Case No. S273887

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

MICHELLE HIMES,
Plaintiff and Appellant,

vs.

SOMATICS, LLC,
Defendant and Respondent.

ON REQUEST FROM THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT FOR ANSWER TO CERTIFIED QUESTIONS OF CALIFORNIA LAW

AMICUS CURIAE BRIEF OF THE CIVIL JUSTICE ASSOCIATION OF CALIFORNIA IN SUPPORT OF DEFENDANT AND RESPONDENT

FRED J. HIESTAND (SBN 44241)
COUNSELOR AT LAW
fred@fjh-law.com
3418 Third Ave., Suite 1
Sacramento, CA 95817
Tel: (916) 448-5100

General Counsel for *Amicus Curiae*
The Civil Justice Association of California

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INTRODUCTION

A. IMPORTANCE OF ISSUE

The Civil Justice Association of California ("CJAC") welcomes the opportunity to address as *amicus curiae*[1] the issue certified by the Ninth Circuit to this Court and accepted for decision:

> **In a claim against a manufacturer of a medical product for a failure to warn of a risk, is the plaintiff required to show that a stronger risk warning would have altered the *physician's decision* to prescribe the product? Or may the plaintiff establish causation by showing that the *physician* would have communicated the stronger risk warnings to the plaintiff, either in their patient consent disclosures or otherwise, and a prudent person in the patient's position**

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[1] By separate accompanying application, amicus asks the court to accept this brief for filing.

would have declined the treatment after receiving the stronger risk warning?

This question arises in the context of a negligence and product liability failure to warn action by petitioner (plaintiff below) against respondent Somatics as manufacturer of the "medical device" machine the physician prescribed for her Electroconvulsive Treatments ("ECT"). Reference in the certified question to the "physician" evokes consideration of the "learned intermediary" defense that respondent Somatics raised and the district court found applicable.

This long-standing, venerable doctrine means that physician prescribers can make risk/benefit analyses to determine what medical devices their patients need for their treatment. As part of that process, the physician necessarily evaluates what risks to tell – and not tell – their patients. One consequence of a physician's presumed medical competence is that a learned intermediary is within his or her rights to disregard a manufacturer's warning altogether, to decide that a particular risk was not severe enough to make a difference, or to conclude that such a risk did not exist or was not material in the context of a particular patient's medical needs. In all of these situations, the physician-prescriber's independent evaluation of what risks to credit, which to

ignore, and which to omit in counseling patients relieves the manufacturer from liability to the patient.

Assuming *arguendo* that the learned intermediary doctrine does not apply, however, plaintiffs must still show *causation*. Here, two different tests of causation are posited in the certified question: either (1) that a stronger risk warning would have altered the physician's decision to prescribe the product; or (2) that the physician would have communicated stronger risk warnings to the plaintiff if they had been given, and a prudent person in the patient's position would have declined the treatment after receiving the stronger warning.

Both parties focus their briefs on the second causation test, petitioner asserting that despite her express informed consent agreement the first test would somehow "violate this Court's precedents concerning the autonomy of patients and the importance of patient consent." (Petitioner's Opening Brief, p. 23 ("OB").)

CJAC agrees with the Ninth Circuit and petitioner that this case involves "the interplay between the learned intermediary doctrine and causation." We disagree, however, with petitioner's argument that the "learned intermediary" doctrine does not apply here because Somatics failed to give adequate warnings to her physician that she believes he

should have given about the risk of long-term memory loss. We also disagree with petitioner's contention that causation is shown when petitioner states she would not have consented to ECT if her doctor had given her the warnings she wished he had given (OB, p. 3), warnings he testified he did give and petitioner's signed informed consent agreement reveals he in fact gave.

CJAC's opposition stems from the resulting effects should petitioner's proposed test be adopted by the Court—gutting of the "learned intermediary" doctrine, leaving it an empty shell, and a concomitant expansion of liability for medical device manufacturers in general and, here, for two domestic manufacturers of machines made for the treatment of patients by physician-prescribed ECT. Numerous "medical device" manufacturers will likely face increased liability claims if petitioner's arguments succeed, including Lasik surgical machines, heart-lung machines, ventilators, incubators, dialysis machines and many others.

Courts should not become embroiled in weighing and deciding complicated questions over what "true" (petitioner's term) risks should be disclosed by medical device manufacturers to physicians who have substantial clinical experience using those devices in prescribed medical treatments for their patients. That issue is best decided by

the expertise of "learned intermediary" physicians themselves, those who, having used the devices previously in treating numerous patients, not only exercise their judgment and expertise in deciding how and to what medical devices to use for patient treatment, but also obtain the patients' informed consent before beginning treatment. This is especially so when, as here, those medical devices are used *only* under the *physician's supervision*, in a *medical setting* and are not implanted in the patient.

> In the case of prescription drugs and [medical devices], the physician stands in the shoes of the product's ordinary user; a patient learns of the properties and proper use of the drug or [device] from the physician. . .. (*Gall v. Smith & Nephew, Inc.* (2021) 71 Cal.App.5th 117, 122.)

The learned intermediary doctrine exists to serve the tort goal of accident cost avoidance, which is accomplished by requiring patient warnings to be given by the party in the best position to provide them—the physician through an informed consent agreement with the patient.

This reflects the realities of the doctor-patient relationship. Patients prescribed drugs or treatment using medical devices necessarily interact with their prescribing physician. The physician, based on professional knowledge and experience, is presumed to know the risks to the patient from use of these devices, and will use that information in the

context of the individual patient's medical history and current condition when prescribing treatment. These risks will be communicated to the patient through the process of obtaining written informed consent. This method of communicating warnings to the patient is the most effective means of passing along information about risks and should result in the best health outcomes for patients.

B. Interest of Amicus

CJAC is a long-standing non-profit corporation of businesses, professional associations and financial institutions. Our principal purpose is to educate the public about ways to make our civil liability laws and doctrines more fair, efficient and certain in their application and administration. Toward this end, CJAC has participated in numerous cases deciding who should pay, how much, and to whom when the conduct of some occasions harm to others. This is such a case.

A strong learned intermediary doctrine is important for drug and medical device manufacturers defending lawsuits in California because most claims involving physician-prescribed treatments with drugs or medical devices are based on a failure to warn theory. Though California's learned intermediary doctrine remains strong, petitioner's proposed

reworking of it and its corollary "causation" element would, if adopted by the Court, divest it of viability.

The ensuing outcome: plaintiffs dissatisfied with their physician-prescribed treatment outcomes involving use by their physician of a "medical device" that plaintiffs feel was unaccompanied by sufficiently adequate warnings to their doctor or themselves, will be understandably attracted to file damage claims. This will mean increased liability and defense costs for medical device manufacturers, an overall rise in the price of heath care, and the discontinuation of certain medical devices beneficial to the treatment of countless patients. As *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1114 warns:

> [I]f a manufacturer could not count on limiting its liabilities to risks that were known or knowable at the time of manufacture or distribution, it would be discouraged from developing new and improved products for fear that later significant advances in scientific knowledge would increase its liability. . ..

SALIENT LEGAL AND FACTUAL BACKGROUND

While the scope and application of the "learned intermediary" doctrine and its relationship to the causation issue is one of law, this Court's consideration need not occur in a vacuum. The record of summary judgment proceedings before the federal district court provides factual information

that informs the legal issues presented and, in turn, those legal issues determine which facts are important for their resolution. Similarly, "[s]cience informs law about facts that give rise to legal issues, and law reciprocates by relying on science for factual information to optimize the understanding of [those] issues." (Rhonda Gay Hartman, *Coming of Age: Devising Legislation for Adolescent Medical Decision-Making* (2002) 28 *AM. J.L. & MED.* 409, 414.) Thus, from the federal court record and briefs of the parties filed here this Court knows the following pertinent facts and law:

Facts about Petitioner's ECT Treatment

Petitioner Michelle Himes was suffering from severe mental health problems, including depression and other life-threatening ailments, when she requested medical treatment in 2011 from psychiatric specialist Dr. Raymond Fidaleo. After undergoing extensive treatments of psychotherapy, various prescribed medications ("at least nine different antipsychotics and antidepressants") and repeated hospitalizations that failed to provide her sufficient relief, Dr. Fidaleo recommended to petitioner that, as "*a last resort,*" she consider ECT.

ECT, commonly referred to as "shock treatment," began in the 1930s and during the 1940s and 1950s was an

accepted way of treating mental illness. But depictions of its misuse in literature and movies based on that literature – including Sylvia Plath's *The Bell Jar*, Anthony Burgess's *A Clockwork Orange*, and Ken Kesey's *One Flew Over the Cuckoo's Nest* – made it publicly controversial. ECT, however, is now considered safe and successful in treating patients with severe mental disorders. (See Respondent's Brief, p. 8. ("RB").)

According to the Mayo Clinic, "ECT is a procedure, done under general anesthesia, in which small electric currents are passed through the brain, intentionally triggering a brief seizure. ECT seems to cause changes in brain chemistry that can quickly reverse symptoms of certain mental health conditions."[2] "Because of improvements in the administration of ECT, the only significant side effect of the treatment is memory loss, with recall performance returning to pretreatment level or better within a few weeks after the last ECT treatment. In fact the side effects of ECT are often less severe than the side effects associated with antidepressant drugs." (Stuart Y. Johnson, *Regulatory Pressures Hamper the*

[2] Mayo Clinic, *Electroconvulsive Therapy*, https://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/about/pac-20393894.

Effectiveness of Electroconvulsive Therapy (1993) 17 *LAW & PSYCHOL. REV.* 155, 156-57.)

Dr. Fidaleo explained the risks of ECT to petitioner and she signed a written consent form that discloses them. Her consent form states she understands that "ECT involves passage of an electrical stimulus across my brain for a few seconds, sufficient to induce a seizure. In my case the treatments will be probably be given three times per week for four and one-half weeks, not to exceed a total of fifteen treatments and not to exceed 30 days from the first treatment. Additional treatments cannot be given without my written consent." (*Himes v. Somatics, LLC* (9th Cir. 2021), Appellant's Excerpt of Record, ("ER") Vol. II, 159.)

Petitioner was expressly warned in the consent form she signed that "there may be some *memory loss* which could last less than an hour or there may be *permanent spotty memory loss*. Memory loss and confusion may be lessened by the use of unilateral (one-sided) electrical brain stimulation rather that bilateral (two-sided) stimulation." (*Id.*; italics added.)

In addition to the informed consent form petitioner signed, Dr. Fidaleo explained to petitioner that he was not concerned with "brain damage" to her from ECT, and confirmed that even if he were informed of a risk of

permanent memory loss, he would not be deterred from recommending ECT and applying it after obtaining informed consent.

Himes began her prescribed ECT therapy treatments in April 2011 and ended them in early January 2012 after completing 26 total treatments. She signed additional informed consent forms each new month that she had this therapy.

Years later, in 2017, petitioner noticed, in addition to memory difficulties she was then experiencing, that "she was having difficulty communicating." (ER, Vol. 5, 951.) So she started "researching psychiatric medicine . . . *specifically looking into* ECT. . . Once she 'suspected that ECT could have caused [her] memory problems,' she 'sought out an attorney' and soon after filed suit against Somatics." (*Id.*; italics added.)

Federal and California Law Governing ECT

In 1976, Congress passed the 1976 Medical Device Amendment (21 U.S.C. § 360) amending the Food, Drug, and Cosmetic Act of 1938 to authorize the FDA to regulate medical devices. The amendment gave the FDA authority and responsibility to assure consumers that medical devices are safe and effective. The FDA is required to classify all devices for human use marketed in the United States into one of

three regulatory classes so that the FDA can appropriately control each device. (See 21 U.S.C. §§ 360c (a)(1)(C), 360e(d)(2) & 360e(b)(1)(B).)

In 1990, Congress passed the Safe Medical Devices Act (*id.*) requiring medical device user facilities and manufacturers to report to the FDA deaths, serious illnesses, and serious injuries related to medical devices. (*Id.*) Pursuant to this amendment, the FDA may order manufacturers to stop distributing and physicians to stop using a medical device. The FDA may also order a recall. Further, medical device manufacturers must monitor new patients and warn them directly if serious problems arise. However, because the new law is not retroactive, manufacturers do not need to notify patients who had medical devices prior to the law's enactment if serious problems develop. (21 U.S.C. §§ 301(d), 360 (I).) Notably, the Thymatron IV has not been subject to any of these statutory provisions. However, the FDA in 2018 adopted 21 C.F.R. 882.5940 to require several disclosures and reporting requirements by manufacturers to prescribing physicians for ECT treatment of their patients.

California's only statutory and regulatory provisions regarding ECT deal with its application to patients who are involuntarily treated, which do not apply to petitioner. (Welf. & Inst. Code § 5326.85 & 15 CCR § 3999.348.)

SUMMARY OF ARGUMENT

There are, to be sure, many situations where a manufacturer's failure to adequately warn a physician of risks to a patient from use of its "medical device" obviates application of the learned intermediary defense. This case, however, is not one requiring that result. Instead, the Court here is faced with circumstances that "cry out" for application of the learned intermediary doctrine, which serves as a defense that relieves the manufacturer from liability to the patient:

- First, the physician has substantial clinical experience in prescribing and administering to patients who suffer severe mental and emotional disabilities the treatment of ECT.

- Second, the physician discusses the risks associated with ECT to the patient and presents it as a "last resort" to the previously prolonged but unsuccessful treatment of therapy, various prescription medicines, and hospital admissions.

- Third, in advance of her treatment, the patient is presented with an informed consent agreement disclosing the risks, including "short term" and "permanent" memory loss, which the patient accepts and signs.

- Fourth, the medical device in question, the machine that emits the short electrical bursts for ECT, is neither advertised to patients nor available for purchase by them from the manufacturer, but is only sold to licensed health care providers.

- Fifth, the machine and its accompanying role in ECT treatment is applied exclusively in a medical setting by a licensed professional under the physician's supervision; it is neither implanted in, or self-administered by, the patient.

In other words, while there are exceptions to application of the "learned intermediary" doctrine, the circumstances animating this case in no way warrants the creation of another exception. Adoption of petitioner's proposition to excise the learned intermediary doctrine under these circumstances would render it a nullity.

Finally, no causation exists here since causation must be shown rather than presumed (assuming the "learned intermediary" doctrine somehow does not apply). The prescribing and treating physician has testified that he would still recommend and use ECT for patients (who consent to it), including petitioner, even if he was given a stronger warning, one that petitioner, after succumbing to buyer's remorse from the results of her treatments, wishes (but does not remember

whether) her doctor did give to her. This defeats causation as the inadequate warnings must be a "producing cause" of the plaintiff's injuries.

ARGUMENT

I. A PHYSICIAN WHO PRESCRIBES USE OF A "MEDICAL DEVICE" ABOUT WHICH HE HAS SUBSTANTIAL KNOWLEDGE FROM EXTENSIVE CLINICAL EXPERIENCE – AND OBTAINS THE PATIENT'S INFORMED CONSENT FOR THAT TREATMENT – ACTS AS A "LEARNED INTERMEDIARY," RELIEVING THE DEVICE MANUFACTURER OF LIABILITY FOR LACK OF WARNINGS IT GAVE THE PHYSICIAN.

A principal reason underlying the learned intermediary doctrine for physician drug prescriptions finds expression by Judge Wisdom in *Reyes v. Wyeth Laboratories* (5th Cir. 1974) 498 F.2d 1264:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an *informed one, an individualized medical judgement bottomed on a knowledge of both patient and palliative*. (*Id.* at 1275-76; italics added.)

The foundational premise of what has since been formally recognized as the "learned intermediary" doctrine

can be traced back to the 1948 decision in *Marcus v. Specific Pharmaceuticals, Inc.* (App. Div. 1948) 77 N.Y.S.2d 508, 509-510, which addressed a drug manufacturer's failure to warn the prescribing physician of the danger of overdosing a suppository to a child:

> The sole claim is . . . a negligent *failure to give adequate information*, and in some instances a failure to use adequate means to call attention to the information given. It may be safely conceded that these allegations would be sufficient if the product were *sold to the public generally* as a drug for which no physician's prescription was necessary. The situation alleged [here] is materially different. There is no reason to believe that a physician would care to *disregard his own knowledge* of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer. . . In the absence of any such grounds for belief there would be no negligence. (Italics added.)

A. The Leeway Permitted a Physician to Decide what Information should be Disclosed to a Patient Regarding use of a "Medical Device" in Prescribed Treatment of the Patient is Greater than that Required for Pharmaceuticals.

Here we are concerned with a doctor's prescription for use in a health care provider's office of a "medical device," not drugs – specifically, Somatics' Thymatron System IV machine used in the administration of ECT to a patient. Though the learned intermediary doctrine applies to both "drugs" and

"medical devices," there are significant differences between them when it comes to the liability analysis applicable to each:

> While both drugs and medical devices are manufactured by pharmaceutical companies, are "mentioned in the same tort-breath" and share the *same purpose* – providing significant health benefits to society – they are *distinct* and should be treated as such for purposes of imposing liability for failure to warn. ((Note) Sheryl Calabro, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where it Belongs* (2004) 25 *CARDOZO L. REV.* 2241, 2280; italics added.)

Substantial and frequent use of a medical "device" that, like the Thymatron IV, is sold *only* to health care providers for prescriptive and occasional administration under physician supervision exclusively in a medical setting (as opposed to implantation in, or self-administration by, the patient) makes the learned intermediary doctor more knowledgeable about its risks and side effects than physicians generally possess with respect to the choice of drugs they prescribe.

Unlike ECT machines, for which there are only two manufacturers in the country, there are often several comparable competing drugs (brand name and generic) available for use in treating similar symptoms on vastly more

patients than those comparatively few for whom ECT therapy is prescribed. And unlike medical devices, drugs are sometimes chosen and ordered by patients directly from pharmaceutical advertising and internet sales without the physician's knowledge.

> Practical and ethical concerns limit the . . . ability to eliminate the information deficits related to *medical device* risk. . .[M]edical devices are used in fewer patients than are drugs, making large device studies impractical. . .[B]oth by [law]. . .and in. . .practice the information requirements for high-risk medical devices are not as robust as the requirements for new drugs. (George Horvath, *Emergent Regulatory Systems and Their Challenges: The Case of Combination Medical Products* (2019) 94 *WASH. L. REV.* 1697, 1712.)

Moreover, the nature and circumstances of use for the particular "medical device" – as well as how it is used – affects the analysis of when the "learned intermediary" doctrine comes into play to protect the manufacturer from liability. As this Court observed in *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 319:

> [T]he [learned intermediary] doctrine does not apply to medical devices . . . which require the *patient* to *use and apply the medical device themselves*. Unlike prescription drugs (which may have only rudimentary patient instructions, *e.g.*, take by mouth twice daily) or *implantable* medical devices (which may have no patient instructions at all),

> medical devices . . . intended to be *operated by the patient outside the medical environment* [does not protect the device manufacturers from liability]. (Italics added.)

This observation implies the Court's understanding that a device, like the machine manufactured by Somatics for ECT treatment, which "may have no instructions," but is exclusively *used and applied* by the *prescribing physician* always in a "medical environment," is precisely the type of "medical device" entitled to the essential "core" of the learned intermediary defense.

This "core" recognizes that while there are judicially recognized exceptions to it, those exceptions do not swallow its essence or weaken it; the core still remains and should be enforced. Exceptions to the learned intermediary doctrine are made for mass immunizations, oral contraceptives and direct marketing of drugs and devices by manufacturers to consumer-patients. "Courts adopted these exceptions because the justifications for applying the. . .doctrine do not apply. . .. [M]ass immunizations, oral contraceptives [and direct marketing to consumers], . . . decrease the role of the physician and increase the role of communication between the manufacturer and the patient." ((Comment) Ashley Porter, *Old Habits Die Hard: Reforming the Learned Intermediary Doctrine in the Era of*

Direct-to-consumer Advertising (2012) 43 *McGEORGE L. REV*. 433, 441).)

The reasons for these exceptions, however, do not apply when the "medical device" in question is, like the Thymatron IV for ECT treatment to the petitioner, only available for purchase by a health care provider (not a patient directly), must be then prescribed for use in a patient's treatment by a physician, and must always be administered by a licensed medical professional in a medical setting under the physician's supervision. These circumstances are uniquely suited for application of the "core" learned intermediary doctrine.

B. The Informed Consent and Learned Intermediary Doctrines Go "Hand in Glove," Complementing Each Other for Determining how much and what Information should be Disclosed to the Patient.

Numerous courts and legal commentators recognize the intertwined relationship between a physician's duty to warn under the learned intermediary doctrine and the duty to disclose risks as part of informed consent. After all, the purpose behind each duty is the same: *to provide the patient with information concerning the risks involved of medically-prescribed treatment so the patient can make an informed decision about whether to undergo it*. Accordingly, it is logical to analogize the products liability duty to warn, under the

learned intermediary doctrine, to the duty to disclose under the doctrine of informed consent.

"The . . . informed consent between a physician and a patient is central to the [device] manufacturer's defense of the learned intermediary doctrine." ((Note) Brenda Lin, *Federal Right to Try Act: Heightened Informed Consent and Price Regulation Measures Will Improve Quality, Autonomy, and Exploitation Issues* (2020) 16 *HASTINGS BUS. L.J.* 207, 217.) 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 the country. (See *Cobbs v. Grant* (1972) 8 Cal.3d 229.)

The learned intermediary doctrine envisions the doctor supplying the patient with information the patient needs to make an informed decision to undergo the treatment, thus governing the legal adequacy of what "warning information" is to be provided the patient. (See, *e.g.*, *Canterbury v. Spence* (D.C. Cir. 1972) 464 F.2d 772, 784 (stating that a risk is "material when a reasonable person in what the physician

knows or should know to be the patient's position would be likely to attach significance to the risk . . . in deciding whether or not to forego the proposed therapy").)

The learned intermediary doctrine rests on the assumption that "prescribing physicians, and not pharmaceutical or medical device manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs [and devices]." ((Note) (Catherine A. Paytash, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-related Injury* (1999) 51 *STAN. L. REV.* 1343,1354).)

"[E]ven when a plaintiff alleges that warnings to a physician were *inadequate*, under California law the learned intermediary doctrine applies . . . Plaintiffs have not demonstrated that the learned intermediary doctrine somehow does not apply when plaintiffs allege that the warnings to physicians are inadequate. Nor that the absence of an adequate warning about a prescription drug to a physician somehow results in a duty to provide a warning to the patient." (*Amiodarone Cases*, Cal. Court of Appeal, 2022 WL 16646728,*8 (finding application of the learned

intermediary doctrine though physician prescribed a drug for an "off-label" use); italics added.)

And "even without the [learned intermediary] doctrine in place to shield manufacturers from liability, . . . informed consent imposes an independent duty on physicians to utilize their unique position to inform patients of the risks associated with treatment options, including prescription drugs [and medical devices]." (Porter, *supra*, 43 *McGEORGE L. Rev.* at 455.)

"The obligation to obtain the patient's informed consent *dovetails* with the learned intermediary doctrine. Under [it], doctors, not drug companies, are responsible for informing patients of the risks of prescription drugs [and use of medical devices]. The rule reflects the courts' view that warnings from drug [and medical device] companies would not be feasible and would interfere with the doctor-patient relationship. The rationale is that . . . medical professionals have the [best] required knowledge, training, and judgment to determine which drugs [and medical devices] [sh]ould be . . . [used in] treatment for individual patients. . . ." (Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-label Prescriptions and Conflicts of Interest* (2007) 58 *HASTINGS L. J.* 967, 1010; italics added (footnotes omitted).)

Far from ignoring or downplaying the principle of patient autonomy, the advent of "informed consent," complemented with the "learned intermediary" doctrine, strengthens patient choice and autonomy. "The doctrine of informed consent reflects the value we place on patient autonomy. . . The doctrine of informed consent – now adopted in all fifty states – transformed this understanding and with it the doctor-patient relationship." (*Id.* at 1008; footnotes omitted.)

When unavoidable risk warnings associated with prescription medical devices are involved, an *adequate* warning to a physician who, as here, does not concur with petitioner's assertion about what the content of that warning should be but is nonetheless knowledgeable about risks of the device from extensive past use of it, means only that the learned intermediary should incorporated "additional risks" into his decisional calculus and communicate that to the patient. "The burden remains on the plaintiff to demonstrate that any additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." (See, *e.g.*, *Thomas v. Hoffman-LaRoche, Inc.* (5th Cir. 1992) 949 F.2d 806, 814.) Here, Dr. Fidaleo's uncontradicted testimony is that if the warning petitioner asserts should have been given to him by

Somatics was in fact given, it would not have affected his decision to prescribe ECT treatment for her with use of the Thymatron IV.

II. THERE IS NO CAUSATION HERE.

Petitioner contends this Court should *presume* causation because Somatics did *not* give adequate warnings to the prescribing physician about the risks to patients from use of its product. (OB, p. 29; italics original.) But presuming something that is nonexistent somehow exists is magical thinking, speculation that is no substitute for causation analysis.

In a companion case involving petitioner Himes, the district court found in favor of Somatics and against petitioner on her failure to warn claim, explaining why she cannot show causation.

> Where the [learned intermediary] doctrine applies, a plaintiff who asserts claims "based on a failure to warn must prove not only that *no warning was provided* or the warning was inadequate, but *also* that *the inadequacy or absence of the warning caused the plaintiff's injury*. See *Wendell v. GlaxoSmithKline LLC* (9th Cir. 2017) 858 F.3d 1227, 1238 (quoting *Motus [v. Pfizer Inc.* (C.D. Cal. 2001) 196 F. Supp2d 984, 991]). [A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.

> *Motus v. Pfizer Inc. (Roerig Div.)* (9th Cir. 2004) 358 F.3d 659, 661 (italics added). (*Riera v. Mecta Corp.* (C.D. Cal. May 14, 2021) 2021 WL 2024688.)

California law recognizes that plaintiffs must show that any warnings deemed deficient must still be found to be the legal cause of their injuries. (See, *e.g.*, *Webb v. Special Elec. Co.* (2016) 63 Cal.4th 167, 181-82 (liability only occurs when "the absence of a warning *caused* the plaintiff's injury"); *T.H. v. Novartis Phrmaceuticals Corp.* (2017) 4 Cal.5th 145, 156 (plaintiff claiming that a manufacturer's warning is inadequate "still needs to prove that [this] deficien[cy] proximately caused the injury").) As Somatics' brief points out: "Requiring causation evidence doesn't pass the manufacturer's burden of warning the physician onto someone else; it simply ensures that the manufacturer's failure to meet that burden actually caused the injury." (RB, p. 27.)

California law is consistent with other jurisdictions that the plaintiff must independently *establish proximate cause*; and if the warning, or lack thereof, had no effect on the treating physician's decision to prescribe the drug or device, her claim fails. (Carol Rooney, *The Learned Intermediary Doctrine: an Update* (2010) 29 No. 1 *TRIAL ADVOC. Q.* 6, fn. 16,

citing *Colville v. Pharmacia & Upjohn Co., LLC* (N.D. Fla. 2008) 565 F. Supp. 2d 1314).)

A long line of opinions from numerous jurisdictions also hold just the opposite of what petitioner urges this Court to do: presume causation whenever adequate warnings by the manufacturer are not given to the prescribing physician or patient.

For instance, *Hoffmann-La Roche, Inc. v. Mason* (Fla. App. 2009) 27 So.3d 75, reversed a plaintiff's verdict for entry of JNOV where the prescriber testified that he would still be willing to prescribe the drug to his patients even if there was evidence showing that it could cause plaintiff's condition in rare cases. He also testified that even if the warning label contained all of the information suggested by plaintiff's expert, he would still have prescribed the medication for plaintiff. (*Id.* at 77.)

Lineberger v. Wyeth (Pa. Super. 2006) 894 A.2d 141, affirmed summary judgment because even if the omitted risk "had been added to the 'warnings' section of the label," the prescribing physician testified he "would still have prescribed the drug for [plaintiff]." (*Id.* at 150-51.)

Federal courts of appeal applying state law have repeatedly reached the same conclusion when prescribing

physicians have reaffirmed their prescription decisions despite whatever plaintiffs thought the manufacturers' warnings to them required that they did not provide. *Salinero v. Johnson & Johnson, Inc.* (11th Cir. 2021) 995 F.3d 959, found that the implanting surgeon's testimony "shut[] down" the plaintiff's warning claim because, warnings "containing more information on the risks posed by [defendant's device] would not have altered his decision to use the implant in [plaintiff's] surgery." (*Id.* at 966.)

See *e.g.*, *In re Zyprexa Products Liability Litigation* (E.D.N.Y. Dec. 10, 2009) 2009 WL 5062109, at *14-15 (no causation where prescriber's "testimony shows that she would not have changed her decision to prescribe the drug even if defendant had provided a different warning"), aff'd (2d Cir. 2010) 394 F. Appx. 817, 819 (because prescriber "stated explicitly that alternative warnings about [the drug] would have had no effect on her prescribing habits") (applying Arizona law); *Missouria v. Eli Lilly & Co.*, 394 F. Appx. 825, 827 (2d Cir. 2010) (no causation where the prescribing physician "continues to prescribe [the drug] to patients in similar positions to [plaintiff] today") (applying California law); *Enborg v. Ethicon, Inc.* (E.D. Cal. March 15, 2022) 2022 WL 800879, at *21 (no causation where implanting surgeon "stands by his decision to recommend and use device in

treating [plaintiff]" and "would offer a woman with [plaintiff's] symptoms the same treatment plan today") (citations and quotation marks omitted); and *Thomas v. Abbott Laboratories* (C.D. Cal. July 29, 2014) 2014 WL 4197494, at *7 (no causation where the prescriber "testified that had he been aware" of what plaintiff alleged, "he still would have prescribed").

All the aforementioned authorities confirm that the petitioner here must be able to show that "the inadequate . . . warning must 'be a producing cause' of the plaintiff's injuries." (*Patteson v. AstraZeneca, LP* (D.D.C. 2012) 876 F.Supp.2d 27, 34.)

This she cannot do because her treating physician, Dr. Fidaleo, testified that based on his extensive clinical experience he would still have prescribed ECT therapy for her using Somatics' machine provided she consented to it. Though he disagreed with petitioner's assertion that the administration of ECT with the Somatics' machine caused her "long term memory problems," he nonetheless disclosed that potential risk to her in her signed informed consent agreement, just not as detailed as petitioner feels, in retrospect, he should have warned her.

Petitioner's post-treatment assertion that she would have refused ECT if informed about its risks in the way she wanted Dr. Fidaleo to inform her is, however, dubious.

> The patient-plaintiff may testify on this subject but the issue extends beyond [her] credibility. Since at the time of trial the [alleged] uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had [s]he been informed of the dangers [s]he would have declined treatment. Subjectively [s]he may believe so, with the 20/20 vision of hindsight, but we doubt that justice will be served by placing the physician in jeopardy of the patient's bitterness and disillusionment. (*Cobbs*, *supra*, 8 Cal.3d at 245.)

To be sure, while the FDA did not require the warnings petitioner says she wanted to receive when she consented to ECT treatment, it now (since 2018) requires manufactures of "medical devices" such as Somatics' ECT machine to provide instructions and warnings concerning possible cognitive injuries. (21 C.F.R. § 822.5940.) Unsurprisingly, Somatics complies with this recent regulation by informing visitors to its website, and in its user manuals for the device, that "ECT may result in anterograde or retrograde amnesia" (4 ER 653) and, "in rare cases, patients may experience permanent memory loss or permanent damage." (*Id.*)

Notably, petitioner concedes that these current warnings are "too late" for her to bolster her claims. They are,

however, consonant with the informed consent agreement petitioner signed, which warned her that "there may be some memory loss . . . or there may be a *permanent spotty memory loss*." (2 ER 159; italics added.) Petitioner claims that the actual words "long term memory loss" should have been in her signed informed consent agreement, but the informed consent warning about "permanent memory loss" was sufficient to alert her to memory loss risks of ECT and whether she should choose to undergo it as "a last resort" after previous pyschotherapeutic and drug administered treatments had proven unsuccessful in relieving her medical problems.

CONCLUSION

This is a quintessential case for application of the learned intermediary doctrine. It is also one for which petitioner cannot show causation. For these reasons, and all the aforementioned authorities and logic supporting them, the Court should answer the Ninth Circuit's certification questions accordingly.

Dated: November 21, 2022

/s/ Fred J. Hiestand
Fred J. Hiestand
CJAC General Counsel

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Fred J. Hiestand
CJAC General Counsel

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Bijan Esfandiari
Monique Alarcon
R. Brent Wisner
BAUM, HEDLUND, ARISTEI & GOLDMAN, PC
10940 Wilshire Blvd., Suite 1600
Los Angeles, CA 90024
Attorneys for Plaintiff/Appellant

Jonathan M. Freiman
WIGGIN AND DANA LLP
265 Church Street
New Haven, CT 06510
Attorneys for Defendant/Respondent

Jason A. Benkner
David S. Poole
POOLE & SHAFFERY & KOEGLE, LLP
25350 Magic Mountain Pkwy.
Suite 250
Santa Clarita, CA 91355
Attorneys for Defendant/Respondent

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Supreme Court of California

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Bijan Esfandiari Baum Hedlund Aristei & Goldman 223216	besfandiari@baumhedlundlaw.com	e-Serve	11/21/2022 4:29:36 PM
Jason Benkner Poole & Shaffery & Koegle, LLP 286790	jbenkner@pooleshaffery.com	e-Serve	11/21/2022 4:29:36 PM
Valeriya Adlivankina Baum Hedlund Aristei & Goldman	vadlivankina@baumhedlundlaw.com	e-Serve	11/21/2022 4:29:36 PM
Jonathan Freiman Wiggin & Dana LLP 418928	jfreiman@wiggin.com	e-Serve	11/21/2022 4:29:36 PM
Cassidy Davenport Cole Pedroza LLP 259340	cassidydavenport@colepedroza.com	e-Serve	11/21/2022 4:29:36 PM
Ashley Simonsen Covington & Burling LLP 08355	asimonsen@cov.com	e-Serve	11/21/2022 4:29:36 PM
Monique Alarcon Baum, Hedlund, Aristei & Goldman, PC 311650	malarcon@baumhedlundlaw.com	e-Serve	11/21/2022 4:29:36 PM
Alan Lazarus Faegre Drinker Biddle & Reath, LLP	ajlazarus@dbr.com	e-Serve	11/21/2022 4:29:36 PM
Samuel Price Law Office of Barry Edzant	sprice@valencialaw.com	e-Serve	11/21/2022 4:29:36 PM
Cher Gonzalez Gonzalez Government Consulting 210026	cher@gonzalezconsult.com	e-Serve	11/21/2022 4:29:36 PM

Audra Kalinowski Wiggin and Dana LLP	appellateclerk@wiggin.com	e-Serve	11/21/2022 4:29:36 PM
Freddi Lindsey Cole Pedroza LLP	flindsey@colepedroza.com	e-Serve	11/21/2022 4:29:36 PM
David Gonzalez Gonzalez Government Consulting 215728	david@gonzalezconsult.com	e-Serve	11/21/2022 4:29:36 PM
Fred Hiestand Fred J. Hiestand, Counselor at Law 44241	fred@fjh-law.com	e-Serve	11/21/2022 4:29:36 PM
Alan Lazarus Faegre Drinker Biddle & Reath LLP 129767	alan.lazarus@faegredrinker.com	e-Serve	11/21/2022 4:29:36 PM
Nicole Lyons Poole & Shaffery, LLP	nlyons@pooleshaffery.com	e-Serve	11/21/2022 4:29:36 PM
Reid Figel Kellogg Huber Hansen Todd Evans & Figel 135684	rfigel@kellogghansen.com	e-Serve	11/21/2022 4:29:36 PM

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Date

/s/Fred Hiestand

Signature

Hiestand, Fred (44241)

Last Name, First Name (PNum)

Fred J. Hiestand, Counselor at Law

Law Firm