S273887

IN THE

Supreme Court

OF THE STATE OF CALIFORNIA

MICHELLE HIMES,
Plaintiff and Appellant,

v.

SOMATICS, LLC,
Defendant and Respondent.

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

AMICI CURIAE BRIEF OF CALIFORNIA MEDICAL ASSOCIATION, CALIFORNIA DENTAL ASSOCIATION, AND CALIFORNIA HOSPITAL ASSOCIATION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

State Cases **Pages**

Federal Cases

Statutes

Other Authorities

QUESTION PRESENTED

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

Overall, the question is about *medical decision-making*, a process which involves *both* physicians *and* patients. There are three parts to the question, all three of which relate to plaintiffs' burden of proof.

The first part, in the first sentence of the question, is about *physician* decisions to *treat* patients, referred to as "therapeutic decision-making": **(1) must plaintiff show the hypothetical manufacturer warning would have altered their physicians' *prescribing* conduct?** In other words, whether there is a causal relationship between the manufacturer 's warning and the physician decision to treat?

The second part, in the second sentence of the question, is about *physician* decisions to *communicate* warnings to patients, to the end of assuring patients give "informed consent" to treatments: **(2) must plaintiff show the hypothetical warning would have altered the physician's own *warning***

conduct? In other words, whether there is a causal relationship between the manufacturer's warning and the physician decision about what risks to communicate to the patient?

The third part, in the second sentence of the question, is about *patient* decisions to *consent* to treatments: **(3) must plaintiff show an objective patient, if informed of the manufacturer warning, would have *refused* to consent to the treatment?** In other words, whether there is a causal relationship between the manufacturer's warning and the patient decision to consent?

To be clear, both physicians and patients decide by *weighing the benefits of the treatments against the risks*. The normal order of their decision-making is (a) the physician assesses the benefits and risks, and then (b) decides what to recommend to the patient. (c) The physician *communicates* that recommendation to the patient, and (d) they *discuss* the benefits and risks. (e) The patient decides either to *consent* or *refuse*. (f) The physician formally prescribes that, some other, or no treatment depending on the patient's decision. (g) The patient receives the treatment prescribed, with (h) the physician implementing suitable precautions to *minimize* the risks they discussed. Overall, that decision-making process for *balancing* the benefits and the risks is a *joint* exercise in which the physician and patient decisions essentially are *successive*. For that reason, the three parts of the question certified by the Ninth Circuit to this Court are correctly viewed as *successive* inquiries.

ISSUE PRESENTED

The issue is about "the causation standard" in California. (Order Certifying Question, p. 4 ["disposition of the appeal with respect to Himes's claims hinges on the resolution of the causation standard"].) That is because the plaintiffs in the federal litigation argued for *a less rigorous standard* (*id.* at p. 4 ["the appellants contend that the district court erred in applying an unduly demanding causation standard"]), an argument that is very apparent in the Opening Brief on the Merits filed by plaintiff Himes. She argues for a combination of a *subjective* standard, for the less demanding "*substantial factor*" test of causation, and ultimately for shifting the burden of proof.

California law analyzes causation objectively, by means of *counter-factual reasoning,*[1] which technique is consistent with *the scientific method.* That is why the Ninth Circuit's question is in the form of *hypothetical counterfactuals*. The hypothetical fact in this case is "a stronger risk warning" about complications of treatment, which warning should be based on *scientific evidence*.[2]

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[1] "Determining causation always requires evaluation of hypothetical situations concerning what might have happened, but did not[,]" and "the very idea of causation necessarily involves comparing historical events to a hypothetical alternative." (*Viner v. Sweet* (2003) 30 Cal.4th 1232, 1242.)

[2] "Well-performed randomized trials provide the least biased estimates of treatment benefit and harm by creating groups with equivalent prognoses." (Federal Justice Center, *Reference Manual on Scientific Evidence* (3d ed. 2011) (hereafter *Reference Manual*), "Reference Guide on Medical Testimony," p. 729.)

STATEMENT OF INTERESTS AND CONCERNS

The California Medical Association ("CMA") is a nonprofit, incorporated, professional association of more than 50,000 member-physicians practicing in the State of California, in all specialties. The California Dental Association ("CDA") represents over 27,000 California dentists, more than 70 percent of the dentists practicing in the State. CMA's and CDA's memberships include most of the physicians and dentists engaged in the private practices of medicine and dentistry in California. The California Hospital Association ("CHA") represents the interests of more than 400 hospitals and health systems in California, having approximately 94 percent of the patient hospital beds in California, including acute-care hospitals, county hospitals, nonprofit hospitals, investor-owned hospitals, and multi-hospital systems. Thus, *Amici* represent much of the health care industry in California.

Interests of *Amici* in rational, unbiased decision-making

CMA, CDA, and CHA have been active before the Courts in all aspects of litigation affecting California healthcare providers.[3]

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[3] Such cases have included *Fein v. Permanente Medical Group* (1985) 38 Cal.3d 137, *Central Pathology Service Medical Clinic, Inc. v. Superior Court* (1992) 3 Cal.4th 181, *Western Steamship Lines, Inc. v. San Pedro Peninsula Hospital* (1994) 8 Cal.4th 100, *Delaney v. Baker* (1999) 20 Cal.4th 23, *Covenant Care, Inc. v. Superior Court* (2004) 32 Cal.4th 771, *Howell v. Hamilton Meats & Provisions, Inc.* (2011) 52 Cal.4th 541, *Rashidi v. Moser* (2014) 60 Cal.4th 718, *Flores v. Presbyterian Intercommunity Hospital* (2016) 63 Cal.4th 75, and *Winn v. Pioneer Medical Group, Inc.* (2016) 63 Cal.4th 148.

CMA, CDA, and CHA have long been concerned about the potential for unpredictable and unreasonably large awards in professional negligence actions against health care providers. CMA, CDA, and CHA provided substantial input to the legislative process that led to enactment of the Medical Injury Compensation Reform Act ("MICRA"), and they continue to support MICRA's ongoing viability.

CMA, CDA, and CHA have advocated rational and unbiased decision-making by judges and juries, primarily in personal injury litigation, where medical care is an important factual consideration. The MICRA statutes, for example, require damages to be assessed according to their various characteristics: economic damage versus noneconomic damage, past damage versus future damage, medical expense damage versus loss of earnings damage, and insurance-compensated damage versus other compensation for damage. MICRA requires lawyers, judges, jurors, arbitrators, and all others involved in the resolution of medical malpractice cases to think more precisely about the reasons and the methods for calculating damages. In other words, MICRA has resulted in improved decision-making and fairness, particularly in assessing damages during jury trials, which in turn has improved the administration of justice in tort litigation generally.

Rational and unbiased decision-making also is the reason why *Amici* filed briefs in the most significant cases on the issue of causation, *Mitchell v. Gonzales* (1991) 54 Cal.3d 1041, and *Viner v. Sweet, supra,* 30 Cal.4th 1232. It also is why *Amici* filed briefs

on the issue of expert witness opinion testimony regarding causation in *Jennings v. Palomar Pomerado Health Systems, Inc.* (2003) 114 Cal.App.4th 1108, and *Sargon Enterprises, Inc. v. University of Southern California* (2012) 55 Cal.4th 747.

Most recently, *Amici* filed briefs on the causation and noneconomic damages issues in *Johnson & Johnson Talcum Powder Cases* (2019) 37 Cal.App.5th 292, *Johnson v. Monsanto Company* (2020) 52 Cal.App.5th 434, *Hardeman v. Monsanto Company* (2021) 997 F.3d 941, and *Pilliod v. Monsanto Company* (2021) 67 Cal.App.5th 591, arguing the analysis of specific causation should be rigorous and demanding and the analysis of noneconomic damages should not be based on bias or emotion.

Concerns of *Amici* about plaintiffs' invocation of bias, fallacy, and emotion

Amici are concerned the litigation filed by the plaintiffs in District Court – including plaintiff Himes – is an attack on ECT, generally,[4] and is based on emotion rather than reason, by invoking dramatic anecdotes. Plaintiffs broadly claim that, in discussions between psychiatrists and their patients, the benefits of ECT are *overstated* and the risks are *understated.* Plaintiffs' goal in the litigation apparently is to *replace* that allegedly inadequate information with different information, in the form of

[4] While the Ninth Circuit's "Order Certifying Question" does not explain whether the two questions are about risk of the treatment *generally*, risk of the manufacturer's medical device *specifically*, or *both,* its "Memorandum" explains the two questions are only about the risk of electroconvulsive treatment *generally.* (Memorandum, p. 2 ["certain risks of ECT"].)

warnings by the manufacturers of ECT devices, stating the risks of ECT *more strongly* than what psychiatrists tell patients. That obviously implicates the psychiatrists who use ECT to treat their patients and the hospitals where the ECT takes place.

Amici are concerned that the same arguments plaintiffs and others pursue *against manufacturers* of medical devices for ECT in this case are being pursued in other cases *against psychiatrists* who prescribe ECT and *hospitals* where ECT is administered.[5]

Amici are concerned that *Himes v. Somatics, LLC,* and the other cases targeting psychiatric treatment by ECT – many if not most of which include psychiatrist and hospital co-defendants – have features similar to those in the wave of high stakes "failure to warn" litigation against manufacturing defendants like Johnson & Johnson and Monsanto.[6] *Amici* have seen similar waves of litigation against other manufacturers and health care providers, most notably the campaign directed at defendant manufacturers that produced silicone, defendant manufacturers

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[5] An example is *Carranza v. Somatics, LLC, Elektrika, Inc., Loma Linda University Medical Center, Ronald L. Warnell, M.D., and Bryan Martin Wick, M.D.* (Los Angeles Superior Court case no. 20STCV28892, Second Appellate District case no. B313920).

[6] Counsel for plaintiffs Himes, Riera, and Benjamin in this "failure to warn" litigation against manufacturing defendants Somatics, LLC, and Mecta Corp. is the Baum Hedlund Aristei & Goldman law firm, which also represents plaintiffs in the *Carranza* case described in the foregoing footnote, and which was counsel for plaintiffs in the *Johnson, Hardeman*, and *Pilliod* cases against Monsanto.

that used the silicone in breast implants, and defendant plastic surgeons who implanted those implants into patients. (See, *e.g.*, *In re Silicone Gel Breast Implants Products Liability Litigation* (C.D.Cal. 2004) 318 F.Supp.2d 879; *Artiglio v. Corning Inc.* (1998) 18 Cal.4th 604.) That campaign against those manufacturer and plastic surgeon defendants ultimately collapsed for lack of scientific evidence.[7]

Amici are concerned that the question certified by the Ninth Circuit implicates virtually *all* medical products used in treatments.

Finally, *Amici* are concerned that, in litigation for "failure to inform," some plaintiffs argue for causation analysis that is not rigorous. *Amici* are *very* concerned that plaintiff Himes argues for analysis that is *subjective*, based on hindsight. She argues against counterfactual causation, generally (Opening Brief on the Merits ("OBM"), p. 64 ["the objective factor test is not appropriate in this case"]), and she argues against having to prove either of the two hypothetical counterfactual questions, specifically.

In summary, *Amici* are concerned because the arguments implicate California health care providers, in many ways.

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[7] That campaign and its collapse was described in detail by Dr. Marcia Angell, Executive Director of the New England Journal of Medicine, in her book entitled *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* (W.W. Norton & Co. 1996).

Disclaimer by *Amici*

Amici reassure the Court that this brief was not authored, either in whole or in part, by any party to this litigation or by any counsel for a party to this litigation. No party to this litigation or counsel for a party to this litigation made a monetary contribution intended to fund the preparation or submission of this brief.

That said, some funding for this brief was provided by organizations and entities that share *Amici*'s interests and concerns, including physician-owned and other medical and dental professional liability organizations and nonprofit entities engaging physicians, dentists, and other health care providers for the provision of medical services, specifically The Cooperative of American Physicians, Inc., The Dentists Insurance Company, The Doctors Company, Kaiser Foundation Health Plan, Inc., Medical Insurance Exchange of California, Norcal Mutual Insurance Company, and The Regents of the University of California.

SUMMARY OF REASONS WHY PLAINTIFF'S "CAUSATION STANDARD" SHOULD BE REJECTED

A plaintiff who claims to have suffered injury as a result of medical treatment to which she would not have consented, if only she had known about the risks, not only must prove the cause of the injury was a complication of the treatment but also must prove the cause of the decision to treat. In other words, such a plaintiff must prove both medical *injury* causation and medical *decision-making* causation.

Here, as to medical *decision-making* causation, plaintiff Himes claims there was a *flaw* in the decisions of her physician and herself to treat her with ECT and, in turn, to the complication of that treatment she claims to have suffered. She argues the *cause* of that flawed decision was the failure of the device manufacturer to provide her physician "a stronger risk warning" about the treatment. To prevail at trial, she will have to prove that "a stronger risk warning" was scientifically required.

Now, to reverse the summary judgment, plaintiff must show (1) based on that warning, her physician would recommend against the treatment, *and* (2) her physician would communicate the warning to her, *and* (3) even though any objective and reasonable patient would want the potential benefit of the treatment, that patient nevertheless would agree with the physician's recommendation not to have the treatment. Those three facts, if found by the trier-of-fact, logically lead to the conclusion that, but for the manufacturer's failure to provide the

hypothetical warning, there would have been no treatment and there would have been no complication.

Plaintiff has two problems: she cannot prove step (1), and she cannot prove step (3). She only can prove step (2). To overcome those problems, plaintiff proposes a different "causation standard," to use the Ninth Circuit's phrase, one that will change California law and adversely impact health care providers.

To overcome step (1), plaintiff contrives *a false dichotomy* – between her physician, whom she characterizes as an "unlearned intermediary," and herself, whom she characterizes as an entirely "autonomous" patient – so that the analysis changes from a question of *both* (1) *and* (3) to a question of *either* (1) *or* (3). After *falsely framing* the question in that way, she argues a patient's decision is more important than that of the patient's physician. It is a one-dimensional or, to use her word, "autonomous" standard for determining medical decision-making causation. It is in that way she proposes to avoid step (1) altogether.

To overcome step (3), plaintiff argues that her own after-the-fact testimony about what she would have decided, if her physician told her about the hypothetical "stronger risk warning," should be determinative. Specifically, she proposes that proof of medical decision-making causation should turn on her subjective, hindsight-based, "self-serving" testimony of what she would have done in the hypothetical situation, not what the trier-of-fact finds an objective, reasonable patient would have done. It is in that way she proposes to satisfy step (3).

There are many problems with plaintiff's approach, but the most obvious is plaintiff's reliance (and, she hopes, the trier-of-fact's reliance) on *hindsight bias*. Other problems are that plaintiff invokes *representativeness bias* and *availability bias*, both of which are calculated to invoke an *emotional response* about ECT and thereby distort the trier-of-fact's analysis of and findings on medical decision-making causation about ECT. Those and other biasing techniques already are apparent in plaintiff's appellate briefs.

What is not apparent are the two most important aspects of the medical decision-making process: (1) physicians and patients decide by *weighing* benefits and risks of treatments, such that (2) the decision is *joint,* that is, *shared* by physicians and patients. When physicians and patients decide whether and how to treat patient medical problems, their decision will be shared if there is *communication between physicians and patients who together weigh* – or, some would say, *balance* – the benefits and the risks of that treatment, against benefits and risks of the alternative treatments and benefits and risks of no treatment at all. If the decision is one-sided, emphasizing the patient and deemphasizing the physician as plaintiff does, the process is not shared.

Plaintiff's argument not only emphasizes the patient; it emphasizes *risks*. If the patient decision is to be "informed," the decision requires patient consideration and balancing of *both* benefits and risks. Again, if the decision-making is one-sided, emphasizing the risk and deemphasizing the benefit as plaintiff does, the decision is not informed.

Another aspect of plaintiff's proposed "causation standard" is her rejection of counterfactual causation: *but for* the failure of the manufacturer to provide the physician "a stronger risk warning," would the treatment decision have been different? Plaintiff argues for a less rigorous test: was the manufacturer a *substantial factor* in the treatment decision, along with other substantial factors? Notably, plaintiff does not explain what other factors are to be considered in the analysis, the most obvious of which is her physician's recommendation. She rules that out as a factor because she has the right to refuse for *any* reason – regardless of potential benefit – the medical treatment he recommends.

In summary, the "causation standards" plaintiff proposes should be rejected. In addition to the biases plaintiff proposes to bring into the courtroom, plaintiff proposes to make the analysis less rigorous. More importantly to health care providers, plaintiff proposes a fundamental change in focus for physician/patient discussions, from the benefits and risks documented in evidence-based medicine to the risks described in manufacturers' product labeling. That will adversely impact patients.

In the Legal Analysis section of this brief that follows, under point heading I., *Amici* explain how the Ninth Circuit's question and request for guidance arose and how it should be understood. II. *Amici* describe the ways in which plaintiff rejects the Ninth Circuit's approach to causation. III. *Amici* warn that plaintiff's approach will lead to flawed if not irrational fact-finding. IV. *Amici* explain why the correct analysis is objective

and scientific. V. *Amici* urge the Court to affirmatively answer *all three parts* of the Ninth Circuit's question.

LEGAL ANALYSIS

I. The Best Technique For Analyzing Causation Is Counter-Factual Reasoning, Which Is Why The Question Certified By The Ninth Circuit Consists Of Hypothetical Counterfactuals

A. The causation issue arises out of the testimony of plaintiff's treating physician, Dr. Fidalio, from which plaintiff focuses on the "autonomy" of patients and defendant focuses on "learned intermediary" physicians

1. Dr. Fidalio testified in response to questions about what he would do in the hypothetical counterfactual situation where there was a manufacturer "stronger risk warning"

The Ninth Circuit's holding was summarized by that court:

> with respect to Himes's claims, we held that while there was a genuine issue of fact as to *whether her treating physician would have learned of stronger warnings and communicated them to Himes*, no reasonable juror could find that the physician would have altered his decision to prescribe the treatment. Accordingly, we concluded that *the disposition of the appeal with respect to Himes's claims hinges on the resolution of the causation standard*.

(Order Certifying Question, p. 4. Emphasis by italics added.)

Plaintiff's treating physician was Dr. Raymond Fidaleo. As plaintiff explains,

> Dr. Fidaleo testified that the risk of brain injury is a serious risk and *if he knew that a drug or device has the potential to cause brain injury, he 'would be reluctant to use it ….'* 3-ER-337. Dr. Fidaleo testified that, 'had Somatics provided [him with] warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories[,]' *he would have relayed those warnings to his patients and such warnings 'would be in the informed consent' form*. 3-ER-344.

(OBM, pp. 17-18. Emphasis by italics added.)

Plaintiff seized upon the testimony of Dr. Fidalio that supported her theory of the case, medical decision-making by the "autonomous" *patient*, to defeat summary judgment. That is, plaintiff argued that the patient would have learned of the hypothetical manufacturer "stronger risk warning" and would have refused to consent to the procedure.

Defendant seized upon the testimony of Dr. Fidalio that supported its theory of the case, medical decision-making by the "learned intermediary" physician. That is, defendant argued that the physician would have recommended the procedure notwithstanding the hypothetical manufacturer "stronger risk warning."

2. Plaintiff emphasizes the role of "autonomous" patients in medical decision-making

Now that the question is before this Court, plaintiff renews the argument she unsuccessfully made to the District Court and the Ninth Circuit, that the learned intermediary doctrine should not apply to her claim. She makes the argument even though the

Ninth Circuit's Order Certifying Question does not refer to the learned intermediary doctrine.[8] Not only does plaintiff renew the argument,[9] but plaintiff devotes *most* of her Opening Brief to arguing why the doctrine should not apply. (OBM, pp. 3 ["Introduction"], 21-24 ["Summary of Argument"], 24-44 ["Argument," point I], 57-58 ["Argument," summary of points I and II], and 66 ["Conclusion"].)

Specifically, plaintiff argues, "A manufacturer cannot assert the learned intermediary defense when it fails to provide adequate warnings to intermediaries, rendering the intermediaries 'un-learned.' " (OBM, p. 27. Emphasis in heading deleted.) That is, "*if* adequate warnings were not given to the intermediary, the defense is unavailable; any intermediary is, by definition, no longer 'learned.' " (OBM, p. 31. Emphasis by italics in original.) Essentially, plaintiff challenges the doctrine itself, while at the same time insulting psychiatrists.

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[8] Plaintiff explains, "The certified question concerns the interplay between the learned intermediary defense and a plaintiff's causation burden in medical device products liability failure to warn claims." (OBM, p. 3.)

[9] One possible reason why the argument is being made again to this Court is the hope of Himes' counsel that the claims of his other clients will be revived. Another, additional reason is that this case is but one aspect of a larger campaign against ECT, generally, which counsel hopes to advance by a favorable ruling.

3. Plaintiff implicates, then insults, and ultimately condemns psychiatrists for using ECT

Notably, throughout her Opening Brief, plaintiff Himes refers to physicians as though they are potential co-defendants. For example, she argues the learned intermediary doctrine is a "defense" in which the manufacturer defendant will "point to any conduct of the doctor to absolve itself of its own negligence" (OBM, p. 3), but "a manufacturer's liability for failing to provide adequate warnings is not absolved by a doctor's intervening conduct." (OBM, p. 38. Emphasis in heading deleted.) "Himes is not required to show that, had Somatics warned, her doctor would not have 'prescribed' ECT; rather, Himes can establish causation by showing that, had Somatics warned, her doctor would have relayed those warnings to her, and armed with the warnings, Himes would have refused ECT." (OBM, p. 46. Emphasis in heading deleted.) Although plaintiff Himes did not sue her psychiatrist, there are other plaintiffs who do sue their psychiatrists,[10] and if this Court agrees to adopt plaintiff's proposed "causation standard" there will be many more.

Plaintiff's other arguments are far more pointed in discussing, if not condemning, the medical specialty of psychiatry for its use of ECT. In Point III of her Opening Brief on the Merits, for example, plaintiff argues, "In determining that causation is lacking, the District Court impermissibly concluded

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[10] For example, there is the aforementioned ECT case against Dr. Ronald L. Warnell and Dr. Bryan Martin Wick. (See fns. 5 and 6, *supra*.)

that the doctors' decision to 'prescribe' ECT trumps the patients' right to 'refuse to consent'." (OBM, p. 58. Emphasis in heading deleted.) Plaintiff characterizes the District Court's ruling as "the wholesale disregard of patient autonomy" because, as plaintiff interprets that ruling, "the only thing that matters is if their doctors choose to administer ECT or not." (OBM, p. 58.)

Plaintiff's hyperbole at the outset of the discussion in the Opening Brief is followed by far more inflammatory language toward the end. (OBM, pp. 60 ["Himes was robbed of that fundamental 'right of self-decision' "], 61 ["in order to conclude that causation is lacking, the district court had to presume and conclude that, in violation of California common law (*Cobbs* [*v. Grant* (1972) 8 Cal.3d 229]), criminal law (*battery*) and statutory law (CAL. WELF. & INST. CODE § 5326.85)", footnote omitted], and 61, fn. 14 ["a violation of the Nuremberg Code and the International Covenants on Human Rights"].)

4. Defendant emphasizes the role of "learned intermediary" physicians in medical decision-making

Defendant, relying largely on the learned intermediary doctrine, dismisses all of plaintiff's arguments. (Respondent's Answer Brief on the Merits ("ABM"), pp. 14-18 ["Summary of Argument"], 18-31 ["Plaintiff must prove causation under the learned intermediary doctrine"], 31-53 ["Causation should focus on the physician's prescription decision"], and 61 ["Conclusion"]. Emphasis in headings deleted.) As defendant explains at the outset of its Answer Brief on the Merits, "a plaintiff challenging

the adequacy of a medical manufacturer's warnings must offer evidence that a stronger warning would have changed her physician's prescription decision" (ABM, p. 4), which defendant characterizes as "a physician focused causation requirement." (*Ibid*.)

In summary, the question certified by the Ninth Circuit is about the medical decision-making process, specifically what was the *cause* of the decision to treat? That the physician is "the learned intermediary" and the patient is "autonomous" does not contradict the basic idea of medical decision-making (as explained in the subsection B. 1.), that they *jointly* participate or *share* in the process. The two sentences in the question set forth three successive steps in the process, not "alternative paths," as plaintiff argues.

B. The Ninth Circuit asked this Court to provide "resolution of the causation standard" as it is applied in California litigation for allegedly inadequate warnings about the complications known to be caused by medical treatments

1. The Ninth Circuit framed the question in terms of medical decision-making "causation," and the question has three parts

The issue the Ninth Circuit asks this Court to resolve relates to known medical complications: What must plaintiffs prove in order avoid summary judgment on their claim of allegedly inadequate warnings about the complications known to be caused by medical treatments? Is it sufficient to prove that

the risk warnings should have been stronger? Obviously, that implicates all physicians, hospitals, and others who provide medical treatment that involves medical products.

The federal litigation from which the appeal to the Ninth Circuit arose, however, is only against the manufacturer of the medical device used in plaintiff's specific treatment, and the focus is on the "labeling" of the manufacturers' specific products. The question certified to this Court by the Ninth Circuit is far broader than that, however. The question is about medical decision-making, first by physicians and then by patients, based on their weighing the benefits and the risks of treatment using medical products – *all* manufactured products used in medical treatment.

In its Order Certifying Question, the Ninth Circuit framed the question in terms of causation, and there are three parts to the question. The first part, based on defendant's theory of the case, is about the burden of proving causation as it relates to treatment recommendations by physicians. The second part, based on plaintiff's theory of the case, is about the burden of proving causation as it relates to warning communications by physicians to patients. The third part, based on plaintiff's theory, is about the burden of proof as it relates to medical decision-making by patients. Thus, assuming hypothetically the patient's physician had read "the stronger risk warning" that plaintiff claims manufacturers should provide and then the physician shared that warning with the patient: (1) would the physician have decided differently, (2) would the physician "pass on" the

warning, *and* (3) would an objective patient have decided differently?

Amici submit that, if the information in the manufacturer's warning is based on the same scientific evidence as the information in the physician-patient discussions, the answers should be the same. *No, the physician would not have decided differently*. *No, the objective patient would not have decided differently*. That is because, based on the same scientific evidence, both a reasonable and objective physician and a reasonable and objective patient would decide to go forward with the treatment, based on their together weighing the benefits and risks of that treatment against the benefits and risks of the alternatives. The decision would be *shared* and *informed*.

2. The Ninth Circuit characterizes the issue as the "causation standard," but the parties disagree as to what that standard should be

To further broaden the inquiry, the Ninth Circuit characterizes the issue in its Memorandum as "the causation standard" and requests guidance from this Court in that regard. The parties disagree as to what that "standard" is.

First, as it applies to the patient's decision regarding causation, plaintiff argues for a *subjective* standard and defendant argues for an *objective* standard. As it applies to the physician decision, however, plaintiff seems to argue for an *objective* standard, meaning that there is a professional standard of care that requires physicians not only to read but to *heed* manufacturer "enhanced warnings" (see, *e.g.,* Reply Brief on the

Merits ("RBM"), pp. 33-37, emphasis in heading deleted), and defendant seems to argue for a *subjective* standard, meaning that the individual treating physician's own "prescription decision" is controlling. (ABM, pp. 31-39 ["the physician's prescription decision"]. Emphasis in heading deleted.)

Second, plaintiff argues for the "*substantial factor*" test of causation, as opposed to the "*but for*" or counterfactual test of causation. Defendant does not respond to that argument. Neither plaintiff nor defendant refer to this Court's decision on the point, *Viner v. Sweet, supra.*

Plaintiff and defendant spend most of their effort, however, arguing about things that have little or nothing to do with the *standard* for causation.

For example, plaintiff focuses on "patient self-determination and autonomy," and defendant focuses on the physician as the "learned intermediary," even though the Ninth Circuit did not use those phrases in the question. Plaintiff essentially approaches the decision-making process as unilateral, by the patient, and defendant essentially approaches the process as unilateral, by the physician. Both plaintiff and defendant are wrong; it is a joint decision-making process. That is, the decision is shared. Regardless, the distinction between unilateral or joint decision-making has nothing to do with the *standard* for causation.

For another example, plaintiff argues the question is whether the hypothetical manufacturer's "stronger risk warning" alters the physician "warning" conduct, and defendant argues it

is whether the hypothetical manufacturer's "stronger risk warning" alters the physician "prescribing" conduct. Both are true, but that too has nothing to do with the *standard* for causation.

In summary, even though the Ninth Circuit's question and request for guidance are about medical decision-making causation, generally, and the "causation standard," specifically, the parties essentially reargue the case, as if this Court was asked to decide the appeal rather than review the question and issue presented by the Ninth Circuit.

II. Plaintiff Not Only Rejects Both Questions Certified By The Ninth Circuit To This Court, But Plaintiff Disagrees With The Ninth Circuit Framing The Causation Standard In Scientific Terms

A. Even though her claim is about medical treatment she received from her physician, based on medical decision-making in which she participated with him, plaintiff essentially argues she should not be required to prove his medical recommendation would have changed

Plaintiff argues the first sentence in the question should be answered in the negative: "Himes is not required to show that, had Somatics warned, her doctor would not have 'prescribed' ECT." (OBM, p. 46. Emphasis in heading deleted.) "While that is certainly *one* path to establishing causation, it is not the sole path under California law." (OBM, p. 45. Emphasis by italics in original.) Plaintiff argues the two sentences in the question raise

two, alternative "paths" for analysis of causation in claims of inadequate risk warnings. That is not to say she agrees with the second sentence, however. In the remaining pages of her brief, however, plaintiff makes very clear that she rejects the second sentence, just as she rejects the first.

Plaintiff argues the second sentence in the question should be reframed: "the causation/consent should *not* be judged by an objective prudent person standard." (OBM, pp. 62-63. Emphasis by italics in original.) She explains that "causation is established under the *substantial factor* test" (OBM, p. 63, emphasis by italics in original), under which plaintiffs "establish causation by providing 'self-serving' testimony as to how they would have altered their conduct in failure to warn cases." (OBM, p. 63.) To be sure, plaintiff also argues for the causation burden in wrongful death cases to be shifted to defendant manufacturers. (OBM, p. 58, fn. 12.)

Plaintiff relies heavily on this Court's decision on medical professional negligence for failure to provide informed consent, *Cobbs v. Grant, supra,* 8 Cal.3d 229 (cited at OBM, pp. 59, 60, 63, 64), and, by implication, the D.C. Circuit's seminal decision in *Canterbury v. Spence* (1972) 464 F.2d 772, upon which this Court relied in deciding *Cobbs*, to emphasize the principle of "patient self-decision and autonomy." (See, *e.g.,* OBM, p. 2.) Plaintiff rejects, however, the objective standard that was announced by this Court in *Cobbs.* (OBM, p. 63-65.) Plaintiff reasons that, "after *Cobbs,* this Court in *Mitchell* [*v. Gonzales, supra,* 54 Cal.3d 1041] and *Rutherford* [*v. Owens-Illinois* (1997) 16 Cal.4th 953]

recognized that, in negligence and products liability cases, causation can be established through the *substantial factor* test." (OBM, p. 64. Emphasis by italics in original.) Plaintiff ignores this Court's subsequent decision in *Viner v. Sweet, supra,* 30 Cal.4th 1232, that squarely contradicts plaintiff's argument and establishes the continued viability of "but for" or counter-factual causation in all but the relatively rare cases of what it called "concurrent *independent* causation," the so-called "two fires" causation scenario.

Plaintiff is wrong. Medical decision-making should be based on objective, scientific evidence – not subjective, hindsight-based, "self-serving" testimony, as plaintiff proposes – and litigation about medical decision-making should be no less rigorous. The analysis should *begin* by examining the physician's assessment of risk that led to the treatment about which plaintiff complains. Because physicians rely on evidence-based medicine to make their decisions about patient treatment, that analysis invariably will turn on what is known to physicians, as scientists, and it should be objective, not subjective. The analysis should end by examining what an objective, prudent patient in plaintiff's position would have decided, after discussion with the physician. The discussion will be about the benefits and risks, both of the treatment recommended by the physician and of the alternative treatments not recommended by the physician.[11]

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[11] There is an in-depth discussion of "Informed Consent" in the section of the *Reference Manual, supra,* entitled "Reference Guide on Medical Testimony," at pages 734-740.

B. Plaintiff rejects the objective causation standard in the Ninth Circuit's question and argues for a subjective standard

Rather than the trier-of-fact being required to decide the hypothetical counterfactual about patient decision-making based on an *objective* standard – that is, to use the Ninth Circuit's phrase, "a prudent person in the patient's position" – plaintiff would have the trier-of-fact decide the case based on a *subjective* standard, that is, what plaintiff testifies she would have done if told about the hypothetical manufacturer "stronger risk warning." Her testimony, of course, will be hindsight-based and, as she puts it, "self-serving." (OBM, pp. 63-64.)

Plaintiff argues not just to be allowed to testify to her own, subjective answer to the hypothetical counterfactual, but that the "causation standard" by which her testimony is to be analyzed also be subjective. She argues her testimony about what she would have done is *sufficient to prove subjectively* that the manufacturer of the medical device by which her ECT was administered caused her to suffer a known complication of ECT, which argument apparently is what prompted the Ninth Circuit to observe that "disposition of the appeal with respect to Himes's claims hinges on the resolution of the causation standard." (Order Certifying Question, p. 4.)

Defendant correctly points out that plaintiff's subjective standard is "hindsight-influenced" (ABM, p. 56, emphasis in heading deleted) and that "this Court has long rejected subjective testimony due to the patient's hindsight bias[ ]." (*Id.* at p. 57, citing *Cobbs v. Grant, supra,* 8 Cal.3d at 245.) Defendant

explains that, as it relates to "materialized medical risks" (*id.* at p. 58), "[a]n objective standard merely requires *reliable evidence* regarding consent" (*id.* at p. 59, emphasis by italics in original) and concludes "if the Court adopts Plaintiff's physicians-as-messengers theory (which it shouldn't), then the Court should use an objective prudent-person standard." (*Ibid.*)

Defendant goes further, however. Defendant proposes, rather than have the hypothetical question about objective patient decision-making be presented to the trier-of-fact, the question should not even be asked. Defendant urges the Court to decide the question of medical benefit: "as a matter of law, an objective prudent person would not refuse last-resort, life-saving treatment because of a small risk of side effects" because "[n]o objectively prudent person would refuse a prescribed treatment where (1) the patient is facing a serious risk of death, (2) all other treatment options have failed, and (3) a physician prescribes and urges the use of a medical treatment to save the patient's life – and the doctor never previously saw a patient experience the alleged side effect." (ABM, p. 60. Footnote omitted.) In the footnote, defendant concedes this is a factual question "the Ninth Circuit will need to determine" based on "the case record[.]" (*Id.* at p. 60, fn. 23.)

Defendant's proposal is case-specific, of course. The question of medical decision-making by patients will come up in many if not all cases against manufacturers of medical products for failure to warn, however, and the question will not always be as easily resolved as defendant proposes here. Unless this Court

is prepared to conclude that, *as a matter of law*, benefits of treatments *always* outweigh the risks of side effects, the second question will need to be answered by a trier-of-fact, and plaintiffs always will have the burden of proof on that fact.

To be sure, it is important to repeat that plaintiffs must prove medical decision-making causation objectively. For the reasons explained in the next section of this brief (under point heading III.), plaintiff's subjective analysis should be rejected.

C. Plaintiff's agenda is the same in this Court as it was in the Ninth Circuit, to avoid the "unduly demanding" causation standard and, instead, achieve one that is far less rigorous

As the Ninth Circuit noted, "the appellants contend that the district court erred in applying an unduly demanding causation standard[.]" (Order Certifying Question, p. 4.) As is all too apparent in her Opening Brief on the Merits, that still is plaintiff's position. What is striking is how many ways plaintiff proposes to make her burden of proof less rigorous.

Plaintiff argues she should not be required to show either that (1) *the treating physician would have decided differently* (OBM, point II, pp. 46-58) or that (2) *an objective patient would have decided differently*. (OBM, point IV, pp. 62-65.) She proposes to avoid having to answer *either* of the two hypothetical counterfactuals about causation the Ninth Circuit certified.

Not content with avoiding those counterfactuals, plaintiff also urges this Court to dramatically change California law as it

relates to causation, by adopting a causation standard that is less rigorous than what California law requires.

Plaintiff proposes to prove causation *subjectively*, by her own "self-serving" testimony (OBM, pp. 62-65) that "she would not have undergone the procedure had Somatics adequately warned of the risk of brain injury and permanent memory loss." (OBM, p. 65.) In other words, but for a stronger warning, she would not have consented.

Even then, however, plaintiff argues for the less demanding "*substantial factor*" test of causation, rather than "*but for*" or counterfactual causation. (OBM, pp. 62-65.) She should not even have to prove that, but for a stronger warning, she would not have consented.

Finally, to be sure she avoids any "unduly demanding" causation standard, plaintiff proposes that the burden of proof of causation in wrongful death cases be shifted to defendants. (OBM, pp. 55-56, 58 at fn. 12, and 65-66 at fn. 15.) Plaintiffs in those cases should not even have to satisfy the substantial factor causation standard she proposes be applied to her case for personal injury.

Each of these three steps in plaintiff's approach to causation are calculated to make her burden of proof less "demanding" and, if adopted, will require this Court to rewrite California law as it relates to causation. That will significantly increase the likelihood of flawed if not irrational decisions by triers-of-fact.

III. Plaintiff's Approach To Causation Could Lead To Flawed If Not Irrational Factual Findings By Triers-Of-Fact, Resulting In Erroneous Judgments Against Defendants, Including Physicians And Hospitals, In Failure To Warn Cases

A. Decision-making by triers-of-fact – particularly when deciding questions of causation – should be based on rationality and impartiality, not biases or noise

Obviously, trier-of-fact decisions should be *rational*, and that is true of their findings of fact on causation. The technique by which to rationally analyze causation is counter-factual reasoning. Just as obviously, decisions by triers-of-fact should be *impartial*.

"Rationality requires that we distinguish what is true from what we want to be true" (Pinker, *Rationality: What It Is, Why It Seems Scarce, Why It Matters* (2021), p. 201 (hereafter Pinker)),[12] and "the core of morality is impartiality: the reconciliation of our own selfish interests with others'. So, too, is impartiality the core of rationality: a reconciliation of our biased and incomplete notions into an understanding of reality that transcends any one

[12] Professor Pinker is the author of many popular books on cognitive psychology, psycholinguistics, and related topics, including *How the Mind Works, The Blank Slate, The Stuff of Thought,* and *Enlightenment Now*. He was elected to the National Academy of Sciences, was named one of *Time's* "100 Most Influential People," and was named one of *Foreign Policy's* "100 Leading Global Thinkers."

of us. Rationality, then, is not just a cognitive virtue but a moral one." (*Id.* at p. 317.)

Human reasoning, unfortunately, is known to be affected by fallacies, biases, noise, and other things that distort human judgment to the point of irrationality.[13]

Even more unfortunately for purposes of this Court's review of the question certified by the Ninth Circuit and the issue for which the Ninth Circuit requests guidance, that is particularly true in litigation, where the parties are highly motivated to persuade triers-of-fact to rule their way. "Many of the biases that populate the lists of cognitive infirmities are tactics of *motivated reasoning*" (Pinker, *supra,* at p. 290, emphasis by italics added),[14] for example, "sophistry, spin-doctoring, and the other arts of persuasion." (*Id.* at p. 290.)

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[13] "Human reasoning has its fallacies, biases, and indulgence in mythology ... the paradox of how our species could be both so rational and so irrational … lies in the duality of self and other: our powers of *reason* are guided by our motives and limited by our points of view." (Pinker, *supra,* at p. 317. Emphasis by italics added.)

[14] "The mustering of rhetorical resources to drive an argument toward a favored conclusion is called motivational reasoning." (Pinker, *supra,* at p. 290. Footnote omitted.) "So much of our reasoning seems tailored to winning arguments that some cognitive scientists, like Hugo Mercier and Dan Sperber, believe it is the adaptive function of reasoning. We evolved not as intuitive scientists but as intuitive lawyers." (*Id.* at p. 291. Footnote omitted.)

Worse, some legal tactics are virtually *calculated* to provoke biased decision-making by triers-of-fact, particularly juries.

Cognitive scientists, behavioral economists, and others in related fields warn that human "[j]udgments are susceptible to both bias and noise." (Daniel Kahneman, Olivier Sibony, Cass F. Sunstein, *Noise: A Flaw In Human Judgment* (2021), p. 8 (hereafter Kahneman, Sibony, Sunstein).)[15] Biases are "systematic, predictable errors of judgment" (*id.* at p. 161) in that biases cause "systematic deviation" in human judgment. (*Id.* at p. 4.) "Noise," on the other hand, is the "random scatter" of human judgments on the same question. (*Id.* at p. 4.) "We say that *bias* exists when most errors in a set of judgments are in the same direction." (*Id.* at p. 362. Emphasis by italics in original.) "Statistical bias" refers to "measurements or judgments that mostly deviate from the truth in the same direction" (*id.* at p. 161), and "psychological biases create statistical bias when they are broadly shared. However, psychological biases create system

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[15] Daniel Kahneman is recognized for the groundbreaking work he conducted with Amos Tversky in applying psychological insights to economic theory, particularly in the areas of judgment and decision-making under uncertainty. He was awarded the Nobel Prize in Economic Sciences. Cass Robert Sunstein is one of the most frequently cited contemporary American legal scholars. He served as Administrator of the White House Office of Information and Regulatory Affairs in the Obama administration from 2009 to 2012. Sibony is a professor and advisor who specializes in the quality of strategic thinking and the design of decision-making processes, having spent 25 years with McKinsey & Company. Their book *Noise* appeared on multiple bestseller lists worldwide, including the *New York Times* list.

noise when judges are biased in different ways, or to a different extent. Whether they cause statistical bias or noise, of course, psychological biases always create error." (*Id.* at pp. 161-162.) "System noise is inconsistency, and inconsistency damages the credibility of the system." (*Id.* at p. 53.) "Eliminating bias from a set of judgments will not eliminate all error. The errors that remain when bias is removed are not shared. They are the unwanted divergence of judgments, the unreliability of the measuring instrument we apply to reality. They are *noise.* Noise is variability in judgments that should be identical." (*Id.* at p. 363. Emphasis by italics in original.) "To improve the quality of our judgments, we need to overcome noise as well as bias." (*Id.* at p. 7.)

Decision-making by juries, in theory, is a means by which to assure decision-making is rational: "When people evaluate an idea in small groups with the right chemistry, which is that they don't agree on everything but have a common interest in finding the truth, they catch on to each other's fallacies and blind spots, and usually the truth wins." (Pinker, *supra,* at p. 291.) Unfortunately, bias can be a problem because jury deliberations are "noisy" to begin with. (Kahneman, Sibony, Sunstein*, supra,* at pp. 103-105.)

There are features of plaintiff's proposed approach to analyzing medical decision-making causation that will tend to increase irrationality, partiality, bias, and noise in jury decision-making on the issue of causation, the most distorting of which is *hindsight bias*.

B. Plaintiff's subjective, "self-serving" standard for analysis of medical decision-making causation is based on hindsight, which introduces a psychological bias that will lead to flawed factual findings by triers-of-fact

The final argument in plaintiff's Opening Brief on the Merits is that the Ninth Circuit incorrectly framed the question it certified in terms of the *objective* causation standard this Court announced in *Cobbs v. Grant, supra.* Instead, plaintiff proposes that this Court reframe the question in terms of a *subjective* standard. (OBM, pp. 62-65.)

Setting aside concern that plaintiff is *falsely framing* the inquiry, there is another, more significant concern: plaintiff's subjective testimony will introduce *hindsight bias* into the analysis. As this Court explained hindsight bias in *Cobbs v. Grant*,

> [s]ince 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 physician in jeopardy of the patient's bitterness and disillusionment. Thus an objective test is preferable: *i.e.*, what would a prudent person in the patient's position have decided if adequately informed of all significant perils.

(8 Cal.3d at 245. Emphasis by italics added.) Or, as defendant explains it, "plaintiff cannot establish causation through *subjective hindsight-influenced testimony*" (ABM, p. 17, emphasis by italics added), *i.e.,* "her own subjective post-hoc declaration

that she would have refused treatment, even if doing so were objectively unreasonable." (ABM, pp. 56-57.) Defendant correctly argues a subjective test is "inherently less reliable than an 'objective' test[,]" whereas an "objective test 'ease[s] the fact-finding process and better assure[s] the truth as its product' " (OBM, p. 58) in that it "requires *reliable evidence* regarding consent." (OBM, p. 59. Emphasis by italics in original.)

Hindsight bias is one of the psychological biases that is known to distort judgments. (Kahneman, Sibony, Sunstein, *supra,* at p. 218.) Hindsight bias will be particularly distorting in the analysis of medical decision-making causation, which consists of weighing benefit and risk, particularly when the analysis ignores benefit, as plaintiff proposes.

The outcome of causation analysis using plaintiff's subjective standard will, inevitably, be based on plaintiff's testimony about what she sees in hindsight. If that is the causation standard, it means the trier-of-fact's decision will be based on hindsight. As such, hindsight bias will be incorporated into the analysis of medical decision-making causation.

C. Plaintiff's approach invokes other biases and aggravates noise in assessment of risk

Setting aside the *hindsight* bias that plaintiff's approach invokes, plaintiff's approach (OBM, pp. 62-65) invokes at least two other biases that impact the assessment of risk, *representativeness bias* and *availability bias.* The concern is that "people's intuitive sense of probability . . . is driven by *representative stereotypes* and *available memories* rather than on

a systematic reckoning of possibilities." (Pinker, *supra,* at p. 27. Emphasis by italics added.) "Like the *availability* heuristic … the *representativeness* heuristic is a rule of thumb the brain deploys in lieu of doing the math." (*Id.* at p. 155. Footnote omitted. Emphasis by italics added.) That is, "we *neglect the base rate*, which is usually the best estimate of the prior probability." (*Id.* at p. 154. Footnote omitted. Emphasis by italics added.) "Whether they cause *statistical bias* or *noise*, of course, psychological biases always create error." (Kahneman, Sibony, Sunstein, *supra,* at p. 162. Emphasis by italics added.)

Base rate neglect summarizes plaintiff's simplistic approach to analyzing risk. In place of *base rate* probabilities of medical complications from medical treatments, plaintiff invokes bias: "stereotypes and available memories rather than on a systematic reckoning of possibilities." (Pinker, *supra,* at p. 27.) One example is plaintiff's reference to the image of ECT in "One Flew Over the Cuckoo's Nest." (OBM, p. 8.) Another is plaintiff's comparison to the electric chair. (OBM, p. 21.) Those memorable images, as well as the dramatic anecdote about the early Italian experiment using ECT (OBM, pp. 6-8), are examples of plaintiff's "arguments directly aimed at the limbic system rather than the cerebral cortex. These include the *appeal to emotion*[.]" (Pinker, *supra,* at p. 92. Emphasis by italics in original.) Arguably, it is calculated to invoke "communal outrage" that inspires "a victim narrative." (*Id.* at p. 124.) "Outrages cannot become public without media coverage." (*Id.* at p. 125.)

Risk aversion summarizes the effect plaintiff seeks to achieve, either as bias or noise or both. Plaintiff's focus entirely on risk and disregard of benefit is an obvious illustration of *false framing* of the choice between risks and rewards (Pinker, *supra,* at p. 192) to invoke *risk aversion.* That is, plaintiff adds "decision weights" to anyone who tries to apply probability analysis (*id.* at p. 194) to the case, which will distort, if not "violate," or even "flout the axioms of rational choice." (*Id.* at pp. 184-196.)

Availability also is a distortion of risk perception (Pinker, *supra,* at p. 122), and plaintiff invokes *availability* bias as it relates to risk. Risk assessment should be based on scientifically proven probabilities: "whenever we say that one event is more probable than another, we believe it will occur more often given the opportunity. To estimate risk, we should tally the number of instances of an event and mentally divide it by the number of occasions on which it could have taken place." (Pinker, *supra,* at p. 119.) In "the *availability heuristic*[,]" unfortunately, "[w]e use the ranking from our brain's search engine – the images, anecdotes, and mental videos it coughs up – as our best guess of the probabilities. The heuristic exploits a feature of human memory, namely that recall is affected by frequency: the more often we encounter something, the stronger the trace it leaves in our brains." (Pinker, *supra,* at p. 119. Footnote omitted. Emphasis by italics in original.) *Availability* is a "distorter of risk perception." (*Id.* at p. 122.)

Plaintiff's anecdote about the early experiment in Italy is an example of *availability*.

> The press is an availability machine. It serves up anecdotes which feed our impression of what's common in a way that is guaranteed to mislead. Since news is what happens, not what doesn't happen, the denominator in the fraction corresponding to the true probability of an event – all the opportunities for the event to occur, including those in which it doesn't – is invisible, leaving us in the dark about how prevalent something really is.

(Pinker, *supra,* at p. 125.)

In summary, plaintiff's proposed subjective causation standard, as plaintiff presents it in her briefs, will introduce a number of distortions into the analysis of medical decision-making causation, particularly because it consists of weighing benefit and risk.

D. Plaintiff's basic argument, about patient "autonomy," is an example of a false dichotomy fallacy

Plaintiff's basic argument pits medical decision-making by the "learned intermediary" physician against medical decision-making by the "autonomous" patient. (See, *e.g.,* OBM, pp. 58-62 ["the district court impermissibly concluded that the doctors' decision to 'prescribe' ECT trumps the patients' right to 'refuse to consent'," emphasis in heading deleted]; RBM, pp. 3-5.) That argument is a classic *false dichotomy fallacy*. (See Pinker, *supra*, at p. 100.)[16]

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[16] Short of that, it is an invocation of the *slippery slope* fallacy (Pinker, *supra,* at pp. 100-102) in which plaintiff argues, when the "learned intermediary doctrine" limits manufacturer liability, "patient self-determination and autonomy" is diminished.

Plaintiff's approach is based on several false assumptions about what is required of health care providers, one of which is physicians decide what treatment to recommend based on what manufacturers recommend. As the testimony of the physicians deposed in the federal litigation demonstrated, physicians do not rely upon manufacturer warnings for information about treatments, *generally*. For that, physicians rely upon their own training, experience, and evidence-based medicine.[17]

Another false assumption by plaintiff is that physicians have a duty to *quantify* the risks for their patients. They do not, neither in terms of severity nor frequency.[18] In California,

> when a given procedure inherently involves a known risk of death or serious bodily harm, a medical doctor has a duty to disclose to his patient the potential of death or serious harm, and to explain in lay terms the complications that might possibly occur. Beyond the foregoing minimal disclosure, a doctor must also reveal to his patient such additional information as a

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[17] Evidence-based medicine "is aptly defined as 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.' " (*Reference Manual, supra,* at p. 723. Footnote and citation omitted.)

[18] "The informed consent process involves the disclosure of alternative treatment options including no treatment and the risks and benefits associated with each alternative. Discussion should include severe risks and frequent risks, but the courts have not provided explicit guidance about what constitutes sufficient severity or frequency." (*Reference Manual, supra,* at p. 735.)

skilled practitioner of good standing would provide under similar circumstances.

(*Cobbs v. Grant, supra,* 8 Cal.3d at 244-245.)

In summary, plaintiff's approach to medical decision-making tends to defeat rationality and impartiality.

IV. Plaintiff's Proposed Causation Standard Is Contrary To California Law, Which Requires Causation To Be Analyzed Objectively And, In Medical Cases, Scientifically

A. Although the question whether ECT has more risk than what psychiatrists tell their patients, as well as other medical questions the case presents, should be analyzed scientifically, plaintiff argues medical decision-making causation in simplistic terms

The basic assumption of plaintiff's case is that physicians are not adequately informing patients about ECT. That is contrary to what currently is known about ECT.[19]

Regardless of whether plaintiff can prove that psychiatrists understate the risk of ECT, the rest of plaintiff's case consists of

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[19] For example, the *Reference Manual*, in the "Reference Guide to Mental Health Evidence," includes a discussion of "Electro-convulsive and other brain stimulation therapies." (*Reference Manual*, *supra,* at pp. 861-862. Emphasis in heading deleted.) It notes, "[a]lthough temporary confusion and memory loss often occur, long-term adverse effects are uncommon, making ECT a safe procedure – indeed, for elderly patients with complex medical problems, it may be preferable to the use of medications." (*Id.* at p. 861.) "ECT is used today primarily for the acute treatment of depression, for which it has been demonstrated to be effective." (*Id.* at p. 862. Footnote omitted.)

scientific questions, many of which are about *scientific causation*. There are questions about the *medical treatment* she received and the *medical diagnosis* of her mental condition after that treatment. There are questions whether ECT *causes* brain damage, generally, and whether ECT *caused* her brain damage, specifically. The answers to all of those and other questions in this case should be based on scientific evidence.

The focus of plaintiff's appeal from summary judgment is on the question of medical decision-making causation: whether the manufacturer *caused* her to suffer a known complication of ECT. Technically stated, did the manufacturer cause her to consent to ECT by misrepresenting the risks to her physician? That too should be analyzed scientifically.

Plaintiff's argument is neither objective, nor scientific. To the contrary, her approach to medical decision-making causation is simplistic. The relevant causal factor in her analysis is the manufacturer's failure to provide to her physician "a stronger risk warning," and the causal mechanism is plaintiff herself: "had she been warned of the risks either from the intermediary or the manufacturer, she would not have agreed to the ECT procedure[.]" (RBM, p. 39.) That is, "the subjective attestation of the plaintiff as to what she would have done had she been adequately warned are sufficient to establish causation[.]" (RBM, pp. 6-7.) As plaintiff explains it, her "subjective testimony" to that effect is sufficient to "establish" causation under "the substantial factor test for causation." (OBM, p. 62; RBM, p. 37. Emphasis in headings deleted.)

Plaintiff does not explain what other factors are to be considered, but her argument strongly suggests that her physician's recommendation is not a factor to be compared against the manufacturer warning. In plaintiff's analysis, her physician's recommendation is completely trumped if she exercises her right to refuse treatment. For that matter, under her analysis, virtually everything else that might be a factor – such as the potential benefits of treatment – is irrelevant because the decision to consent is entirely hers to make, for whatever reason she states. As she puts it, "*armed* with the stronger warnings, she would not have consented[.]" (OBM, p. 25. Emphasis by italics added.)

In the following discussion of *the causation standard* – which is the standard on which plaintiff's appeal "hinges" – *Amici* explain why the analysis in this and all other cases about medical decision-making should be scientific, using counterfactual reasoning.

B. Contrary to plaintiff's argument, the Restatement Third of Torts and, more importantly, this Court reaffirmed the but for test and limited the substantial factor test to the rare situation in which there is concurrent independent causation

Plaintiff opposes not only the "objective" patient standard for causation (OBM, pp. 62-65; RBM, pp. 37-39) but also "the objective factor test" of causation (OBM, p. 64), the so-called "but for" test of counterfactual causation. Plaintiff argues that her "subjective testimony" should be sufficient to "establish"

causation under the "substantial factor" test of causation. (OBM, pp. 62-64; RBM, pp. 37-39.) Plaintiff reasons that it is "the substantial factor test for causation in products liability cases which allows plaintiff's subjective testimony to establish causation" (OBM, p. 62, and RBM, p. 37, emphasis in headings deleted), and the "objective" standard and "but for" test should be limited to medical malpractice cases for lack of informed consent. (OBM, pp. 63-64; RBM, pp. 37-39.)

Like other plaintiffs in personal injury litigation where evidence of causation is weak – plaintiff Himes complains that the *but for* test of causation is more demanding than the *substantial factor* test and asks for "a relaxation of the 'but for' test of causation[.]" (*Viner v. Sweet, supra,* 30 Cal.4th at 1241.) Her argument against *but for* causation (OBM, pp. 63-64) is based on *Mitchell v. Gonzales, supra,* 54 Cal.3d at 1052-1053, *Rutherford v. Owens-Illinois, Inc., supra,* 16 Cal.4th at 968-969, and the Restatement Second of Torts. (OBM, p. 63.)[20]

Plaintiff is wrong. In California, the "but for" test of causation definitely has *not* been replaced by the "substantial factor" test. As explained in *Viner v. Sweet, supra, "Mitchell* did not abandon or repudiate the requirement that the plaintiff must

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[20] Plaintiff also relies on those authorities, *Mitchell* and *Rutherfeld,* to distinguish *Cobbs v. Grant, supra,* 8 Cal.3d 229, 245, upon which the Ninth Circuit relied for "the objective prudent person standard for causation." (OBM, pp. 63-64, citing *Himes v. Somatics, LLC* (9th Cir., Apr. 1, 2022, No. 21-55517) 2022 WL 989469, at *3, fn. 3.)

prove that, *but for* the alleged negligence, the harm would not have happened." (30 Cal.4th at 1239. Emphasis by italics in original.) "*Mitchell* also stated that 'nothing in this opinion should be read to discourage the Committee on Standard Jury Instructions from drafting a new and proper "but for" instruction.' " (*Ibid.*, quoting *Mitchell, supra,* 54 Cal.3d at 1054, fn. 10.) Moreover, as the Court further explained in *Viner*, "the 'substantial factor' test *subsumes* the 'but for' test" of causation. (*Ibid.,* quoting *Mitchell, supra,* 54 Cal.3d at 1052. Emphasis by italics in original.) Indeed, to this day, California juries routinely are instructed on the but for test of causation by CACI 430, which states that "[c]onduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct."

That said, the "substantial factor" test definitely *has* been criticized — and it has been criticized repeatedly. As explained in Witkin,

> The primary function of the substantial factor test was to permit the factfinder to decide that factual cause existed when there were multiple sufficient causes, i.e., each of two separate causal chains sufficient to bring about the plaintiff's harm, thereby rendering neither a but-for cause [read: the two-fires scenario]. However, the substantial-factor test has revealed a tendency to be understood as permitting something less than a but-for cause, or as demanding something more than a but-for cause, to constitute a factual cause. (Rest.3d, Torts: Liability for Physical and Emotional Harm § 36, Comment a.) Thus, "[t]he substantial-factor test has not . . . withstood the test of time, as it has proved confusing and been misused." Confusion has resulted from the different ways that the substantial-factor test has been employed in the fields of negligence and comparative negligence and in

> enhanced-injury cases when proof of the amount of harm caused by a second actor is uncertain. (Rest.3d, Torts: Liability for Physical and Emotional Harm § 26, Comment j.)

(6 Witkin, Summary of Cal. Law (11th ed. 2018) Torts, § 1334.)

Because "substantial factor" was criticized as a source of controversy and confusion in the proof of causation, that phrase was eliminated in the Restatement Third of Torts. Instead, the exception to the but for test in the Restatement Second of Torts (at §§ 431-432) that was formerly known as "substantial factor" is now stated in the Restatement Third of Torts as "multiple sufficient causes."[21] The pertinent sections read as follows:

> **§ 26 *Factual Cause.*** Tortious conduct must be a factual cause of harm for liability to be imposed. Conduct is a factual cause of harm when the harm would not have occurred absent the conduct. Tortious conduct may also be a factual cause of harm under § 27.
>
> **§ 27 *Multiple Sufficient Causes.*** If multiple acts occur, each of which under § 26 alone would have been a factual cause of the physical harm at the same time in the absence of the other act(s), each act is regarded as a factual cause of the harm.
>
> **§ 36 *Trivial Contributions to Multiple Sufficient Causes.*** When an actor's negligent conduct constitutes only a trivial contribution to a causal set that is a factual

[21] Causation now appears in the volume entitled "Liability for Physical Harm" of the multiple volume Restatement Third of Torts.

cause of harm under § 27, the harm is not within the scope of the actor's liability.

In *Viner,* the Court noted "various labels" (other than "substantial factor") that could be used to describe the exception to the but for test: "concurrent independent causes," "combined force criteria," and "multiple sufficient causes." (30 Cal.4th at 1240.) The Court explained the exception as "multiple forces *operating at the same time* and *independently*, each of which would have been *sufficient by itself* to bring about the harm." (*Ibid.* Emphasis by italics added.)

In summary, the broad "substantial factor" test that originally appeared in the first Restatement of Torts and then reappeared in the Restatement Second of Torts has been eliminated.[22] For purposes of analyzing the issue of medical causation in this case, the Court should reject plaintiff's argument, based on the "substantial factor" test.

C. Causal reasoning in both medicine and law is an "alternative reasoning process" of "ruling out" the alternative, i.e., counterfactual reasoning

While the medical and legal professions may use the same words in discussing causation, they often use those words

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[22] "Expelled" is another word that has been used. (See, *e.g.*, Sebok, *Actual Causation in the Second and Third Restatements: Or, the Expulsion of the Substantial Factor Test* in Causation in European Tort Law (Infantino & Zervogianni edits., 2017) pp. 60-84.)

differently. Yet whether they are discussed in the clinic or in the courtroom, the concepts are basically the same:

> [M]edical terms shared in common by the legal and medical professions have differing meanings, for example, differential diagnosis, differential etiology, and general and specific causation. The basic concepts of diagnostic reasoning and clinical decision-making and the types of evidence used to make judgments as treating physicians or experts involve the same overarching theoretical issues: (1) alternative reasoning processes; (2) *weighing risks, benefits, and evidence*; and (3) *communicating those risks*.

(*Reference Manual, supra,* at pp. 740-741. Emphasis by italics added.)

The point is that both medical and legal analyses of causation are based on a deductive process of ruling out the hypothetical alternatives. In medicine, this process is commonly referred to as "ruling in" the disease causing a patient's symptoms and signs. In law, it is commonly known as the "but for" test of factual causation.[23] Either way, the process is the same: it "requires evaluation of hypothetical situations concerning what might have happened, but did not[.]" (*Viner v. Sweet, supra*, 30 Cal.4th at 1242.)

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[23] The deduction-driven analysis of "factual causation" is distinguished from the policy-driven analysis commonly known in the past as "legal causation" or "proximate cause." That concept now is being referred to as "scope of liability." (See, *e.g.*, Dobbs et al., The Law of Torts (2d ed. 2011) vol. 1, ch. 18, "Scope of Liability (Proximate Cause)," § 198 et seq., pp. 679-760, and Restatement Third of Torts (Liability for Physical and Emotional Harm), § 29 et seq., "Scope of Liability (Proximate Cause)," pp. 492-542.)

V. In Failure To Warn Cases, Whether Against Physicians Or Manufacturers Or Both, Plaintiffs Must Prove All Aspects Of Causation, Objectively And Scientifically, Including Medical Decision-Making Causation

A. Plaintiff argues for a relaxed causation standard in product liability cases, as opposed to medical professional liability cases

Ultimately, after more than one hundred pages of briefing, plaintiff explains in the very last section of her Reply Brief on the Merits why she should not have to prove that her physician would recommend against the treatment using the medical device and why her proof of causation should not be "unduly demanding." She argues there are different causation standards for manufacturers of medical products and the physicians who use those products to treat their patients. (RBM, pp. 37-39.) Plaintiff reasons that the objective causation standard is one of "various exclusive protections to physicians," such as in the Medical Injury Compensation Reform Act, and that " 'California courts have repeatedly held that strict liability may not be imposed against health care providers for injuries suffered by their patient.' " (RBM, p. 38. Citation omitted.) Neither MICRA nor those cases, however, have anything to do with the causation standard applicable in professional liability cases.

Plaintiff is wrong, if only because product liability cases against manufacturers of medical products obviously *implicate* the physicians who use those products to treat patients. Plaintiff also is wrong because, while California courts allow plaintiffs to

testify subjectively to what they would have done, including in professional liability cases for alleged "lack of informed consent," those courts have not held that such subjective testimony, by itself, is sufficient to "establish causation" as plaintiff claims. The causation standard is objective, both in cases against manufacturers and in cases against physicians.

To be sure, in cases where medical decision-making causation is an issue, the standard also should be scientific, meaning rational, impartial, and not biased by hindsight.

B. In order for a plaintiff to prove that the manufacturer was the cause of injury from a complication of treatment to which plaintiff would not have consented, plaintiff must prove *all* three parts of the question certified by the Ninth Circuit

As to the question certified by the Ninth Circuit, *Amici* disagree with plaintiff and agree with defendant but would go further than defendant, particularly in cases where the liability of health care providers is implicated. *Amici* urge the Court to require in *all* such cases – most importantly in those cases which include physicians and hospitals as defendants – that plaintiffs *also* be required to prove that a prudent patient in plaintiff's situation would agree with her physician's recommendation *against* treatment. Simply stated, all parts of the Ninth Circuit question should be answered in the affirmative.

Amici propose that there are four basic scenarios to consider.

1. The first sentence in the Ninth Circuit's question, on decision-making by the treating physician, is about the effect of a hypothetical "stronger risk warning" from the manufacturer

There are two possible responses to the hypothetical counterfactual about "a stronger risk warning" to the physician, in the first sentence of the question:

Response 1 (a), where "a stronger risk warning" will change the physician recommendation *against* the treatment: The patient's physician testifies that the hypothetically "stronger risk warning" about the manufacturer's product *would have altered* the physician's decision to prescribe the product for treatment of the patient, in which event the physician would explain the altered decision in terms of the stronger risk warning from the manufacturer, *leaving the patient to decide whether to accept the risk nevertheless.*[24]

Response 1 (b), where "a stronger risk warning" will *not* change the physician recommendation *for* the treatment: The patient's physician testifies that the hypothetically "stronger risk warning" about the manufacturer's product *would* ***not*** *have altered* the physician's decision to

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[24] As plaintiff points out, "California law continues to respect patient self-decision and autonomy" (OBM, p. 2) and "California has recognized that each patient has a right to refuse treatment" (OBM, p. 59) recommended by her physician. The converse also is true, however. California recognizes that each patient has a right to *decide* to have the treatment and not to have the alternative treatment (or no treatment at all) that was recommended by her physician.

prescribe the product for treatment of the patient, but the physician nevertheless would have communicated the stronger risk warning to the patient, either in patient consent disclosures or otherwise, *leaving the patient to decide whether to accept the recommendation and the risk nevertheless.*

Thus, the second sentence in the question, also will have to be decided, regardless of how the physician testifies on the first question.

2. The second sentence in the question, on decision-making by the patient, is about the effect of a hypothetical "stronger risk warning" that the physician describes to the patient

The second and third part of the question, in the second sentence, is analyzed in the same, objective fashion as the first. To be clear, the second question only arises where the physician testifies that his or her own, individual position would be to tell the patient about the manufacturer warning, as Dr. Fidalio did here. There are two possible responses to the second hypothetical question about an objective, "prudent person in the patient's position":

Response 2 (a), where the physician recommendation is *against* the treatment based on the manufacturer warning, and the physician tells an objective patient about the manufacturer warning: Would a hypothetical prudent person in the patient's position have *demanded* the treatment, based on the benefits, despite the physician's hypothetical recommendation *against* the treatment? Plaintiff

ignores this hypothetical scenario, apparently because plaintiff essentially assumes that patients decide whether to undergo treatment – in this case, ECT – based entirely on the risk and without any consideration of the benefit. Defendant ignores this scenario as well, because defendant essentially assumes that patients always follow the recommendations of physicians for treatment.

Response 2 (b), where the physician recommendation was *for* the treatment despite the manufacturer warning, and the physician tells an objective patient about the manufacturer warning: Would a hypothetical prudent person in the patient's position have *declined* the treatment after receiving the hypothetically "stronger risk warning" despite the physician's hypothetical recommendation *for* the treatment? Plaintiff focuses entirely on this scenario, virtually to the exclusion of all others, but objects to the "prudent person in the patient's position" standard.

C. It is important to remember that, at this stage of the case, plaintiff's basic theory – that risk of ECT is understated by psychiatrists – is nothing more than an assumption; it has yet to be proven objectively and scientifically

At this point (given the procedural posture of plaintiff's case, appeal from summary judgment on the issue of causation), the basic theory of plaintiff's case is nothing more than an assumption, albeit one necessary for the hypothetical counterfactual question by which causation is analyzed. The

hypothetical fact that the risk of ECT is greater than what psychiatrists tell their patients has not been scientifically demonstrated. At trial, plaintiff will have to prove that fact, by expert witness opinion testimony based on epidemiology and other evidence-based medicine, as this Court made clear in *Sargon Enterprises, Inc. v. University of Southern California, supra,* 55 Cal.4th 747, and the expert witness will have to provide a reasoned explanation for his or her opinion on causation, otherwise the testimony is *speculative*. (55 Cal.4th at 770, citing *Jennings v. Palomar Pomerado Health Systems, Inc., supra,* 114 Cal.App.4th at 1117.) In other words, the testimony not only must be based on scientific evidence, but it must be rational.

Rationality requires that juries not be allowed to see or hear inadmissible evidence or improper argument, not just because it is wrong but "because human minds are incapable of ignoring it." (Pinker, *supra*, at pp. 57-58.) That has several important implications. First, if plaintiff does not present scientific evidence proving the fundamental assumption of her case – that the actual risk of ECT is routinely understated by psychiatrists – the question of medical decision-making causation should not even be presented to the jury. Second, even assuming plaintiff presents evidence to prove that assumption, she still must present additional evidence – both scientific and objective – to prove medical decision-making causation, pursuant to the three parts of the question certified by the Ninth Circuit. Third, even then, there must not be any testimony or argument that

introduces bias, fallacy, or anything else that could result in flawed or, at the extreme, irrational jury decision-making.

The most important point is that medical decision-making causation is about the process for weighing benefits and risks. It is particularly important that analysis of such decision-making by physicians and patients not be biased by *hindsight*.

D. Plaintiff also has not proven either that the medical decision leading to the complication was uninformed or that the complication was the cause of the harm she claims, "permanent memory loss and brain damage"

1. There are multiple steps to plaintiff proving medical decision-making causation objectively and scientifically, which means scientific analysis of scientific evidence

There are a number of steps in the analysis of causation in this case.

Step one. Are "permanent memory loss and brain damage" known to be inherent complications of the treatment, ECT? Technically, that means the medical etiology of "permanent memory loss and brain damage" includes ECT. If not, general causation is not established. The parties disagree as to whether there is such broad general causation of harm.

Step two. If so, is plaintiff's harm, her claimed "permanent memory loss and brain damage," a result of complications of her treatment? If not, specific causation is not established. The

parties disagree as to whether there is specific causation of plaintiff's harm.

Step three. And, if so, the next question is who or what caused the complication to happen? Was it because the treating physician negligently performed the procedure, either by increasing the chance of complication or by failing to reduce the chance of complication? If not, it is an inherent complication of non-negligent treatment. The parties do not claim the physician was negligent.

Step four. If an inherent complication occurs, the question is whether the medical decision that led to the treatment was flawed? Plaintiff argues it was flawed, because the risk warning should have been "stronger." In effect, plaintiff argues, the risk outweighed the benefit. Defendant argues it was not flawed, because "a stronger risk warning" would not have changed the decision. The benefit outweighed the risk.

Step five. If so, who if anyone is responsible for the flawed decision? Is the physician responsible for failing to assure that the patient's consent was informed? Is the manufacturer of the medical device by which the physician provided the treatment responsible for failing to warn the physician? Plaintiff argues the manufacturer is responsible. Defendant argues the physician is responsible, for not reading the manufacturer warning, but goes on to argue it would not have changed the outcome, and the decision was correct because the benefit outweighed the risk.

Those last two steps, whether the decision was flawed and who is responsible for the flawed decision, turn on the first step,

whether ECT causes "permanent memory loss and brain damage" and, if so, with what frequency and severity? That is a purely scientific question, turning on epidemiology and other sources of evidence-based medicine. Anecdotal evidence alone is not sufficient proof.[25]

In summary, plaintiffs must prove causation, both as it relates to the medical decision and the complication and as it relates to the complication and plaintiff's claimed harms, both of which turn on general causation. Arguably, general causation is the most important step because it is the factual predicate for most of the other steps.

2. Medical decision-making takes into consideration many factors, not just risk

There are many things that cause physicians and patients to decide to treat,[26] obviously beginning with the nature and severity of the underlying medical problem, that is, the diagnosis. In this case, there is no dispute plaintiff had a medical problem. The other factors in medical decision-making are the treatment

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[25] See fn. 2, *supra.*

[26] "Medical decisionmaking often involves complexity, uncertainty, and tradeoffs because of unique genetic factors, lifestyle habits, known conditions, medication histories, and ambiguity about possible diagnoses, test results, treatment benefits, and therapeutic harms. Given inherent diagnostic and therapeutic uncertainty, physicians often make treatment decisions in the face of uncertainty." (*Reference Manual, supra,* at pp. 728-729. Footnote omitted.)

alternatives, the benefits and risks of each alternative treatment, and the benefits and risks of doing nothing.

Analysis of past medical decisions essentially is re-examination of the factors that were taken into consideration by the people who made the decisions, the physician and the patient. To avoid *hindsight* bias, *representativeness* bias, and *availability* bias, it must be done objectively.

CONCLUSION

Insofar as the question certified by the Ninth Circuit implicates health care providers, this Court should answer the question in the affirmative, meaning all three parts of the question should be answered in the affirmative. Assuming plaintiff can prove that "a stronger risk warning" is scientifically required, plaintiff must show (1) plaintiff's physician would not have recommended treatment using the manufacturer's device, *and* (2) plaintiff's physician would have communicated the manufacturer's warning to the patient, *and* (3) a prudent patient in plaintiff's situation would not have consented.

Insofar as the issue for which the Ninth Circuit requested guidance implicates health care providers, this Court should reject plaintiff's proposed approach. The proper causation standard is "objective," the proper causation analysis is by counter-factual reasoning, and the proper proof is by scientific evidence.

Dated: November 4, 2022 COLE PEDROZA LLP

By: _____
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CALIFORNIA DENTAL ASSOCIATION, and
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CERTIFICATION

Appellate counsel certifies that this document contains 13,517 words. Counsel relies on the word count of the computer program used to prepare the document.

Dated: November 4, 2022 COLE PEDROZA LLP

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Executed this fourth day of November 2022.

Freddi Lindsey

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/s/Freddi Lindsey

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Davenport, Cassidy (259340)

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