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Supreme Court of California
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Supreme Court No. S273887

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

MICHELLE HIMES,

Plaintiff-Petitioner,

vs.

SOMATICS, LLC,

Defendant-Respondent.

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

AMICUS CURIAE BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC.

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I.

ISSUES PRESENTED

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

II.

IDENTITY AND INTEREST OF AMICUS CURIAE

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers.[1] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the laws governing and influencing the liability of manufacturers of products and those in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred leading product litigation defense attorneys are

[1] A list of PLAC's corporate members can be found at https://plac.com/PLAC/Membership/Corporate_Membership.aspx.

sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 1,200 briefs as amicus curiae in state and federal courts, including this Court, on behalf of its members, while presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

PLAC's interest in this case stems from its concern over maintaining fair standards for causation, protecting the ability of prescription medical product manufacturers to improve and develop life-saving and pain ameliorating therapies, and preserving the key role of the learned intermediary doctrine in the delivery of beneficial therapies to those who need them. Plaintiff's positions in this case threaten all these interests.[2]

III.

INTRODUCTION/SUMMARY OF ARGUMENT

The Ninth Circuit Court of Appeals held that the learned intermediary doctrine ("LID") applied to Plaintiff Michelle Himes' failure-to-warn claim against Somatics, LLC. It also rejected her argument that she could establish proximate cause by proving that (1) her doctor would have "relayed" a stronger warning to her and (2) she then would have refused ECT treatment, even though her doctor recommended it and it was a treatment of last resort for her grave condition. *Himes v. Somatics, LLC*, 2022 WL

[2] No party or counsel for a party in this appeal, nor any other person or entity other than PLAC, its members, and its counsel, authored or funded this brief, in whole or in part. Cal. Rule of Ct. 8.520(f) (4), (5).

989469, *1, 3 & n.3 (9th Cir. Apr. 1, 2022). These issues have been finally resolved in federal court and are not legitimately at issue here, though Plaintiff continues to attempt to litigate them.

The Ninth Circuit has asked this Court to determine a single straightforward, controlling question of California law: whether causation in a failure-to-warn case involving a prescription medical product is established by the impact of the warning on the prescribing decision of the plaintiff's physician. Or alternatively, is the test whether (1) a better warning would have been communicated to the plaintiff, and (2) a reasonably prudent patient would have refused the treatment under the circumstances? *Himes v. Somatics, LLC*, 29 F.4th 1125 (9th Cir. 2022)

This Court accepted the certified question exactly as posed. Nevertheless, Plaintiff's briefing treats the certified question as a suggestion, a virtual afterthought, and seeks to re-litigate the issues finally resolved by the Ninth Circuit. The Court should ignore Plaintiff's entreaties and simply answer the question certified.

The Court should answer the certified question by adopting the causation standard congruent with the applicable duty standard – the LID requirement that manufacturers warn a plaintiff's prescribing physician, who stands in the shoes of the patient for purposes of a product liability failure-to-warn claim. Because the duty runs to the physician, rather than the patient, the causal nexus between a breach of that duty and the plaintiff's injury runs through the physician as well.

This standard is easy to reliably administer. At deposition

or trial, the physician, now fully apprised of the risk and armed with experience making prescribing decisions in light of it, can testify with some certainty how the additional risk information would (and did) impact his prescribing custom and practice. And this factual testimony can be tested on cross-examination.

In contrast, the alternative reasonably prudent patient standard is comparatively problematic. Because it is based on a counterfactual complex hypothetical, it adds an unacceptable layer of speculation and uncertainty. It asks the jury to guess about what a hypothetical patient under the circumstances would have done if given certain information in some manner. This speculation is a significantly less reliable method of factfinding and would create asymmetry between the physician-oriented duty analysis and the patient-oriented causation inquiry.

Most courts have found the physician-focused standard is sensible and workable and strikes an appropriate balance of applicable tort law policies. The proper standard is whether, had the manufacturer satisfied its duty, the physician would have declined to prescribe the therapy. That is the prevailing, well-reasoned rule, and it is the standard this Court should adopt.

Should the Court accept Plaintiff's invitation and reconsider the Ninth Circuit's uncertified holdings applying the LID and rejecting a subjective patient standard, it should adopt the Ninth Circuit's conclusions. Plaintiff's theory that the LID becomes inoperative in every failure-to-warn case would effectively abolish the doctrine. And endorsing a standard that allows causation to turn on the plaintiff's self-serving speculative, hypothetical,

hindsight testimony would lead to unreliable factfinding, operate as a virtually automatic bar to summary judgment, and emasculate the causation element of a failure-to-warn case. Weakening the causation guardrail, the bulwark between strict liability and absolute liability, would disturb the carefully crafted policy balance struck by this Court – a balance intended to regulate the scope of liability for the unavoidable side effects of prescription medical products and manage the burden of litigation on the development and availability of medical breakthroughs.

IV.

DISCUSSION

A. The Court Should Reject Plaintiff's Back Door Attack on the Learned Intermediary Doctrine

Although it's not reasonably encompassed within the certified question, Plaintiff (over)reaches out to mount a fundamental attack on the viability and availability of the LID. Plaintiff argues that because she alleges Somatics failed to adequately warn her doctor, (1) the LID ceases to operate, (2) the duty to warn then ran to her rather than her doctor, and (3) the causation issue should turn on whether the stronger warning she was allegedly owed would have convinced her to refuse treatment, rather than whether it would have convinced her doctor not to prescribe.

The Ninth Circuit found no basis for this position in California law, or logic, and unequivocally rejected it. *Himes,* 2022 WL 989469, at *1.

> As cases from our court and the Supreme Court of California make plain, even when warnings are

> assumed to be deficient, in the context of prescription products, the analysis always relies on the impact of a hypothetical stronger warning on the physician. [*See Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004); *Stevens v. Parke, Davis & Co.*, 9 Cal.3d 51, 67-69 (1973).] After all, because the adequacy of warnings is always challenged in failure-to-warn claims, "[i]f the learned intermediary doctrine became inapplicable when a plaintiff alleged ythat warnings were inadequate, the doctrine would never operate in California." *Sanchez v. Bos. Sci. Corp.,* 38 F. Supp. 3d 727, 734 (S.D. W. Va. 2014) (applying California law).

That logic is unassailable, and the issue is beyond the certified question. And yet, Plaintiff assails it.

The cases describe three reasons for the LID:

(1) Protecting the doctor-patient relationship: The doctor is "intended to be an intervening party" and the rule protects the doctor's independent medical judgment against interference by the manufacturer.

(2) Misunderstanding and danger: Unfiltered communication to a medically unsophisticated patient about the possible risks would be beyond the patient's capacity to understand and apply, resulting in unwarranted hesitation, potentially jeopardizing the patient's health, or even her life.

(3) Impossibility/Impracticality: "It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient."

Carmichael v. Reitz, 17 Cal.App.3d 958, 989 (1971) (quoting Rheingold, *Products Liability – The Ethical Drug Manufacturer's Liability*, 18 Rutgers L.Rev. 947, 987 (1964)).

Plaintiff's attack falters at the outset because she

misconceives the very nature of the LID, pervasively characterizing it as the "learned intermediary *defense*." It is not a "defense." Rather, it is simply a recognition that for reasons of policy and practicality described in cases like *Carmichael*, the prescription medical product manufacturer's warning obligation is directed to informing the physician rather than patient. It is a rule modifying the scope of the manufacturer's *duty* to warn in prescription medical product failure-to-warn cases. *Amiodarone Cases*, ___ Cal.Rptr.3d ___, 2022 WL 16646728, *6 (Cal. Ct. App. Nov. 3, 2022).

In *Amiodarone*, as here, the plaintiffs characterized the doctrine as a "defense," arguing it is an affirmative defense on which the defendant bears the burden of proof. The court disagreed; "[t]o the contrary, it has long been the law in California that the learned intermediary doctrine defines the scope of a manufacturer's duty to warn in the context of prescription drugs." *Id.*

Plaintiff argues that under existing precedent the "learned intermediary defense" is unavailable when "a device manufacturer … fails to provide adequate warnings to an intermediary." AOB 26.

This argument is based on a distorted reading of *Stevens v. Parke, Davis & Co.*, 9 Cal.3d 51, 65 (1973). *Stevens* did *not* hold that application of the LID depends on an adequate warning. Rather, relying on *Love v. Wolf*, 226 Cal.App.2d 378, 402 (1964) (also cited by Plaintiff), *Stevens* addressed whether the manufacturer had discharged its duty to adequately warn the

physician. It had not, as in *Love*, because its overly aggressive promotional activities to the medical community, including the prescribing doctor, had "watered down" the warnings. *Id.* at 65-66. *See Amiodarone,* 2022 WL 16646728, at *7.

Plaintiff's argument centers on language in *Stevens* and several other cases, including *Love*, *Brown v. Superior Court*, 44 Cal.3d 1049 (1988), and *Carmichael*, intended to succinctly explain the rule stemming from the LID. *See, e.g., Brown*, 44 Cal.3d at 1062 n.9 ("It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician."). Plaintiff argues from this and similar language that the cases "provide that a pharmaceutical manufacturer can only invoke the learned intermediary doctrine '*if* adequate warning of potential dangers of a drug has been given to doctors.'" AOB 31. Plaintiff unduly emphasizes the "if," claiming this language means that "*if* adequate warnings were not given to the intermediary, the defense is unavailable; any intermediary is, by definition, no longer 'learned.'" *Id.*[3]

To be sure, courts (including this one) have described the manufacturer's duty under the LID using different language. Some frame it in terms of the obligation, such as the manufacturer's duty is to provide an adequate warning to the

[3] Plaintiff mistakes "learned" for "informed." The licensed physician intermediary is "learned" *generally* by virtue of background, training, experience, and expertise; the intermediary is "informed" by keeping abreast of specific therapeutic information including, but not limited to, that supplied by the manufacturer, and staying abreast of the state-of-the-art in the medical literature.

physician. Others, like *Carmichael*, explain the duty in terms of what is required for its discharge, such as "the manufacturer will not be liable so long as it provides an adequate warning to the physician." There is no substantive difference among these linguistic formulations; the duty is the same, to adequately warn doctors, and the conditional "if" means only that its breach will subject the manufacturer to potential liability. Plaintiff's argument rests not on precedent, or logical reasoning, but solely on unreasonable semantic gymnastics. *See Amiodarone,* 2022 WL 16646728, at *7 (expressly rejecting plaintiffs' interpretation). Again, if Plaintiff's interpretation was correct, the LID would be a dead letter in California. *Himes*, 2022 WL 989469, at *1.

Plaintiff's theory goes one step further. She argues that the manufacturer loses the "protection" of the doctrine if it fails to adequately warn the doctor, and that its obligation then defaults to a duty to warn the patient directly.

First, the argument makes no sense from a structural standpoint. As noted, the doctrine defines the *duty* of a prescription medical product manufacturer to warn. Legal duties are inherently forward-looking. *See Johnson v. American Standard, Inc.*, 43 Cal.4th 56, 73-74 (2008) ("Legal duties must be based on objective general predictions … not case-by-case hindsight examinations ….). As such, duties cannot be made to vary based on post-performance events.

Put another way, legal duties are fixed and generalized; they are not shifting and fact-bound, and they cannot be re-defined retrospectively. But Plaintiff's theory would re-define the

manufacturer's duty based on the manufacturer's performance (or default), making the manufacturer's duty a moving target.

Moreover, because the manufacturer's duty would be limited to warning the physician *only if the warning is ultimately deemed adequate*, the LID would be impossible for the manufacturer to rely on. The nature of the warning required would therefore become as uncertain as Schrodinger's Cat. A warning adequate for physicians may be wholly unsuitable for a lay audience, which is why the FDA limits many drugs' availability as prescription-only.[4] But conditioning the LID on what a plaintiff *later* alleges, or what a jury *later* finds, long after the product is distributed, would as a practical matter force manufacturers to craft warnings at once suitable for both lay and professional audiences. *See Brown*, 44 Cal.3d at 1060 n.8 (holding that the adequacy of a warning is judged based on the date of the drug's distribution). This would gut a core reason for the LID – that the physician is needed to adapt and apply the risk information to the patient's situation and to translate the material risk and benefit information so the patient can understand it in real world terms, under their peculiar circumstances.

A duty to warn patients directly would also impair the quality of warnings. In clinical practice the physician is required to determine which warnings are worth bringing to the patient's attention, and determine how best to do so. *Cobbs v. Grant*, 8

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[4] This Court has recognized that the task of communicating effective warnings to consumers is very different than the task of warning physicians. *See Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal.4th 910, 930, 931, 935 (2004).

Cal.3d 229, 244 (1972). If, pursuant to Plaintiff's theory, this medical assessment may be bypassed and the patient must be warned directly, then the manufacturer would be compelled, as a practical matter, to warn the patient of even the most unlikely potential risks.

This Court has long recognized the mischief of overwarning, including the inevitable dilution of more important warnings, to no one's benefit. *E.g.*, *Johnson*, 43 Cal.4th at 70; *Finn v. G.D. Searle & Co.*, 35 Cal.3d 691, 701 (1984); *Carlin v. Superior Court*, 13 Cal.4th 1104, 1115-16 (1996); *Dowhal*, 32 Cal.4th at 931-32.[5] Indeed, in *Carlin* this Court relied on the intervention of the doctor under the LID to mitigate these concerns and temper the volume of warnings required, reasoning that the LID obviates the need to warn of risks "known to the medical community." *Id.* at 1116. Making the LID erasable after the fact would eliminate this limitation and threaten warning dilution.

For all these reasons, Plaintiff's disappearing doctrine theory makes no sense and would be patently unworkable and contrary to the public interest.

Finally, replacing the limited duty to warn the physician with a duty to warn the patient directly would compromise the

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[5] So does the FDA. "The [FDA] hierarchy of label information is designed to prevent overwarning so that less important information does not overshadow more important information. It is also designed to exclude exaggeration of risk, or inclusion of speculative or hypothetical risks, that could discourage appropriate use of a beneficial drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668, 1673 (2019) (cleaned up).

rationales and the public policy underlying the LID.

As the Court has repeatedly recognized over several decades, public policy strongly supports directing warnings to the physician, because the physician is able to exercise independent medical judgment to evaluate the risks and benefits of the therapy in light of the condition and circumstances of the patient – to individualize the risk information and perform a risk-benefit calculus on behalf of the patient. And the physician is in a far superior position to explain to the patient why the therapy is the right choice for their condition. The manufacturer is unable to effectively communicate directly with the patient. *See Plummer v. Lederle Laboratories*, 819 F.2d 349, 358 (2d Cir.1987), explaining that the duty to warn runs to the physician because

> as a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, and individualized medical judgment bottomed on a knowledge of both patient and palliative.

The court should follow the lead of the recent *Amiodarone* case, 2022 WL 16646728, where the court of appeal expressly rejected Plaintiff's theory and the notion that the manufacturer's duty can be transformed into an obligation to warn the patient directly.

> Thus, even when a plaintiff alleges that warnings to a physician were inadequate under California law the learned intermediary doctrine applies, and a manufacturer's duty is to warn the prescribing physician about dangers associated with

> the drug. … Plaintiffs have not demonstrated … that the absence of an adequate warning about a prescription drug to a physician somehow resulted in a duty to provide a warning to the patient. [*id.* at *7.]

Here as well.

In sum, the certified question involves the appropriate standard for *causation* in prescription medical product failure to warn cases; it does not call for any reexamination of the LID itself, a duty doctrine. There is no need for the Court to address Plaintiff's argument. But if the Court does decide to indulge Plaintiff's frolic and detour, it should reinforce the well-considered and firmly established LID as a firmament in California products liability law.[6]

B. The Prevailing Physician-Focused Causation Standard Is Consistent With the Learned Intermediary Doctrine and Has Proven to Be a Reliable and Workable Approach to Determining Cause-in-Fact in Failure-to-Warn Cases

1. The Physician-Focused Causation Standard in Prescription Product Cases Aligns With the Applicable Duty Standard Under the LID

Though Plaintiff seeks to paint a picture of wide disarray in the case law on the proper causation standard under the LID, even a brief survey of the law reveals that the courts have largely coalesced around a physician-focused causation standard. *See*, *e.g.*, *Plenger v. Alza Corp.*, 11 Cal.App.4th 349, 362 (1992) ("if the

[6] Plaintiff also goes beyond the certified question in asking the Court to issue an advisory opinion and hold that the manufacturer is precluded from arguing that the conduct of the physician is an intervening cause of the patient's injury. The Court should decline this request as well.

risk of death from untreated infection is universally known in the medical profession, the failure to warn the physician of that risk cannot be the legal cause of the decedent's death"); *Rosburg v. Minnesota Mining & Mfg. Co.*, 181 Cal.App.3d 726, 730 (1986) (no causation where "[i]t would have been too late for the physician to decide not to use the product"); *Wendell v. GlaxoSmithKline*, 858 F.3d 1227, 1238 (9th Cir. 2017) ("[A] product defect claim based on insufficient warnings cannot survive summary judgement if stronger warnings would not have altered the conduct of the prescribing physician.") (quoting *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004); *Id.* at 1239 (triable issue of fact existed as to whether the superior warning "would have changed [doctor's] prescribing practices as to [the patient]"); *Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 995-96 (C.D. Cal. 2001) (plaintiff's burden is "to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff"; quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 815 (5th Cir. 1992)); *id.*at 996 (because doctor did not read or rely on manufacturer's disclosures "the inclusion of adequate warnings in that information would not have affected his decision [to prescribe Zoloft].").[7]

[7] *See also Motus*, 196 F.Supp.2d at 997-98 (citing cases); J.Beck, *Don't Forget About A Prescribing Physician's Failure To Read Warnings*, https://www.druganddevicelawblog.com/2013/10/dont-forget-about-prescribing.html (accessed Nov. 16, 2022) (collecting numerous California law cases involving prescription medical products).

The widespread adoption of the standard is understandable, because it makes exquisite sense. Actual causation asks whether there is a factual and logical connection between what the defendant allegedly did wrong and what allegedly happened to the plaintiff – a dispassionate examination of whether there is a but-for connection between the breach of duty and the harm. *See Ramirez v. Plough, Inc.*, 6 Cal.4th 539, 556 (1993) (summary judgment warranted where the relative administering the non-prescription drug failed to read the label; the alleged deficiency in the label's risk disclosure had "no conceivable causal connection" to plaintiff's injury). *See also Ewing v. Cloverleaf Bowl*, 20 Cal.3d 389, 399 (1978) (recognizing the factual nature of the cause-in-fact analysis).

Focusing on the impact of the warning on the prescriber and his prescribing practices assures that the causation inquiry closely tracks the facts, and it limits the need to speculate. The prescriber likely prescribed the particular therapy for patients both before the plaintiff's unfortunate experience with it and afterward. The physician likely has actual clinical experience basing prescribing decisions on both the information that existed at the time of plaintiff's prescription and after the allegedly omitted risk information came to his attention. The physician-focused causation analysis therefore can take account of whether the additional risk information actually did change the physician's prescribing behavior, and if so, how and why. This enhances the reliability of the factfinding process.

Courts have appropriately recognized that given the

treating physician's fiduciary role in guiding the patient's treatment, it is the impact of the counter-factual, hypothetical warning on the doctor's recommendation of treatment that speaks most directly to evaluating the consequences of the omitted information. If the doctor failed to read, heed, or rely on the manufacturer's warnings; or was independently aware of the omitted risk; or would not have altered the prescription decision if the modified risk information had been brought to their attention, then it is quintessentially logical to conclude that the omission in the warnings lacked any significant role in bringing about the patient's injury. *See*, *e.g.*, *Plenger*, 11 Cal.App.4th at 362 (no causation where the risk was commonly known in the medical community or personally known to the physician); *Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89, 112 (2008) (failure of doctor to read or rely on manufacturer's disclosures defeated warning claim); *Motus*, 358 F.3d at 661and 196 F.Supp.2d at 996 (same); *Rosburg*, 181 Cal.App.3d at 730 ("no harm could have been caused by a failure to warn of a risk already known"); *Plummer,* 819 F.2d at 358 (JNOV required where doctor was aware of the risks of vaccine but as a matter of medical judgment and practice chose not to warn patients; therefore plaintiff failed to prove a stronger warning would have altered the doctor's conduct); *Gaghan v. Hoffman-LaRoche, Inc.*, 2014 WL 3798338, at *15 (N.J. App. Div. Aug. 4, 2014) (applying California law) (collecting cases and "conclud[ing] that California law focuses on the prescribing decision of the doctor as the learned intermediary"

much like other jurisdictions to consider the issue).[8] The physician-based approach to causation fits together well with the physician-based duty to warn, for a sensible assessment of the connection between breach of the duty and the connection to plaintiff's harm. There is no reason to jettison it.

2. The Physician-Focused Causation Standard Promotes Rather Than Denigrates Meaningful Patient Decision-Making and Autonomy

The bulk of Plaintiff's argument against the physician-focused standard is aspirational (and hyperbolic), urging that the prevailing standard gives short shrift to patient autonomy and licenses doctors to administer dangerous treatments against the patient's wishes.

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[8] These non-causative scenarios parallel similar results in non-physician, non-prescription product cases. *See*, *e.g.*, *Ramirez,* 6 Cal.4th at 556 (failure of layperson to read OTC drug label warranted summary judgment); *Huitt v. Southern Cal. Gas Co.*, 188 Cal.App.4th 1586, 1603 (2010) (inadequate warning not a substantial factor unless plaintiffs would have learned of the warning and altered their conduct as a result, thereby avoiding the injury); *Altman v. HO Sports Co.,* 821 F.Supp.2d 1178, 1188 (E.D. Cal. 2011) (failure to read warning defeats causation); *M.G. v. Bodum USA, Inc.*, 2021 WL 718839, *21 (N.D. Cal. Feb. 24, 2021) (same). *See generally Osborn v. Irwin Mem. Blood Bank*, 5 Cal.App.4th 234, 254 (1992) ("Ordinarily, of course, the actor's negligent conduct is not a substantial factor in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent") (cleaned up). In prescription medical product cases, however, the prescribing physician "stands in the shoes" of the plaintiff/patient because the latter relies on, and learns of the drug's properties and use from the physician. *Valentine v. Baxter Healthcare Corp.*, 68 Cal.App.4th 1467, 1483 (1999); *Carlin*, 13 Cal.4th at 1118.

> The overshadowing theme underlying Somatics' brief is a desire to create precedent which sacrifices patient autonomy and proclaims the wants of a physician are paramount to the choice and consent of the patient. [Reply Brief at 3]

See also AOB at 23 (physician-based standard "would require an unwarranted presumption that a doctor would have administered electroshock therapy to a patient against the patient's will").

Plaintiff's arguments exhibit a bracingly cynical distrust of physicians and both expressly and implicitly paints them as willing to disregard their oaths and their fiduciary obligations to their patients.[9] It also ignores other threads in the fabric of adjacent tort law that serve to protect patient autonomy. Plaintiff overlooks that other tort doctrines and professional ethics rules regulating the conduct of physicians support patients' autonomy and rights of bodily integrity. For example, professional licensing and disciplinary boards and the specter of tort claims for medical malpractice, lack of informed consent, and

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[9] Plaintiff's accusations that physicians' ethical obligations are routinely compromised by their financial ties to medical product manufacturers, AOB 44 n.11, are not worthy of comment. *See Salinero v. Johnson & Johnson*, 995 F.3d 959, 966, 969 (11th Cir. 2021) (rejecting similar argument). However, the rhetorical question posed in that footnote – how a claim could be allowed to "rise and fall upon the testimony of a single [financially interested] witness" – is, ironically, a good one to ponder when considering Plaintiff's ultimate position that summary judgment on causation should be defeatable based on a simple declaration by the plaintiff that she would have refused treatment with an adequate warning.

even battery, all require that physicians alert their patients to all material risk-benefit information and obtain their meaningful informed consent to prescribed treatment. *Cobbs*, 8 Cal.3d at 242-45. They all serve an important role in protecting the interests of patient autonomy; none of them are impacted by the product liability causation standard at issue. Plaintiff's autonomy argument artificially and misleadingly isolates the role of one component of one legal theory in product liability cases (causation in failure-to-warn claims).

Plaintiff's doomsday concerns are overwought, short-sighted, and misdirected. The primary drivers of legal policy in tort law are the general rules of tort duty, not the fact-bound, case-by-case determinations governing whether any breach of duty caused individual harm. Product liability law imposes a duty on manufacturers to inform the physician of the substantial risks arising from the therapy. Other legal rules regulate the behavior of physicians and require them to keep abreast of the medical literature and the state-of-the-art in scientific and medical knowledge surrounding their practices, to exercise independent medical judgment as fiduciaries to their patients, and to adequately inform patients of the anticipated benefits and substantial risks of proposed medical treatment. *In combination*, this *system* of obligations constructed by the courts, the legislature, and professional boards maximizes overall medical benefit for patients without imposing excessive burdens on manufacturers that might inhibit or impede the availability of critical therapies.

In sum, patient autonomy is more than sufficiently protected by the full array of relevant rules and doctrines. Though Plaintiff seeks to isolate the causation component of product liability failure-to-warn claims, the reality is that this narrow piece of the puzzle is not intended to do the heavy lifting on patient autonomy that Plaintiff chooses to assume for purposes of attacking what she sees as an unfavorable causation rule.

The prevailing causation standard is not the threat to patient autonomy that Plaintiff posits. If the physician is truly acting as a learned intermediary and consistent with professional obligations, then the material risks are brought to the patient's attention and any concerns can be ventilated, one on one, in a meaningful and irreplaceable dialogue with the doctor.

Indeed, properly viewed, the LID bolsters patient autonomy, and the real threat to patient autonomy is Plaintiff's campaign to nullify it and replace it with a direct duty to warn. The intervention of the learned intermediary is crucial to put risk information in its proper perspective for the patient and to allow the patient to make rational choices in their best interest rather than needlessly be self-dissuaded from needed or advantageous treatments by unrealistic and non-contextual fears. *See Bigler-Engler v. Breg, Inc.*, 7 Cal.App.5th 276, 319 (2017) ("Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in

his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life."). It is odd that Plaintiff seeks to undermine the LID, on one hand, and purports to champion patient autonomy, on the other, when the former serves to bolster the latter.

In sum, the Court should reject Plaintiff's effort to evade the prevailing standard. Current law is not broken; a wealth of courts and commentators have found it consistent with the policies and practices underlying the LID, logical and easy to apply. It supports rather than undermines patient autonomy. The Court should adopt the well-reasoned majority rule followed in California courtrooms for decades.

C. The Ninth Circuit's Alternative "Reasonably Prudent Patient" Causation Standard Would Compromise Reliability of Adjudication and Inject Excessive Speculation Into Causation Analysis

To be sure, the alternative reasonable prudent patient standard proffered by the Ninth Circuit is superior to the highly speculative and unreliable subjective standard that the Ninth Circuit rejected and Plaintiff advocates, as we discuss below. But this *objective* patient-oriented standard too would inject a problematic level of speculation and uncertainty in causation adjudications.[10]

While some uncertainty is unavoidable in any causation inquiry in failure-to-warn cases, it is axiomatic that tort law

[10] Though Plaintiff would be expected to prefer the objective patient-based standard to the existing physician-based standard – because it might allow her to avoid summary judgment – her briefing suggests antipathy for that standard. *See* AOB 62-65.

seeks to minimize the likelihood that cases will be decided based on speculation. *See, e.g., People v. Raley*, 2 Cal.4th 870, 891(1992) ("A reasonable inference …may not be based on … imagination, speculation, supposition, surmise, conjecture, or guess work. A finding of fact must be an inference drawn from evidence rather than … a mere speculation as to probabilities without evidence.") (quoting *People v. Morris*, 46 Cal.3d 1, 21 (1988)); *Sargon Enters., Inc. v. University of Southern Cal.*, 55 Cal.4th 747, 753 (2012) (holding that "the trial court has a duty to act as 'gatekeeper' to exclude speculative expert testimony" and enhance the reliability of adjudication); *Saelzler v. Advanced Group 400*, 25 Cal.4th 763, 774 (2001) (in premises liability security cases, "the plaintiff must establish, by nonspeculative evidence, some actual causal link between the plaintiff's injury and the defendant's failure to provide adequate security measures"); *Leslie G. v. Perry & Assocs.*, 43 Cal.App.4th 472, 483-84 (1996) ("it is axiomatic that an inference may not be based on suspicion alone, or on imagination, speculation, supposition, surmise, conjecture, or guess work."); *Jones v. Ortho Pharmaceuticals Corp.,* 163 Cal.App.3d 396, 402-404 (1985) (same, in the context of nonsuit; citizens must be protected "from the speculation of courts and juries").

This fidelity to evidence-based factfinding remains true no matter how difficult it may be to prove causation in certain cases. *See Rutherford v. Owens-Illinois, Inc.*, 16 Cal.4th 953, 977-78 (1997) (rejecting argument that burden to prove causation should be shifted, notwithstanding the difficulty of proving asbestos exposure caused a plaintiff's asbestos-related cancer); *Saelzler*, 25

Cal.4th at 779-80 (rejecting argument for burden shifting in premises security assault cases, and rejecting proposed objective, common sense/common experience standard to overcome the "virtual impossib[ility]" of proving causation in such cases); *Jones*, 163 Cal.App.3d at 403 (cancer causation); *Leslie G.,*43 Cal.App.4th at 487 (premises security assault cases; quoting *Jones*).

Of the two standards posed by the certified question, the reasonable prudent patient test depends on a significant level of speculation and is far more likely to produce unreliable results. The physician-based standard evaluates how the additional risk information, above and beyond the existing pool of information (including the physician's background, training and experience and the risk information acquired from all the various sources of information, such as clinical experience, literature, meetings, colleagues and manufacturers), impacts the physician's risk-benefit calculus in light of his established custom and practice. It is capable of evidence-based analysis of whether the new information truly makes a difference. Indeed, as discussed above, in many cases (perhaps most) the physician continues to prescribe the therapy at issue, and can base causation-related testimony not on hypothetical facts but on actual relevant clinical experience with prescribing the drug or device *after* learning of the new information.[11] This perspective serves to limit the

[11] As in this case, litigants routinely ask the doctor at deposition or trial whether the additional information has changed the doctor's willingness to prescribe the drug or the way he approaches prescribing it for patients.

degree of speculation inherent in answering the question, and provides the fact-finder with a solid factual foundation to evaluate whether the superior warning would have altered the physician's prescribing decision.

In contrast, the reasonable prudent patient standard fundamentally requires the jury to make a relatively abstract prediction of how a fictional lay individual would react to a hypothetical discussion with the physician. This standard necessarily injects a high degree of speculation into the adjudication process and makes the resulting finding less factual and less reliable. Since the overarching goal is to maximize the reliability of adjudications and make them evidence-based to protect defendants from the speculation of juries in the considerable heat of a personal injury trial laden with passion and sympathy, then the choice between the two standards is fairly clear.

This Court has previously rejected use of a hindsight objective "reasonable man" type standard to determine causation, in another tort context posing complex causation issues. In *Saelzler*, a premises liability case where the plaintiff sought to recover from the landowner for failure to adopt security measures that allegedly would have prevented criminal assault, the court of appeal adopted a "common sense and common experience" approach to assess causation. This Court reversed, holding that the causation issue must be resolved based on the evidence rather than resort to "common sense and common experience" – an objective standard overly susceptible to hindsight. The Court

reasoned that "if we simply relied on hindsight, the mere fact that a crime has occurred could always support the conclusion that the premises were inherently dangerous." 25 Cal.4th at 778. This was not a legitimate basis for decision-making.

That same concern is present in this context. Since the jury is deciding causation after the unwarned or under-warned risk has occurred and produced the plaintiff 's injury (from a medical causation perspective), any reasonable person tests poses an intolerable risk that the jury will indulge the temptation of hindsight to connect the omission in warnings to the result, whether or not the deficiency in the warning was a cause-in-fact based on the evidence. *See Huitt*, 188 Cal.App.4th at 1602 (trial court erroneously permitted the jury to bypass the causation issue by using "hindsight to conclude that plaintiffs would have acted differently if they had known of the [risk of] odor fade").

In sum, the reasonable prudent patient test is overly speculative and prone to the influence of hindsight and illegitimate causal inference. It is no substitute for an evidence-based standard focusing on what the actual prescriber actually does and would have done in prescribing the medicine, had the manufacturer provided the subject information.[12]

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[12] *Cobbs v. Grant*'s' adoption of a reasonable prudent patient type of standard is not inconsistent with *Saelzler* and does not suggest that such a test would be preferable. *Cobbs* did not involve the LID's physician-specific duty. In *Cobbs*, the Court had fewer options; dependence on the subjective hindsight view of the patient was not acceptable, and the physician-defendant was also tainted with self-interest. Indeed, *Cobbs* underscores the superiority of a standard that turns on what a relatively

D. The Court Should Decline Plaintiff's Request to Relitigate the Ninth Circuit's Rejection of Her Proposed Subjective Patient Causation Standard, or, Alternatively, Confirm the Ninth Circuit's Well-Reasoned Holding

The Ninth Circuit roundly rejected Plaintiff's argument that causation should turn on her own testimony as to whether she would have refused treatment if provided with the stronger warning – a warning which, in hindsight, referenced the very risk that Plaintiff claims she experienced. Even beyond the obviously self-serving nature of this testimony given the prospect of secondary gain, the Plaintiff's testimony is irremediably tainted by uncontrolled confirmation bias, conscious or subconscious, arising from the fact that the risk, however remote, actually came to pass, with what the plaintiff no doubt considers catastrophic consequences.

For similar reasons, the Ninth Circuit rejected Plaintiff's "contention that in establishing causation through warnings, the effect of a stronger warning on a patient could be determined through the patient's subjective post-hoc declaration." In explaining why that standard is problematic, the court invoked the similar concerns that drove this Court in *Cobbs* to reject a subjective post-hoc standard;

> Since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined treatment. Subjectively he may believe so, with the

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disinterested non-party, like the treating physician in a product liability case, would have done.

> 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. [*Himes*, 2022 WL 989469, at *3 n.3 (quoting *Cobbs*, 8 Cal.3d at 245)].

As speculative as the jury's job would be under the objective test identified in the certified question, the level of speculation required by the Plaintiff's subjective assessment of what she would have done is far greater. The risk information as actually relayed by a physician is not likely to be transmitted in its raw form, without filter, context, nuance, and bedside manner. The dialogue with the physician is a guided one.

The plaintiff's testimony about what she would have done if confronted with the isolated and unvarnished risk information is additionally speculative because it is unlikely to adequately account for the real world presentation by an experienced physician seeking to give the patient the big picture and explain the physician's risk-benefit assessment. If the risk is remote, and the need for the therapy is great, then the physician's presentation would presumably reflect that, but Plaintiff's testimony is unlikely to capture this critical context. [13] Consequently, it will bear little resemblance to the actual decision to be made in a real world setting, especially combined

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[13] The record reflects that this is precisely the case here. It appears that the ECT was a treatment of last resort for Plaintiff. Notwithstanding the redactions in the Respondent's Brief, it appears that Plaintiff's condition was grave and the therapeutic need was great. Indeed, whether these facts would even create a triable issue under the reasonable prudent patient test is doubtful, or at least debatable. *See* RB at 60 & n.23.

with Plaintiff's hindsight bias. Plaintiff's answer to the causation question posed under the subjective standard– even if she subjectively believed it to be accurate – cannot be considered reliable.

Nevertheless, Plaintiff attempts to dress up her proposed subjective standard by arguing that "California courts have routinely allowed plaintiffs to establish causation by providing 'self-serving' testimony as to how they would have altered their conduct in failure to warn cases." Plaintiff cites but a single outlier case, *Colombo v. BRP US Inc.*, 230 Cal.App.4th 1442, 1454 (2014), and adds parenthetically "(collecting cases)." AOB 63. Plaintiff distorts *Colombo* and dramatically exaggerates the support it truly offers. *Colombo* is an exceedingly thin reed; it provides little, if any, support for Plaintiff's position.

Colombo, decided under federal maritime law, not California law,[14] involved serious injuries sustained when passengers fell off a jet ski into the forceful thrust stream. The plaintiffs testified – *without objection* – that they would have read and heeded a better warning by either wearing protective clothing or declining to ride.

Defendant's appeal did not challenge instructions that expressly told the jury they could consider plaintiffs' testimony in deciding whether the jet ski's warnings were defective and whether "the inadequate warnings or instructions were a

[14] Federal maritime law differs from California tort law in that is applied with a "special solicitude" for injured plaintiffs. *Air & Liquid Sys. Corp. v. DeVries*, 139 S.Ct. 986, 995 (2019); *American Export Lines, Inc. v. Alvez*, 446 U.S. 274, 285 (1980).

substantial factor in causing [plaintiffs'] harm." 230 Cal.App.4th at 1454.

On appeal, defendants challenged the causation finding as unsupported by substantial evidence and, notwithstanding their failure to preserve the issue, apparently tried to challenge the admissibility of the plaintiffs' testimony. The court first noted that defendant had forfeited any challenge to the admissibility of the evidence, but then observed, without analysis, that the evidence was in any event, properly admitted "as it is" substantial evidence supporting the causation finding of the jury. *Id.* at 1454. It went on to conclude that the causation verdict was also independently supported by additional substantial evidence in the form of testimony from a warnings expert. *Id.* at 1454-55.

Thus, the court did not hold that a plaintiff's testimony about what they would have done in response to a hypothetical warning is admissible, nor whether it alone would satisfy the plaintiff's burden of proving causation. Indeed, there was no discussion whatsoever of any admissibility objections at all. At most, the court suggested in dicta that the testimony was substantial evidence of causation.

Not surprisingly, *Colombo* has never been cited for the proposition that subjective warnings causation testimony from a plaintiff about what they would have done if confronted with a stronger warning is admissible, or substantial evidence.

As for the "collection of cases" purportedly considered in the opinion, the court actually

- cited one case for the proposition that the evidentiary argument was forfeited, *id.* at 1454;
- cited one case for the definition of substantial evidence, *id.* at 1454-55;
- cited one case for the standard of review applicable to a substantial evidence challenge, *id.* at 1455-56; and
- cited one case, *Bunch v. Hoffinger Industries, Inc.*, 123 Cal.App.4th 1278, 1304 (2004), that involved a plaintiff's testimony about the impact of a hypothetical warning.

Nor does *Bunch* provide any support for Plaintiff's argument. In *Bunch*, an 11 year old child became quadriplegic after suffering a spinal cord injury diving into a backyard pool. She testified, apparently without objection, that an exemplar warning label would have prevented her from taking the fateful dive. Two expert witnesses testified in support of her warning causation claim as well. *The court did not consider the admissibility of the plaintiff's testimony*. It simply held that plaintiff had produced sufficient evidence to support the jury's finding that the design and/or warning defects were a substantial factor in causing the injury.

Plaintiff cites no case actually holding that a plaintiff's speculative self-serving testimony that a better warning would have altered her behavior, is admissible, or even any case substantively discussing the issue. And she puts more weight on the one case she does rely on, *Colombo*, than it can possibly carry.

In contrast, myriad cases around the country have squarely

held that a plaintiff's testimony as to what he would have done under hypothetical circumstances is inadmissible as speculative, self-serving, lay opinion testimony. *See*, *e.g.*, *Magoffe v. JLG Indus., Inc.*, 375 F.App'x 848, 859 (10th Cir. 2010) (plaintiff's affidavit "statement that a hypothetical warning would have prevented the accident" inadmissible as improper lay opinion because his "speculation as to what he would have done is not based on his first-hand perception of actual events"); *Wilson v. Bradlees of New England, Inc.,* 250 F.3d 10, 15 n.8 (1st Cir. 2001) (testimony that a warning label would have changed the witness's behavior was properly excluded as speculative); *Washington v. Department of Transp.*, 8 F.3d 296, 300 (5th Cir. 1993) (co-worker's testimony as to what he would have done had he seen a warning label properly excluded as self-serving speculation); *Kloepfer v. Honda Motor Co.*, 898 F.2d 1452, 1459 (10th Cir. 1990) (plaintiff's mother's testimony that if given a proper warning about danger of ATV she would have refused to allow her son to ride it was properly excluded as speculative and self-serving and improper lay opinion); *Hardie v. Cotter & Co.*, 849 F.2d 1097, 1101 (8th Cir. 1988) ("Speculation regarding what Livingston might have done had the situation been different had no relevance to the issues presented in the case, and was properly excluded."); *Elyria-Lorain Broad Co. v. Lorain J Co.*, 298 F.2d 356, 360 (6th Cir. 1961) ("a witness may not testify to what he would have done had the situation been different from what it actually was" as "[s]uch an answer is too speculative to be admissible").

There are many other cases to the same effect[15], and a

[15] *E.g.*, *M.W. v. Ford Motor Co.*, 2016 WL 7220107, *9-10 (M.D. Fla. Apr. 27, 2016) ("As multiple courts have held when faced with this exact situation, a lay witness's testimony concerning what they *would have done* had a defendant provided a warning is speculative and is not based on that witness's perception.") (emphasis in original); *Howard v. Offshore Liftboat, LLC*, 2016 WL 316716, *4 (E.D. La. Jan. 26, 2016) ("Captain Lawrence may not speculate or give his opinion with respect to how his actions, or the actions of other individuals involved in the incident, would have been different under different factual scenarios"); *Drake v. R.J. Reynolds Tobacco Co.*, 2015 WL 12746105, *1 (S.D. Fla. Jan. 29, 2015) ("opinions from lay witnesses regarding what they would have done under different circumstances would be speculative testimony not rationally based on the witness's perception, and should be excluded"); *Brim v. Midland Credit Mgmt., Inc.*, 795 F.Supp.2d 1255, 1268 (N.D. Ala. 2011) ("A witness's opinion about an event that did not occur is mere speculation."); *Alfano v. BRP, Inc.*, 2010 WL 2202265, *3 (E.D. Cal. June 4, 2010) (in a jet ski case, plaintiff's "testimony that she would have acted a certain way or heeded the warning had it ben adequate is inadmissible as it is too speculative and self-serving"); *Athridge v. Aetna Cas. & Sur. Co.*, 474 F.Supp.2d 102, 105 (D.D.C. 2007) ("speculative testimony as to what a witness would have done under different circumstances cannot possibly be based on the witness's perception."); *Nevada Power Co. v. Monsanto Co.*, 891 F. Supp. 1406, 1415-16 (D. Nev. 1995) (CEO's testimony that the company would have acted differently in purchasing defendant's PCBs if warned about their toxicity, i.e., how it "might have acted under a different set of facts," correctly excluded as speculative, self-serving, improper lay opinion testimony and insufficient to create a triable issue of fact on reliance element of claim for fraud); *Van Dike v. AMF, Inc.*, 379 N.W.2d 412, 415 (Mich. Ct. App. 1985) (plaintiff's testimony that a better warning would have grabbed his attention was improper lay opinion testimony because not rationally based on his perceptions); *Arnold v. Ingersoll-Rand Co.*, 908 S.W.2d 757, 763 (Mo. Ct. App. 1995) (plaintiff may not "speculate about his conduct on different facts" or offer lay opinion of "what he

smattering of cases that go another way. The point of citing these cases is not to demonstrate that Plaintiff's testimony in this case that she would have refused ECT treatment is inadmissible, which is not before this Court, nor the Ninth Circuit. Rather, the point is that this type of evidence is oft-recognized as speculative and unreliable, and – as suggested by this Court in *Cobbs* and the Ninth Circuit in this case – would be a poor, speculative and unreliable basis for a jury's causation finding, and even more so as a standard for proving causation. Current law should not be changed to increase reliance on this type of testimony.

Finally, this Court has recognized that the rules governing the liability of prescription medical product manufacturers must be sensitive to public policy implications impacting the costs and burdens of bringing therapeutic medical products to market and making them available and accessible to those who need them. *See Carlin*, 13 Cal.4th at 1111; *Brown*, 44 Cal.3d at 1058-65, 1067-68. Plaintiff ignores the obvious impact her proposed subjective standard would impose on the industry. Adoption of the standard would essentially give plaintiffs in these cases a heckler's veto over summary judgment motions.[16] Limiting the chances for manufacturers to avoid trials where causation

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believed he would have done in a hypothetical situation"; such testimony "is speculative and immaterial").

[16] *See Saelzler*, 25 Cal.4th at 778 (observing that the Court "hesitate[s} to adopt a rule … that seemingly would prevent summary judgment on the causation issue in every case in which the defendant failed to adopt increased security measures of some kind").

appears lacking and increasing the likelihood of adverse trial verdicts would add considerably to the costs of defense and the toll of judgments, limiting resources and incentives to pursue innovative medical breakthroughs. In decisions like *Brown* and *Carlin* the Court has carefully balanced the competing interests in fairly compensating plaintiffs injured by failure to warn of side effects of prescription drugs and devices without imposing unwarranted and excessive burdens on the manufacturers we depend on to discover and develop new therapies that prolong life and ease suffering, and maintain make sure the availability and affordability of existing beneficial therapies.

Skewing the balance by making failure-to-warn claims virtually summary judgment-proof would disturb the balance, contrary to the public interest.

Accordingly, if the Court decides to entertain this uncertified issue already resolved by the Ninth Circuit, it should adopt the Ninth Circuit's holding and reject the subjective standard as problematic.

V.

CONCLUSION

The Court should answer the certified question, and not second-guess the uncertified holdings of the Ninth Circuit that Plaintiff continues to litigate.

For the foregoing reasons, the Court should adopt the long-standing majority rule and continue to determine the causation issue in prescription medical product failure-to-warn claims by reference to the physician's prescription decision, consistent with

the learned intermediary doctrine and its underlying policies.

Dated: November 18, 2022

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/s/ Alan J. Lazarus

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/s/Alan Lazarus

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