers who fail to warn the intermediary doctor, and, if a manufacturer fails to warn the doctor, then the manufacturer must warn the patient/consumer." OB23. But California doesn't have a learned intermediary *defense*; it has a learned intermediary *doctrine*, which applies whenever plaintiffs bring failure-to-warn claims against medical manufacturers. *See Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187 n.10 (2016).

As amici recognize, changing the doctrine's name can't salvage Plaintiff's arguments. Her purported interpretation of the doctrine would simply eliminate it: Because *every* failure-to-warn claim involves an allegation that a manufacturer provided inadequate warnings, "if the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California."

Himes v. Somatics, LLC, 2022 WL 989469, at *1 (9th Cir. Apr. 1, 2022); *accord* PLAC Br. at 9 ("[I]f Plaintiff's interpretation was correct, the [doctrine] would be a dead letter in California."); CJAC Br. at 21; PhRMA Br. at 20.

Amici highlight recent California appellate precedent soundly rejecting Plaintiff's arguments. *See Amiodarone Cases*, 300 Cal. Rptr. 3d 881 (Cal. Ct. App. 2022); *see also* PhRMA Br. at 25-26; PLAC Br. at 7; CJAC Br. at 29. *Amiodarone* agreed with the Ninth Circuit that, "even when a plaintiff alleges that warnings to a physician were inadequate, under California law the learned intermediary doctrine applies." 300 Cal. Rptr. 3d at 896. The doctrine applies *whenever* medical products "are 'supplied in the context of the doctor-patient relationship.'" *Id*. at 893 (quoting *Webb*, 63 Cal.4th at 187, fn. 10). "Warnings directly to patients do not enter the picture" because "the physician 'stands in the shoes of the product's ordinary user,'" *i.e.*, the patient, and "[t]he 'patient learns of the properties and proper use of the [medical product] from the physician.'" *Id*. at 893-95 (quoting *Gall v. Smith & Nephew, Inc.*, 71 Cal. App. 5th 117, 122 (2021)).

Notably, *Amiodarone* observed that it was "not aware of *any* California case" holding "that the manufacturer has a duty to warn the patient in the absence of an adequate warning to the doctor," *id*. at 895, rejecting the plaintiffs' reliance on the same cherry-picked language from *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51 (1973), on which Plaintiff relies in this case, OB29; RB18-19. *Amiodarone* also rejected a similar effort to relabel the

learned intermediary *doctrine* as a *defense*, stating that it was "not aware of *any* California decision that characterizes the learned intermediary doctrine as an affirmative defense." *Id.* at 894.

Amiodarone aligns with the decisions of courts nationwide affirming the continued viability of the learned intermediary doctrine. As amici emphasize, the doctrine is universal: "Every state in the country, along with the District of Columbia and Puerto Rico, has adopted the learned intermediary doctrine in some iteration." *Dearinger v. Eli Lilly & Co.*, 510 P.3d 326, 329 (Wash. 2022); *see* PhRMA Br. at 20 ("[B]ecause a patient can only obtain a prescription medicine or device from a state-licensed prescriber, *every state* recognizes the learned intermediary doctrine.").[5] And for good reason: the learned intermediary doctrine rests on the sensible principle that only a trained medical professional can weigh the risks and benefits of prescription-only treatments. *See Gall*, 71 Cal. App. at 122

[5] CJAC states that the learned intermediary doctrine has exceptions for direct-to-consumer marketing, oral contraceptives, and mass immunizations, CJAC Br. at 26, but Plaintiff doesn't, and can't, argue that any such exception applies in this case. Moreover, California has not adopted any such exceptions, and other state supreme courts have rejected them. *See, e.g., Dearinger*, 199 Wash. 2d at 572 (no exception for direct-to-consumer advertising); *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 25 (2016) (same); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 164 (Tex. 2012) (same); *Martin by Martin v. Ortho Pharm. Corp.*, 169 Ill. 2d 234, 244 (1996) (no exception for oral contraceptives); *West v. Searle & Co.*, 305 Ark. 33, 44 (1991) (same); *Hurley v. Lederle Lab'ys Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988) (no exception for immunizations administered in the context of a patient-physician relationship).

("[t]he law and medical ethics both demand that doctors, for their patients' benefit, evaluate scientific information about" prescription medical products); *see also Carlin*, 13 Cal. 4th at 1118 (a "patient's expectations regarding the effects of [a prescribed product] are those related to him by his physician"). Plaintiff's attacks on the doctrine minimize and demean the legally-assigned and medically-necessary role of trained experts in interpreting warnings and determining appropriate courses of treatment. *See* CMA/CDA/CHA Br. at 25 (Plaintiff "insult[s] psychiatrists"); APA Br. at 9 (Plaintiff "distort[s] the role of treating physicians").

As CLS notes, Plaintiff also asks this Court to diverge from the clear views of the California legislature. In 2008, the California legislature rejected Assembly Bill 2690, which sought to eliminate the learned intermediary doctrine in California. *See* CLS Br. at 18-21. The legislature recognized concerns that, in "usurp[ing] a *well-established, common sense* judicial doctrine," the bill would lead to "increased litigation" that "could potentially *increase healthcare costs and jeopardize the development and production of life-saving medicines*." *Id*. at 20-21. California lawmakers have rejected the demand Plaintiff makes here: to eradicate well-established common law. This Court should reject it, just as the legislature did.

B. Amici correctly observe that Plaintiff's physicians-as-messengers theory is legally unsupported, unworkable, and untethered to the learned intermediary doctrine's principles.

When finally turning to the question actually presented, Plaintiff argues that this Court should create a new causation

standard for the learned intermediary doctrine. That standard, Plaintiff urges, would not focus on how the learned intermediary would assess a stronger warning, but on how the learned intermediary's lay patient would assess a stronger warning. Amici broadly reject Plaintiff's argument, noting that "courts have largely coalesced around a *physician*-focused causation standard." PLAC Br. at 13. That physician-focused causation standard has been endorsed in almost three dozen jurisdictions, which clarify that causation focuses on the physician's prescription decision. *See* PhRMA Br. at 47-57 (Addendum).[6]

Plaintiff suggests that Texas law endorses her standard, citing *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006) (applying Texas law). *See* RB26-27. But as PhRMA notes, she does not mention that after *McNeil* made an *Erie* guess about Texas law, the Texas Supreme Court clarified that a *physician*-focused standard applies. *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 172 (Tex. 2012) ("a critical element of the [plaintiffs'] claims" is proof that a stronger warning "would have changed *[the*

[6] Somatics' answering brief also identifies numerous decisions rejecting Plaintiff's causation arguments. *See* AB40-47. Plaintiff fails to meaningfully engage with these cases and erroneously suggests that *Gaghan v. Hoffman-La Roche Inc.*, 2014 WL 3798338 (N.J. Super. Ct. App. Div. Aug. 4, 2014) (applying California law), rejected the physicians-as-messengers theory because the physician's testimony was equivocal on whether he would relay warnings, *see* RB28. In fact, *Gaghan* clearly and separately held that the plaintiff couldn't establish causation even with unequivocal testimony about relaying warnings because "California law focuses on *the prescribing decision* of the doctor as the learned intermediary." 2014 WL 3798338, at *14-15.

physician's] decision to prescribe."); *see* PhRMA Br. at 35-36. Moreover, Plaintiff mischaracterizes *McNeil*, which actually held that, "[u]nder Texas law, a plaintiff who complains that a prescription drug warning is inadequate must also show that the alleged inadequacy *caused her doctor to prescribe* the drug for her." 462 F.3d at 372. *McNeil* found a triable issue on causation only because the physician there—unlike Dr. Fidaleo—"testified that he *would not have prescribed* the drug" with a stronger warning and "that such information certainly would have *changed the risk/benefit analysis*." *Id.* Plaintiff cannot identify a decision from any other state supreme court reaching the conclusion she asks this Court to reach.

A standard turning on a lay patient's testimony about how she would respond to warnings intended for learned intermediaries has failed to gain traction nationwide because it contravenes the learned intermediary doctrine's most fundamental rationale: the recognition that patients rely on physicians to help them understand where treatment benefits outweigh risks.[7] The learned intermediary doctrine "effectuates" and "flows naturally from" existing state and federal laws permitting patients to obtain prescription-only treatments like

[7] *See, e.g.*, *Carlin*, 13 Cal. 4th at 1118 (a "patient's expectations regarding the effects of [a prescribed product] are those related to him by his physician"); *Gall*, 71 Cal. App. at 122 (the learned intermediary doctrine recognizes that "[p]atients want to be able to *rely entirely* on their doctors' informed and independent judgments"); *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (1999) ("it is through the physician that a patient learns of the properties and proper use of" prescription products).

ECT *only* through physicians. PhRMA Br. at 23, 25. Because physicians are the legally-assigned gatekeepers of such treatments, manufacturers provide risk information *only to physicians*, in formats that *only physicians* can understand. *See* 60 Fed. Reg. 42,581 (Aug. 16, 1995) (a warning "is written in technical language *intended for health care professionals* and is relatively inaccessible to consumers").[8] A causation standard turning on a lay patient's testimony about how she would respond to warnings intended for learned intermediaries would ignore physicians' roles as receivers and interpreters of warnings and "would create asymmetry between the physician-oriented duty analysis and the patient-oriented causation inquiry." PLAC Br. at 4; *accord* CLS Br. at 22; CJAC Br. at 12.

A standard turning on a lay patient's testimony would also be unworkable and unreliable. As amici explain, the physician-focused causation standard involves posing questions to *an actual physician*, who can testify—and then face cross-examination regarding—how additional risk information impacts his or her medical judgment. *See* PLAC Br. at 4. Often, the physician will have made prescription decisions both before and after the plaintiff experienced the claimed side effect and thus will have "actual clinical experience basing prescribing decisions on both the information that existed at the time of plaintiff's prescription

[8] *See also* 71 Fed. Reg. 3922 (Jan. 24, 2006) (a warning is "written for the health care *practitioner* audience" rather than health care *patients*); 21 C.F.R. § 801.109(c) (manufacturers are tasked with warning of "any relevant hazards, contraindications, side effects, and precautions under which *practitioners* licensed by law to administer the device can use the device safely").

and after the allegedly omitted risk information came to [light]." *Id*. at 15. Removing the need for unreliable speculation, the physician can simply report whether additional risk information *actually did* change his or her prescription decisions.

By contrast, an objective prudent-patient-focused standard asks a jury to speculate about how risk information would impact *a hypothetical patient*, a theoretical entity who cannot be questioned under oath or cross-examined. The prudent-patient-focused standard also requires *presuming that a physician would fail* in her or her professional duty to help the patient understand where treatment benefits outweigh risks. This "adds an unacceptable layer of speculation and uncertainty." PLAC Br. at 4; *accord* CLS Br. at 17. California juries shouldn't be asked to simply "guess about what a hypothetical patient under the circumstances would have done if given certain information in some manner." PLAC Br. at 4. That murky inquiry is a poor substitute for the practical, workable physician-focused standard routinely applied across U.S. jurisdictions.

Further, Plaintiff's proposed *subjective* patient-focused standard would create even more unreliability, as the standard rests entirely on hindsight bias. "[F]ew plaintiffs—having experienced an actual injury, convinced themselves that their medicine or device is to blame, and decided to sue to recover—can be expected to testify that they would have accepted the same course of treatment with additional warnings of the injury they

experienced." PhRMA Br. at 37-38.[9] This Court has previously rejected subjective causation standards for that very reason. *See Cobbs v. Grant*, 8 Cal. 3d 229, 245 (1972) ("Since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined treatment. Subjectively he may believe so, with the 20/20 vision of hindsight, but we doubt that justice will be served by placing the [defendant] in jeopardy of the patient's bitterness and disillusionment."); *see also* AB56-59.

Moreover, there is little utility in asking a plaintiff how she would have reacted to "isolated and unvarnished risk information" because that question won't account for the reality of how physicians discuss risk information with patients. PLAC Br. at 27. When answering, the plaintiff lacks the medical expertise to imagine the risk information in the context of "real world presentation by an experienced physician." *Id.* Thus, the plaintiff's answer, even if honestly given, cannot reliably identify whether the plaintiff actually would have refused treatment.

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[9] *Accord* PLAC Br. at 4-5 ("[E]ndorsing a standard that allows causation to turn on the plaintiff's self-serving speculative, hypothetical, hindsight testimony would lead to unreliable factfinding, operate as a virtually automatic bar to summary judgment, and emasculate the causation element of a failure-to-warn case."); CJAC Br. at 37; CMA/CDA/CHA Br. at 43-44.

Accordingly, as amici's briefs make plain, the only reliable and legally supportable causation standard is the *physician*-focused standard currently applied nationwide.[10]

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[10] CMA/CDA/CHA agrees with Somatics and other amici that, to establish causation, a plaintiff "must show" that, "based on [a stronger] warning, her physician would recommend against the treatment." CMA/CDA/CHA Br. at 19. But CMA/CDA/CHA argues that a plaintiff must *also* prove that she herself would react differently to a stronger warning, through evidence that (a) "her physician would communicate the warning to her" and (b) she "would agree with the physician's recommendation not to have the treatment." *Id.* The Court need not address CMA/CDA/CHA's arguments regarding these additional burdens in this case because Plaintiff offered no evidence that Dr. Fidaleo would have recommended against treatment. *Cf.* 5-ER-1013 (Dr. Fidaleo's unequivocal testimony that a stronger warning "wouldn't stop [him]" from prescribing ECT).

CMA/CDA/CHA oddly attempts to minimize the role of doctors and dentists in prescription decisions, perhaps due to concerns about medical malpractice claims. *See, e.g.*, CMA/CDA/CHA Br. at 26. For example, CMA/CDA/CHA suggests that when a physician determines that prescription treatment is medically *in*appropriate (i.e., the opposite of what happened here), the patient acts as the ultimate decisionmaker. *See id.* at 60 (asserting that a patient may override her physician's judgment and "demand[]" prescription treatment). But federal law prevents patients from obtaining prescription drugs or devices without a health care professional's prescription, which is given only if the health care professional deems a treatment appropriate. *See* 21 U.S.C. § 353(b)(1)(A); 21 C.F.R. § 801.109. If a physician decides, for example, that opioids are not medically necessary and refuses to prescribe them, the patient is not the ultimate decisionmaker; the doctor is. The same is true of ECT, and all other prescription treatments.

C. Amici correctly recognize that a physician's failure to read a manufacturer's warning bars a legal conclusion that the allegedly inadequate warning caused injury.

Somatics asked this Court to clarify that, even under a physicians-as-messengers theory, a doctor's unequivocal testimony that he *did not read* a warning precludes a legal determination that the inadequacy of those warnings caused Plaintiff's injury. AB53-56. Amici ask for that same clarification. *See* PhRMA Br. at 28, 34; PLAC Br. at 16.

Plaintiff suggests that the Ninth Circuit's conclusion on this point—that evidence that Dr. Fidaleo read *other* manufactures' "dear doctor" letters would suffice to establish causation under the physicians-as-messengers theory—is somehow a factual finding insulated from this Court's review. *See* RB33-34, 36. Plaintiff confuses fact and law. That Dr. Fidaleo did not read the disclosures Somatics actually provided to his hospital is a factual matter. That Dr. Fidaleo read "dear doctor" letters sent by other manufacturers is a factual matter. That Somatics provided disclosures exclusively in manuals and pamphlets, not "dear doctor" letters, prior to Plaintiff's treatment is a factual matter. But it is a *legal conclusion* that these facts would suffice to establish causation under Plaintiff's physicians-as-messengers theory. This Court should confirm that, as a matter of *law*, where a doctor fails to read any of a manufacturer's previously-provided warnings, "it is quintessentially logical to conclude that [any] omission in the

warnings lacked any significant role in bringing about the patient's injury." PLAC Br. at 16.[11]

Plaintiff also identifies no legal support for her suggestion that California law lets the Court *presume* that a physician would have read and relied on a stronger warning even where the physician has testified that he did not read warnings provided by the manufacturer. *See* RB34, 37. As amici recognize, Plaintiff's proposed "heeding presumption 'is not recognized in California.'" PhRMA Br. at 28 (quoting *Huitt v. S. California Gas Co.*, 188 Cal. App. 4th 1586, 1603 (2010)). Moreover, "[e]ven in the minority of states that do recognize a heeding presumption, that rebuttable presumption is overcome by testimony that a different warning would not have affected the physician's decisionmaking . . . because the physician never read the label." *Id*. (citing *Moore v. Ford Motor Co*., 332 S.W.3d 749, 763 (Mo. 2011); *Coffman v. Keene Corp*., 628 A.2d 710, 720 (N.J. 1993)).

Plaintiff relies on *Toole v. Richardson- Merrell Inc*., but *Toole*—which involved fraud and breach of express warranty claims, not failure-to-warn claims—held that a jury could

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[11] Similarly, CMA/CDA/CHA states that "a factual question" underlies Somatics' request that this Court clarify that a prudent person would not refuse treatment that her physician explained to her was a last-resort, life-saving measure. CMA/CDA/CHA Br. at 36. But Somatics only asks this Court to address the *legal question* of whether, as a matter of law, a "prudent" person, facing a high risk of death, would refuse the last available treatment to save her life because of a small risk of side effects. *See* AB60. If this Court confirms, as it should, that a prudent person would not do so, then the Ninth Circuit will need to analyze the *factual question* of whether Dr. Fidaleo actually did describe ECT as a last-resort, life-saving treatment. *Id*.

conclude that a physician relied on a manufacturer's statements where, unlike here, the physician explicitly testified that he did. *See* 251 Cal. App. 2d 689, 707 (1967) (physician "stated in his deposition that in prescribing the drug he relied upon the literature supplied by [the manufacturer]"). Moreover, Plaintiff's cited portion of *Grinnell v. Charles Pfizer & Co.*, doesn't address how plaintiffs prove causation for failure-to-warn claims; it addresses how plaintiffs prove their own reliance on manufacturer statements for breach of express warranty claims. 274 Cal. App. 2d 424, 441 (1969). Unlike here, no physician in *Grinnell* testified that he did not read a manufacturer's warnings. *Id.*[12]

III. Amici show the grave harm Plaintiff's causation theory would cause to patients.

Amici show that the learned intermediary doctrine's physician-focused causation standard does not undermine a patient's right to refuse prescription treatment. Plaintiff's argument to the contrary erroneously "conflat[es] the learned intermediary doctrine with the informed consent doctrine." PhRMA Br. at 42.

The learned intermediary doctrine addresses interactions *between manufacturer and physician*, requiring that a manufacturer's warning be tailored to physicians so that they can use their training and expertise to determine the impact of the warning on the appropriate treatment decision. *Id.* at 43-44. By contrast, the informed consent doctrine addresses interactions

[12] *See also* PhRMA Br. at 29 (distinguishing *Toole* and *Grinnell* because "neither . . . involved failure-to-warn claims at all").

between physician and patient, requiring the physician to disclose to the patient certain relevant information and to obtain the patient's consent to treatment. *Id.* at 42-43. The learned intermediary doctrine thus operates comfortably alongside, and in no way overrides, the legal frameworks that already ensure that physicians will obtain informed consent from patients—including criminal laws, regulations of professional licensing and disciplinary boards, and tort doctrines addressing *physician* liability. *See* PLAC Br. at 19; PhRMA Br. at 42, 45.

The learned intermediary doctrine doesn't authorize physicians to administer treatment without consent. It simply recognizes that physicians *obtain* consent by helping patients understand where treatment benefits outweigh risks. While lay patients may initially blanch at necessary treatments carrying serious risks, physicians obtain consent to such treatments by using their training and expertise to tailor warnings to individual medical circumstances. *See Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 n.6 (1992); AB36-37, 49-50. The learned intermediary doctrine plays a crucial role in *protecting* patient autonomy and enabling patients to make sound consent decisions: by delegating to physicians the task of distilling and individualizing warning information for patients, the doctrine "strengthens patients' ability to comprehend" treatment risks and benefits. PhRMA Br. at 45.[13] The learned intermediary doctrine

[13] *See also* PLAC Br. at 20 (explaining that the learned intermediary doctrine "bolsters patient autonomy" because "intervention of the learned intermediary is crucial to put risk information in its proper perspective for the patient and to allow the patient to make rational choices in their best interest rather than needlessly be

and the informed consent doctrine work "in tandem" to safeguard patients, *id*., as "[i]n combination, this system of obligations constructed by the courts, the legislature, and professional boards maximizes overall medical benefit for patients without imposing excessive burdens on manufacturers that might inhibit or impede the availability of critical therapies," PLAC Br. at 19.

As amici explain, Plaintiff's proposed causation standard poses the true threat to healthcare patients as it would, *inter alia*, impede access to treatment and produce worse treatment outcomes.

A. Plaintiff's self-serving causation standard would make life-saving medical treatments less accessible to patients who need them.

Amici describe how Plaintiff's toothless causation standard would affect patients. The new standard would inundate California courts with longer-lasting suits against medical manufacturers, forcing manufacturers to redirect resources to lawyers instead of researchers, reducing the output and availability of treatments and driving up patient costs. *See* PLAC Br. at 2 (Plaintiff's causation theory threatens "the ability of prescription medical product manufacturers to improve and develop life-saving and pain ameliorating therapies" and "the delivery of beneficial therapies to those who need them"); CJAC Br. at 14 (Plaintiff's causation theory would create "an overall rise in the price of heath care, and the discontinuation of certain

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self-dissuaded from needed or advantageous treatments by unrealistic and non-contextual fears"); CJAC Br. at 30-31 (describing how the learned intermediary doctrine works alongside the informed consent doctrine to protect patient rights).

medical devices beneficial to the treatment of countless patients"); CLS Br. at 23 (Plaintiff "risks disincentivizing research and innovation to bring novel therapies to market"); *cf.* APA Br. at 8, 19 (ECT is a "lifesaving" treatment and this Court's ruling could "jeopardiz[e] patient access to ECT").

As CLS explains, biomedical innovation is a field already marked by "tremendous" financial risks. CLS Br. at 23. A staggering ninety percent of potential therapeutics effectively passing preclinical development never reach the market, with innovators spending an average "$100 million to more than $1 billion" on each of these failed products. *Id.* Disincentivizing innovation even further will hurt those suffering from less common diseases the most, because treatments for those diseases may not generate enough revenue to offset the costs of Plaintiff's proposed liability expansion. Potential therapies for life-threatening but rare diseases already "often languish[] in the early development pipeline" due to "the relatively low odds of success and the high costs of drug development." *Id.* at 23 (quoting National Institute of Health, National Library of Medicine, National Center for Biotechnology Information, https://www.ncbi.nlm.nih.gov/books/NBK56179/ (last visited December 28, 2022). When the financial incentive structures tilt even more dramatically against biomedical innovation, "patients, especially those living with a rare disease, are the ones that suffer the most." *Id.* at 16. And reducing biomedical innovation in California will have a worldwide impact, given California's leadership (so far) in such innovation—including sponsoring or

primarily supporting more than a quarter of COVID-19 vaccine developments in the United States. *Id.* at 24.

Because the development of life-saving medical treatments has indispensable social value, this Court has consistently taken pains to ensure that liability risks do not grow so large that they harm innovation. *See, e.g., Brown v. Superior Ct.*, 44 Cal. 3d 1049, 1063-64 (1988); *see also* AB50-53. This Court should reject Plaintiff's request to "disturb the carefully crafted policy balance struck by this Court," which would hurt other suffering patients to allow her own meritless claims to proceed to trial. PLAC Br. at 5.[14]

B. Plaintiff would create a system of warnings that are less useful to patients and produce worse healthcare outcomes.

Plaintiff's causation arguments would also harm patients by creating a warnings system that is *less useful* and *more dangerous*. As PhRMA warns, focusing causation on whether physicians would relay warnings to patients "could induce manufacturers to shield themselves from liability by directing physicians to flood their patients with an onslaught of exhaustive, untailored warnings about every conceivable risk . . . no matter how uncertain or remote." PhRMA Br. at 21, 37.

Overwarning has dire consequences for patient health. As this Court has explained even "a truthful warning of an uncertain or remote danger may mislead the consumer into

[14] *Accord* PLAC Br. at 34 (Plaintiff would upset the "careful[] balance[]" this Court has struck to ensure "the availability and affordability of existing beneficial therapies").

misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision" not to use the product. *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 934 (2004). A layperson patient who is inundated with "the complete and highly technical information on the adverse possibility associated with the use of" a medical product, but who lacks the scientific expertise necessary to evaluate that information, "might actually object to" treatment in her best interest and "thereby jeopardize[e] [her] life." *Plenger*, 11 Cal. App. 4th at 362 n.6; *accord* 73 Fed. Reg. 49,603, 49,605-06 (Aug. 22, 2008) ("overwarning . . . may deter appropriate use of medical products"); PhRMA Br. at 21.

Moreover, when patients receive extensive warnings of even remote risks, they can fail to take *any* warnings seriously. *See Finn v. G. D. Searle & Co.*, 35 Cal. 3d 691, 701 (1984) ("If we overuse warnings, we invite mass consumer disregard . . . ."); *Dowhal*, 32 Cal. 4th at 932 ("less meaningful warnings" can "crowd[] out necessary warnings"); 71 Fed. Reg. at 3935 ("[L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance."); FDA, *Draft Guidance for Industry, Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs* 4 (revised Aug. 2015), https://www.fda.gov/media/70768/download) ("[E]xhaustive lists that include even minor risks detract from, and make it difficult for, consumers to comprehend and retain information

about the more important risks."); *accord* PLAC Br. at 11; PhRMA Br. at 39.

In sum, while Plaintiff attempts to frame her lawsuit as advocacy for patient rights, amici expose the truth: her self-serving causation standard would gravely harm patients and has no basis in California law.

CONCLUSION

For the reasons discussed above, in Somatics' answering brief, and in all six amicus briefs, this Court should hold that a failure-to-warn claim against a medical manufacturer requires evidence that a stronger warning would have altered the physician's prescription decision.

Dated: December 28, 2022

Respectfully submitted,

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Pursuant to Rule 8.204(c) of the California Rules of Court, I hereby certify that this brief including footnotes, contains 6,161 words, as calculated by the Microsoft Word software used to prepare the brief.

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The undersigned declares:

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