S273887

IN THE SUPREME COURT 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 Question of California Law

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APPLICATION BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF SOMATICS, LLC

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November 18, 2022

Attorneys for Amicus Curiae Pharmaceutical Research and Manufacturers of America

Pursuant to Appellate Rule 8.520(f), the Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully seeks leave to file the accompanying *amicus curiae* brief in support of Respondent Somatics, LLC.[1]

PhRMA is a voluntary, nonprofit association comprised of the leading biopharmaceutical research and technology companies. PhRMA members produce innovative medicines, treatments, and vaccines that save and improve the lives of countless individuals every day. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new cures and treatments, including $102.3 billion in 2021 alone. *See* PhRMA, *2022 PhRMA Annual Membership Survey* 3 tbl. 1 (2022), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA_membership-survey_2022_final.pdf. PhRMA advocates in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines.

The issues this case presents directly implicate PhRMA's patient-centered agenda. For decades, courts in California and around the nation have determined that patients benefit from a liability regime that requires appropriate warnings to medically-

[1] No party's counsel authored this brief in whole or in part. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than amicus curiae, its members, or its counsel made such a monetary contribution.

trained professionals, who can then tailor warnings to their individual patients and address questions their patients have about those warnings. This is so because lay patients lack the medical training required to fully understand and apply complex information communicated in pharmaceutical labeling, and pharmaceutical manufacturers lack the ability to tailor that information based on a specific patient's medical history and needs. The undoing of the learned intermediary doctrine that Appellant urges here could create a perverse incentive for companies to flood patients with warnings more effectively conveyed through physicians able to understand the complex medical aspects of treatments and provide personalized care. PhRMA believes its views will assist the Court in resolving this case by providing a unique perspective on the practical implications of Appellant's position.

Respectfully submitted,

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PROOF OF SERVICE

I, Mark S. Shuttlesworth, am a resident of the State of California and over the age of 18 years. Neither I, nor my client, the Pharmaceutical Research and Manufacturers of America, are a party to this action. My business address is Covington & Burling LLP, 1999 Avenue of the Stars, Los Angeles, CA 90067.

On November 18, 2022, I caused the following document entitled:

> APPLICATION BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF SOMATICS, LLC.

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I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed in Los Angeles, California, November 18, 2022.

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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Pursuant to Appellate Rule 8.208, the Pharmaceutical Research and Manufacturers of America ("PhRMA") states that it is a trade association with no parent corporations. No entity or person has a 10% or greater ownership interest in PhRMA. PhRMA does not know of any person or entity, other than the parties themselves, that has a financial or other interest in the outcome of the proceeding that the justices should consider in determining whether to disqualify themselves. A list of PhRMA's member companies can be found at http://www.phrma.org/about.

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SUMMARY OF ARGUMENT

Prescription medicines and devices are unlike any other product in the United States. A patient can only use a prescription medicine or device if a state-licensed prescriber, exercising medical judgment and obtaining informed consent from the patient, determines that the patient should use the product. Because all prescription medicines and devices have risks that are counterbalanced by their benefits, every state's tort law hinges liability in pharmaceutical product liability cases on the adequacy of the warnings provided. And because a patient can only obtain a prescription medicine or device from a state-licensed prescriber, every state recognizes the learned intermediary doctrine. Under this doctrine, the adequacy of a pharmaceutical product's warnings is measured by the warnings *to the prescriber*, who is best positioned to evaluate the complex scientific data for the medicine or device and determine whether the potential benefits outweigh the risks for a particular patient.

Appellant urges the Court to adopt an exception to the learned intermediary doctrine so broad that it would swallow the rule. According to Appellant, "when the device manufacturer fails to warn the intermediary"—a necessary allegation in every failure-to-warn case involving a prescription medicine or device—California courts should instead evaluate whether the manufacturer "warn[ed] the consumer/patient directly." Appellant's Br. 22. This Court should reject Appellant's request to effectively abrogate California's long-settled learned intermediary doctrine, an issue that is not even properly before this Court.

In light of the rationale for the learned intermediary doctrine—that prescription medicines and devices can only be safely administered under the care of a licensed medical professional—this Court should additionally join numerous courts in holding that the relevant inquiry under the learned intermediary doctrine is whether the prescriber would have altered her decision to prescribe the medicine or device to her patient if presented with additional warnings. Focusing instead on whether the physician would have had a different discussion with her patient could induce manufacturers to shield themselves from liability by directing physicians to flood their patients with an onslaught of exhaustive, untailored warnings about every conceivable risk. This over-warning would ultimately harm patients. Inundated with the same level of technical and scientific information as her physician, but without the expertise to understand and evaluate it, an untrained patient may mistakenly overestimate certain risks and underrate others, leading her to second-guess her doctor's prescription choices that would ultimately be most salutary to her health. Because a physician knows the specific needs and susceptibilities of each patient, she can tailor a warning to include the appropriate information, while omitting conditions irrelevant to that patient, and be available to answer a patient's questions directly about the complex medical information presented.

ARGUMENT

I. The Learned Intermediary Doctrine Recognizes the Unique Judgment that Trained Physicians Necessarily Bring to Bear in Prescribing Treatments to Patients

California, like every other state in the nation, has adopted the learned intermediary doctrine for prescription medicines and devices. *See Dearinger v. Eli Lilly & Co.*, 510 P.3d 326, 329 (Wash. 2022) ("Every state in the country, along with the District of Columbia and Puerto Rico, has adopted the learned intermediary doctrine in some iteration."). Adopted initially in California in *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973), the doctrine holds that "the duty to warn runs *to the physician*, not to the patient," *Carlin v. Super. Ct.*, 920 P.2d 1347, 1354 (Cal. 1996). The doctrine follows necessarily from California's (and every other state's) requirement that patients must obtain prescription medicines and devices from a state-licensed prescriber who is able to understand and individually communicate to a patient the complex risks and benefits of a given treatment and secure the patient's informed consent. As this Court recognized in *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988), "a patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties." *See also Webb v. Special Elec. Co.*, 370 P.3d 1022, 1034 n.10 (Cal. 2016) (learned intermediary doctrine applies to medical devices "supplied in the context of the doctor-patient relationship").

A. The Learned Intermediary Doctrine Reflects the Federal and State Regulatory Schemes for Prescription Medicines and Devices

The learned intermediary doctrine flows naturally and directly from state and federal restrictions on how patients may obtain prescription medicines and devices. Federal law defines prescription medicines and devices as those which can safely be used only under the care of a duly-licensed medical professional. *See* 21 U.S.C. § 353(b)(1)(A) (prescription drug is one that "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug"); 21 C.F.R. § 801.109 ("prescription device[]" is "[a] device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device").[1]

Reflecting FDA's informed judgment that prescription medicines and devices are safe for use only with the involvement of a trained medical professional, California (and every other state) allows patients to obtain prescription medicines and

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[1] Electroconvulsive therapy (ECT) devices like the Thymatron device manufactured by Somatics were designated by FDA as "prescription device[s]" in 2018. *See* 21 C.F.R. § 882.5940(a). Long before that designation, the State of California declared in 1989 that ECT could be conducted only by physicians pursuant to a plan of treatment approved by a committee of at least two additional physicians. *See* Cal. Code Regs. tit. 17, §§ 50830–50835.

devices only with a prescription from a state-licensed prescriber. *See T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18, 38 (Cal. 2017) ("A consumer may obtain a prescription medication only through the physician as a learned intermediary."); Cal. Health & Safety Code §§ 110010.1, 111470 (prescription device "shall be sold only upon a written prescription of a practitioner licensed by law to prescribe the . . . device").

The legal regime attendant to prescription medicines and devices thus requires the close involvement of a medical professional. That involvement in turn affects the warnings that must be provided for a prescription medicine or device. The FDA-approved prescribing information for a medicine must include eighteen categories of scientific information. *See* 21 C.F.R. § 201.57(c). This detailed medical information is "written for the health care practitioner audience"—not the general public. FDA Requirements on Content and Format of Labeling for Prescription Drugs, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006).[2] Similarly, prescription device labeling must disclose to practitioners "any relevant hazards, contraindications, side effects, and precautions under which *practitioners licensed by law*

[2] FDA sometimes employs patient-directed warnings on a medicine-by-medicine basis, but even then, it does so as an express complement to physician warnings, not as a replacement for them. *See* Final Rule, Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,386 (Dec. 1, 1998) ("FDA agrees that health care providers should be the primary source of information about medications for their patients. The purpose of written information is to reinforce and supplement, not to interfere with, the doctor-patient relationship.").

to administer the device can use the device safely." 21 C.F.R. § 801.109(c) (emphasis added).

In short, both federal and state law provide that medically-trained prescribers are necessary to understand and properly communicate warnings about potential medical risks to patients. In carrying out this responsibility, prescribers must draw upon their understanding of medical science, their experience, and their professional judgment to weigh the potential risks and benefits of a particular treatment for each individual patient. By requiring adequate warnings to prescribers, the learned intermediary doctrine effectuates federal and state law allowing patients to obtain prescription medicines and devices only through a trained professional.

B. Appellant's Recasting of the Learned Intermediary Doctrine Would Write It Out of Existence

Appellant attempts to gut the learned intermediary doctrine by framing it as a "defense" that applies only "*if* a manufacturer provides adequate warnings to a patient's doctor." Appellant's Br. 28. As the Ninth Circuit rightly recognized in rejecting this interpretation of the doctrine, "because the adequacy of warnings is always challenged in failure-to-warn claims, 'if the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California.'" *Himes v. Somatics, LLC*, No. 21-55517, 2022 WL 989469, at *1 (9th Cir. Apr. 1, 2022) (quoting *Sanchez v. Bos. Sci. Corp.*, 38 F. Supp. 3d 727, 734 (S.D. W. Va. 2014)). Indeed, the California Court of Appeal rejected

this same argument earlier this month. *In re Amiodarone Cases*, Nos. A161023, A161762, 2022 WL 16646728, at *7, __ Cal. Rptr. 3d __ (Ct. App. Nov. 3, 2022) ("Plaintiffs have not demonstrated that the learned intermediary doctrine somehow does not apply when plaintiffs allege that the warnings to physicians are inadequate. Nor that the absence of an adequate warning about a prescription drug to a physician somehow results in a duty to provide a warning to the patient." (citation omitted)).

In reality, the learned intermediary doctrine is neither a defense nor contingent on a pharmaceutical manufacturer making a particular showing. Instead, the doctrine specifies to whom the duty to warn is owed: "the physician, not . . . the patient." *Carlin*, 920 P.2d at 1354; *see also Amiodarone Cases*, 2022 WL 16646728, at *6 ("We are not aware of any California decision that characterizes the learned intermediary doctrine as an affirmative defense. To 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."). "The learned intermediary doctrine within the prescription drug context is not a common-law affirmative defense. . . . While the learned intermediary doctrine shifts the manufacturer's duty to warn the end user to the intermediary, it does not shift the plaintiff's basic burden of proof." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 164–66 (Tex. 2012); *see also, e.g.*, *Heinrich v. Ethicon, Inc.*, 455 F. Supp. 3d 968, 974 (D. Nev. 2020) (learned intermediary doctrine "defines the scope of the defendants' liability" and is not "an affirmative defense"). And

the doctrine applies whenever "drugs or medical devices are supplied in the context of the doctor-patient relationship," *Webb*, 370 P.3d at 1035 n.10, "even when a plaintiff alleges that warnings to a physician were inadequate," *Amiodarone Cases*, 2022 WL 16646728, at *7.

Properly understood, the learned intermediary doctrine does not "shield[]" or "immuni[ze]" manufacturers from the need to provide appropriate warnings. Appellant's Br. 32; Appellant's Reply Br. 19; *see, e.g*, *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 949 (Ariz. 2016) ("Contrary to [plaintiff's] assertion, the [learned intermediary doctrine] does not create a blanket immunity for pharmaceutical manufacturers."); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) ("[T]he learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician."). Instead, it requires manufacturers to give those warnings to the prescriber responsible for determining whether a patient can use a prescription medicine or device. Where manufacturers do not adequately warn prescribers of "known or reasonably knowable" risks, they breach their duty, and liability may attach—subject to a plaintiff proving the remaining legal elements of her claim. *Brown*, 751 P.2d at 483 n.12; *see also, e.g.*, *Watts*, 365 P.3d at 949 (if duty to warn physician is breached, "a patient could sue and directly recover from a drug manufacturer based on its failure to properly warn the prescribing physician"); *Amiodarone Cases*, 2022 WL 16646728, at *6 ("Warnings directly to patients do not enter the picture.").

Appellant next misstates California law to claim that if a manufacturer does not adequately warn prescribers, it matters not whether the plaintiff's prescriber would have heeded an adequate warning. Appellant's Br. 43 (declaring irrelevant "whether the intermediary would have read the warning or what if anything the intermediary might have done had he or she been warned"). Appellant's argument is a not-so-veiled attack on the basic tort requirement of proximate causation, an evidentiary burden that Appellant deems too "onerous." *Compare* Appellant's Reply Br. 32, *with, e.g.*, *Webb*, 370 P.3d at 1030 (requiring proof that "the absence of a warning caused the plaintiff's injury"); *O'Neil v. Crane Co.*, 266 P.3d 987, 997 (Cal. 2012) ("Typically, under California law, we hold manufacturers strictly liable for injuries *caused by* their failure to warn . . . ." (emphasis added)).

By definition, if a physician never read the warnings accompanying a prescription medicine or device, a stronger warning could not have influenced the physician's conduct, and any lack of necessary warning could not have proximately caused the patient's injury.[3] This Court has therefore found causation

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[3] Contrary to Appellant's assertion, California does not presume that a physician would have heeded an adequate warning. *See Huitt v. S. Cal. Gas Co.*, 116 Cal. Rptr. 3d 453, 467 (Ct. App. 2010) (heeding presumption "is not recognized in California"); *Yamaha Rhino Litig.*, No. G052182, 2017 WL 4684618, at *17 (Cal. Ct. App. Oct. 19, 2017) (same); *Corbo v. Taylor-Dunn Mfg. Co.*, No. A135393, 2014 WL 576268, at *13 (Cal. Ct. App. Feb. 14, 2014) ("California does not recognize the heeding presumption."); *Johnson v. Johnson & Johnson*, No. B211123, 2010 WL 4108429, at *13 (Cal. Ct. App. Oct. 20, 2010) ("Although several states

lacking under these exact circumstances. *See Ramirez v. Plough, Inc.*, 863 P.2d 167, 177 (Cal. 1993) ("Plaintiff's mother, who administered the [over-the-counter medicine] to plaintiff, neither read nor obtained translation of the product labeling. Thus, there is no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury."); *see also, e.g.*, *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 319 (Ct. App. 2008) ("There can be no proximate cause where, as in this case, the prescribing physician did not read or rely upon the allegedly inadequate warnings promulgated by a defendant about a product.").[4]

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have adopted this presumption, California has not."); *Lord v. Smithkline Beecham Corp.*, No. B192452, 2007 WL 4418019, at *3 (Cal. Ct. App. Dec. 19, 2007) ("No California court has adopted the heeding presumption in a failure-to-warn case."). Indeed, neither of the cases that Appellant cites involved failure-to-warn claims at all. *See Grinnell v. Charles Pfizer & Co.*, 79 Cal. Rptr. 369 (Ct. App. 1969) (warranty claim); *Toole v. Richardson-Merrell Inc.*, 60 Cal. Rptr. 398 (Ct. App. 1967) (fraud and express warranty claims). Even in the minority of states that do recognize a heeding presumption, that rebuttable presumption is overcome by testimony that a different warning would not have affected the physician's decisionmaking (*e.g.*, because the physician never read the label). *E.g.*, *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 763 (Mo. 2011); *Coffman v. Keene Corp.*, 628 A.2d 710, 720 (N.J. 1993).

[4] Appellant's reply brief goes even further in distorting California's requirements for an adequate warning, suggesting that warning of the precise risk alleged in the product's labeling might not suffice to defeat a failure-to-warn claim, and that instead a manufacturer must reiterate warnings through "more effective means of communications" like "medical literature, dear doctor letters, conferences and other modes that doctors rely upon

C. This Court Should Not Announce a Major Doctrinal Shift on a Question that Was Not Posed to It

Appellant seeks to use California's process for certifying questions from a federal court to upend deeply-established law and make California an extreme outlier in embracing the learned intermediary doctrine in name only. "[A] court should be reluctant to overrule precedent and should do so only for good reason." *Bourhis v. Lord*, 295 P.3d 895, 899–900 (Cal. 2013). There is no reason to revisit the learned intermediary doctrine, the justifications for which have not been eroded since this Court adopted it a half century ago, particularly when the continued viability of the learned intermediary doctrine was not certified to this Court.

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to learn of risks." Appellant's Reply Br. 36. No California case stands for this radical proposition. *Compare Dash v. Roche Lab'ys*, 74 F.3d 1245 (9th Cir. 1996) (unpublished table decision) ("Roche's package insert and [patient information] brochure clearly and explicitly warned Dash's physician of the risk that the use of Accutane might result in a persistent or permanent dry eye condition. We conclude this warning was adequate as a matter of law."); *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1163 (E.D. Cal. 2019) ("These warnings [in the FDA label] are clear, do not appear to be inconspicuous, and appear to warn of the exact danger that tragically befell Mrs. Marroquin. Without elucidation from Marroquin, the warning is adequate."); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 673 (S.D.N.Y. 2017) (holding under California law that "the warnings given on the Eliquis label were, as a matter of law, sufficient to warn of the risks associated with excessive bleeding"); *In re Accutane Prods. Liab.*, No. 8:04-MD-2523, 2014 WL 7896548, at *4 (M.D. Fla. Sept. 23, 2014) (holding under California law that warnings were adequate because "[t]he Physician Package Insert plainly and prominently identified" the risk).

In re-affirming the learned intermediary doctrine as law in California, *Brown* cited approvingly two Court of Appeal decisions, *Fogo v. Cutter Laboratories, Inc.*, 137 Cal. Rptr. 417 (Ct. App. 1977), and *Carmichael v. Reitz*, 95 Cal. Rptr. 381 (Ct. App. 1971), which set forth three rationales for the rule that there is "no duty to warn the patient." *Fogo*, 137 Cal. Rptr. at 423; *Carmichael*, 95 Cal. Rptr. at 400–01.

- *First*, in writing a prescription for a patient, "[m]edical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor." *Id.*
- *Second*, "[w]ere 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." *Id.*
- *Third*, "[i]t 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." *Id.*

Put together, these rationales reflect that physicians are both the only means through which a patient can obtain prescription medicines and devices, and the best conduit for individually-tailored and comprehensible warnings about those products. *See also Dearinger*, 510 P.2d at 331 ("The overarching policy behind the learned intermediary doctrine is relying on a physician's expertise—*i.e.*, acknowledging that a physician is in the best place to understand both the drug and the patient's medical history. . . . This rationale can be broken into four parts:

(1) physicians exercise independent judgment, (2) patients primarily rely on a physician's independent judgment, (3) the physician decides what facts should be told to the patient, and (4) it is difficult for a manufacturer to communicate directly with the consumer.").

Those rationales remain as true today as they were five decades ago. *See id.* ("[T]he policies underpinning the learned intermediary doctrine remain true today."); *Centocor*, 372 S.W.3d at 158 ("The underlying rationale for the validity of the learned intermediary doctrine remains just as viable today as stated by Judge Wisdom in 1974."). A patient today still must obtain a prescription medicine or device through a state-licensed prescriber, who still is best situated to evaluate the nuanced scientific information necessary for the safe use of the product and to effectively convey the most important information to lay patients. Accordingly, there is no basis to cast aside the universally-applied common-law rule that a manufacturer's liability should be measured by evaluating the adequacy of warnings to medical professionals.

In any event, the Court need not address the continued viability of the learned intermediary doctrine because that question is not properly before it. The Ninth Circuit did not seek this Court's guidance on whether the learned intermediary doctrine applies to prescription medicines or devices. Accordingly, this Court did not grant certification over whether warnings are owed to physicians versus patients. Nor would certification of that question have been appropriate under

California Court Rule 8.548(a)(2) because "controlling precedent" exists on that topic: "[I]n the case of prescription drugs, the duty to warn runs to the physician, not to the patient." *Carlin*, 920 P.2d at 1354; *see also Webb*, 370 P.3d at 1035 (extending doctrine to prescription devices).

Instead, the Court granted certification of the question of *what* the learned intermediary doctrine requires vis-à-vis the physician warnings—*i.e.*, whether the doctrine requires a plaintiff to show that "a stronger risk warning [to the physician] would have altered the physician's decision to prescribe," or whether it suffices to show that "the physician would have communicated the stronger risk warnings to the plaintiff." *Himes v. Somatics, LLC*, 29 F.4th 1125, 1127 (9th Cir. 2022). In deciding a question on request of another court, comity dictates that the Court's role be limited to answering the state-law question posed. *See Pooshs v. Philip Morris USA, Inc.*, 250 P.3d 181, 184 (Cal. 2011) ("In addressing the issue presented here, we emphasize that our role is only to answer the 'question of California law' that the Ninth Circuit posed to us."). Because the continued viability of the learned intermediary doctrine was not included in the "order specifying the issues to be briefed" or "fairly included in them," the Court need not address it here. Cal. R. Ct. 8.520(b); *see also Neighbors for Smart Rail v. Exposition Metro Line Constr. Auth.*, 304 P.3d 499, 506 n.3 (Cal. 2013) (declining to address question that was "not fairly included in the merits of the baseline issue on which we granted review"); *People v. Delgado*, 297 P.3d 859, 863 n.2 (Cal. 2013) (declining to

address claim that was "beyond the scope of the issues we directed the parties to brief").

Even the question the Ninth Circuit actually posed to this Court would appear not to determine the outcome of this case. Appellant urges that "an injured plaintiff/patient can establish causation by demonstrating that, had an adequate warning been provided to her doctor, the doctor would have relayed that warning to the patient, and the patient armed with the warning would have refused to undergo the treatment." Appellant's Br. 26–27. But since Appellant's prescribing physician does not "recall reading the operator's manual for the Thymatron device," he would have had no occasion to learn of any additional warnings that he could relay to Appellant. 5-ER-1005. "The rendering of advisory opinions falls within neither the functions nor the jurisdiction of this court." *People ex rel. Lynch v. Super. Ct.*, 464 P.2d 126, 127 (Cal. 1970); *see also* Cal. R. Ct. 8.548(a)(1) (allowing resolution of question of California law where "[t]he decision could determine the outcome of a matter pending in the requesting court").

II. Because the Learned Intermediary Doctrine Is Rooted in the Physician's Role, It Should Focus on the Physician's Prescribing Decision

Given the policy underlying the learned intermediary doctrine—that physicians control access to prescription medicines and devices—the proper focus of the learned intermediary doctrine is on the physician's prescribing decision. Unsurprisingly, numerous courts have rejected attempts to re-focus the causation inquiry on the doctor-patient conversation.

See, e.g., *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 994 F.3d 704, 708–09 & n.4 (5th Cir. 2021) (Louisiana law: "causation analysis . . . is focused on the prescribing physician's decision to prescribe," and not on "whether and how the doctor would have advised the patient"); *Hubbard v. Bayer HealthCare Pharms. Inc.*, 983 F.3d 1223, 1236 (11th Cir. 2020) (Georgia law: "a change in *communication* practices says nothing about the 2012 label's impact on [the prescribing physician's] decisionmaking regarding whether to *prescribe*," which is "the central question in this case"); *Stewart v. Bos. Sci. Corp.*, No. 2:12-CV-03686, 2015 WL 5842762, at *6 (S.D. W. Va. Oct. 6, 2015) (Utah law: "[The prescribing physician's] testimony that he would have passed the warnings off to [Plaintiff] does not suffice to establish that [he] would have altered his decision to prescribe the product had he known of additional warnings."); *Gaghan v. Hoffman-La Roche Inc.*, Nos. A-3211-11T2, A-3217-11T2, A-2717-11T2, 2014 WL 3798338, at *15 (N.J. Super. Ct. App. Div. Aug. 4, 2014) ("[a] number of other jurisdictions" agree that "the relevant conduct that would be altered by a stronger warning is the doctor's decision to prescribe the drug," not "the doctor's decision to provide a stronger warning to the patient").[5]

[5] The attached Addendum to this brief lists 34 jurisdictions that have held, through decisions by state courts or *Erie* predictions by federal courts, that the learned intermediary doctrine requires proof of a different prescribing decision. Undersigned counsel has not located, and Appellant does not cite, any decision from a state's highest court adopting the contrary rule Appellant seeks here. Instead, Appellant replies principally on *McNeil v. Wyeth*,

Important policy considerations support the physician's decision to prescribe the medicine or device serving as the touchstone of the causation inquiry.

A. An Interpretation of the Learned Intermediary Doctrine Aimed at How a Plaintiff Would Have Responded to a Different Counseling Discussion Would Harm Patient Welfare

The federal statutory and regulatory scheme for prescription medicines and devices recognizes that learned medical professionals are best situated to comprehend the risks and benefits of a given treatment and distill the most important information to communicate to patients to secure their informed consent. *See* Part I.A. Warnings for prescription medicines and devices, by necessity, contain complex scientific information, chemical and pharmacological data, and medical terminology. As

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462 F.3d 364, 372–73 (5th Cir. 2006), for a holding that the Texas Supreme Court subsequently repudiated. *See Centocor*, 372 S.W.3d at 172 (holding that "a critical element of the [Plaintiffs'] claims" is proof that additional warnings "would have changed [the prescriber's] decision to prescribe"); *see also Lewis v. Johnson & Johnson*, 601 F. App'x 205, 208 n.1 (4th Cir. 2015) (rejecting argument based on *McNeil* that "a plaintiff may prevail on a failure-to-warn claim by showing that a stronger warning would have led *the plaintiff* to withhold consent to the procedure," because "the Supreme Court of Texas recently reaffirmed [in *Centocor*] that the inquiry under Texas law remains whether the warning would have changed the decision of the prescribing physician"); *Gutierrez v. Ethicon, Inc.*, 535 F. Supp. 3d 608, 631 (W.D. Tex. 2021) ("[T]he Fifth Circuit's *McNeil* decision is not an accurate statement of Texas law. The Fifth Circuit itself cited no on-point Texas case for its analysis, and *McNeil* conflicts with the Supreme Court of Texas's more recent treatment of the learned intermediary doctrine [in *Centocor*].").

Congress recognized by creating a special category of medicines and devices that may be used only under a health care professional's supervision, lay patients simply do not possess the ability to understand the technical language necessary to explain all the dangers of the treatment and how they may best be avoided. *Fogo*, 137 Cal. Rptr. at 423 (patients "have no way to evaluate" "highly technical information on the adverse possibility associated with the use of the drug"); *Carmichael*, 95 Cal. Rptr. at 400 (same). Thus, contrary to Appellant's suggestion, the role of a learned intermediary is not simply to "pass those warnings [provided by a manufacturer] to patients," Appellant's Reply Br. 19; it is instead to exercise independent judgment regarding *which* warnings should be distilled and communicated to individual patients.

Focusing on whether a different warning might have altered the physician's discussions in some way could upset this balance and encourage manufacturers to direct physicians to provide their patients comprehensive, universal warnings about all of the potential adverse effects of a given treatment, no matter how uncertain or remote.[6] This is particularly so because few plaintiffs—having experienced an actual injury, convinced themselves that their medicine or device is to blame, and decided to sue to recover—can be expected to testify that they would have accepted the same course of treatment with additional warnings

[6] If accepted, Appellant's position that courts should presume a deceased plaintiff would have rejected treatment when presented with additional warnings would magnify the over-warning problem discussed herein. Appellant's Br. 58 n.12.

of the injury they experienced. *See Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972) ("Since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined treatment. Subjectively he may believe so, with the 20/20 vision of hindsight . . . ."); *Warren v. Schecter*, 67 Cal. Rptr. 2d 573, 583 (Ct. App. 1997) (an injured plaintiff "inevitably will assert at trial that he or she would have refused the procedure if duly advised of the risk"). After all, even where the probability of an adverse effect is remote, a plaintiff who experienced that outside risk can hardly be expected to un-know that she would be among the unlucky few when evaluating whether she would have accepted the risk. Instead, an injured plaintiff is likely to underweight the benefits she experienced and overweight the risks.[7]

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[7] For this reason, any weight afforded to whether a patient would have accepted treatment had a different conversation transpired should be based solely on an objective reasonable patient. *See, e.g.*, *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 859 F. App'x 692, 694 (5th Cir. 2021) ("The relevant question, however, is not what [Plaintiff] now testifies that she herself might have done. The relevant question is what a reasonable person in [Plaintiff's] position would have done."); Sheryl Calabro, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 Cardozo L. Rev. 2241, 2293 (2004) ("[T]he objective test eliminates the danger of hindsight bias and has the potential for being a more reliable test of causation."). Courts routinely take this approach in the medical malpractice context. And while Appellant asserts that the objective test in that context "is provided exclusively for the benefit of physicians," Appellant's Reply Br. 38, the protection exists at least as much to protect the

Requiring pharmaceutical manufacturers to attempt to reach patients with exhaustive warnings about every potential adverse effect of prescription medicines and devices, no matter how uncertain or remote, would harm consumers in two ways. *First*, a lengthy discussion of non-serious or speculative risks might cause patients to become so inundated with warnings that they fail to take any of the warnings seriously. *See Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 13 (Cal. 2004) ("'Against the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings . . . .'" (quoting *Carlin*, 920 P.2d at 1365 (Kennard, J., concurring in part and dissenting in part))); *Finn v. G. D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984) ("[L]iability ought not to be imposed for failure to warn based on every piece of information in a manufacturer's possession. . . . If we overuse warnings, we invite mass consumer disregard . . . ."); 71 Fed. Reg. at 3935

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truth-seeking function of our judicial system—a rationale that applies equally here. *See Cobbs*, 502 P.2d at 11–12 ("[W]e 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." (citing *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972))); *Canterbury*, 464 F.2d at 790 ("when causality is explored at a postinjury trial with a professedly uninformed patient," a patient's own testimony "hardly represents more than a guess, perhaps tinged by the circumstance that the uncommunicated hazard has in fact materialized").

(overinclusive warnings could "cause meaningful risk information to 'lose its significance'"); FDA, Draft Guidance for Industry, *Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs* 4 (revised Aug. 2015), *available at* https://www.fda.gov/media/70768/download (noting that "exhaustive lists that include even minor risks detract from, and make it difficult for, consumers to comprehend and retain information about the more important risks").

Second, a flood of incomprehensible warnings might scare patients from heeding the advice of their prescribing physicians and the beneficial use of medicines and devices. *See, e.g.*, *Dowhal*, 88 P.3d at 14 ("[A] truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision."); *Fogo*, 137 Cal. Rptr. at 423 (presented with a "complete" list of every possible adverse effect, a patient might "object to the use of the drug, thereby jeopardizing his life"); *Carmichael*, 95 Cal. Rptr. at 400 (same); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605–06 (Aug. 22, 2008) ("[O]verwarning . . . may deter appropriate use of medical products . . . .").

Warnings on pharmaceutical labeling are extensive. The average package insert today lists 49 potential adverse events, and one out of every ten labels contains over 500 warnings. J. Duke et al., *A Quantitative Analysis of Adverse Events and*

"Overwarning" in Drug Labeling, 171 Archives of Internal Med. 944, 945 (2011), *available at* http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/487051. Without their physicians' assistance in filtering these potential adverse events to focus on the most likely and serious risks, the risk that patients will overlook important warnings or refuse life-saving treatments is real. *See* Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995) (full prescribing information is of "questionable" value when provided directly to patients because it is "relatively inaccessible to consumers").

FDA has long been aware of the dangers that litigation-driven over-warning presents. Since 1979, the agency has stated that "it would be inappropriate to require statements in drug labeling that do not contribute to the safe and effective use of the drug, but instead are intended solely to influence civil litigation." Labeling and Prescription Drug Advertising, 44 Fed. Reg. 37,434, 37,435 (June 26, 1979); *see also* 71 Fed. Reg. at 3935 ("'defensive labeling' to avoid State liability" could "result in scientifically unsubstantiated warnings and underutilization of beneficial treatments," or, conversely, "cause meaningful risk information to 'lose its significance'").

FDA's judgment that patients ought not be warned about every conceivable adverse effect of prescription medicines and devices is reflected in its labeling rules. Physician-directed labeling for medicines must include a Patient Counseling Information section with advice on how to counsel patients about risks. 21 C.F.R. § 201.57(c)(18). Intended to guide the

physician's discussion with the patient, that section should contain only "the *most important* information for providers to convey to patients for the safe and effective use of a drug"—*i.e.*, the "major risks of the drug." FDA, Guidance for Industry, *Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format Guidance for Industry* 3, 4 (2014), *available at* https://www.fda.gov/media/86734/download (emphasis added). "Not every risk discussed in labeling will always be included in the Patient Counseling Information section . . . ." *Id.* at 4. Hinging the learned intermediary doctrine on the counseling discussion risks upsetting this careful balance.

B. The Informed Consent Doctrine Amply Protects Patient Autonomy

Appellant maintains that in focusing on the physician prescribing decision, dozens of courts around the country somehow "disregard . . . patient autonomy." Appellant's Br. 58. Appellant can reach that conclusion only by conflating the learned intermediary doctrine with the informed consent doctrine.

Under the informed consent doctrine, physicians must appropriately discuss the risks and benefits of the treatments they prescribe in light of the patient's particular circumstances. To enable patients to "make the ultimate informed decision regarding the course of treatment to which [they] knowledgeably consent[] to be subjected," California physicians have a fiduciary duty to disclose to their patients "the potential of death or serious harm," to "explain in lay terms the complications that might

possibly occur," and to "reveal to [their] patient[s] such additional information as a skilled practitioner of good standing would provide under similar circumstances." *Cobbs*, 502 P.2d at 10–11. Where they fail to meet their "due care duty to disclose pertinent information," physicians may be sued in negligence. *Id.* at 8.

The informed consent doctrine reflects the practical reality that the treating physician knows the patient far better than the pharmaceutical manufacturer and is therefore "in a better position . . . than the manufacturer" to decide which of the risks addressed in the prescriber label to address with the patient. *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003); *see also Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928–29 (Utah 2003) ("The physician . . . has the ability to combine medical knowledge and training with an individualized understanding of the patient's needs, and is the best conduit for any warnings that are deemed necessary."). The informed consent doctrine thus centers on the relationship between the patient and her doctor, and on the duty of the doctor to communicate information to her patient.

The learned intermediary doctrine, on the other hand, addresses the relationship between the manufacturer and the physician. When FDA designates a medicine or device for sale by prescription only, pharmaceutical manufacturers have a duty to provide comprehensive warnings about the product's risks to physicians, who uniquely have the expertise necessary to properly evaluate all the available treatments and the information concerning their relative benefits and risks. If the

physician would have prescribed the treatment even faced with a different warning, then the patient has no claim against the manufacturer.

Properly interpreted, the learned intermediary doctrine reflects the reality that manufacturers cannot effectively communicate complex and personally-tailored warnings about complicated medical issues to individual patients in the same way that a physician can. Only the physician has information about both the risks of a certain treatment and the medical history or condition of a particular patient. Applying this information to make an individualized risk assessment, provide individualized warnings relevant to and understood by the patient, and address questions that the individual patient has about those warnings properly remains the physician's central role, for "[t]he doctor is intended to be an intervening party in the full sense of the word." *Fogo*, 137 Cal. Rptr. at 423; *Carmichael*, 95 Cal. Rptr. at 400 (same); *see also Brown*, 751 P.2d at 477 ("[A] patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties."). Pharmaceutical manufacturers have no control over what is or is not discussed between physicians and patients or the decisions resulting from those discussions, and the learned intermediary doctrine accordingly does not make manufacturers guarantors of that discussion. *See Brown*, 751 P.2d at 477–78 ("The manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his duty to transmit these

warnings to the patient . . . ."); *Gall v. Smith & Nephew, Inc.*, 286 Cal. Rptr. 3d 108, 112 (Ct. App. 2021) (what physician communicated to patient "might be pertinent to [patient's] lawsuit against [physician], but that case is not before us").

The informed consent doctrine and the learned intermediary doctrine work in tandem. Far from undermining patient autonomy, the learned intermediary doctrine strengthens patients' ability to comprehend the risks that prescription medicines and devices pose by requiring manufacturers to provide doctors with comprehensive risk information, which they in turn distill for their patients on an individualized basis to obtained their informed consent.

CONCLUSION

For the foregoing reasons, the Court should answer the certified question by holding that in a claim against a manufacturer of a medical product for failure to warn, a plaintiff is required to show that an additional warning would have altered the physician's decision to prescribe the product.

Respectfully submitted,

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Dated: November 18, 2022

ADDENDUM

Selected Authorities from 34 U.S. Jurisdictions
Holding that Proximate Causation Requires a Different Prescribing Decision

* * *

1. **Arizona**: *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (granting summary judgment on failure-to-warn claim where "[t]here is no testimony before the Court from [plaintiff's physician] that he would have not used the [device] on [plaintiff] if different warnings had been given").

2. **Arkansas**: *Meade v. Ethicon, Inc.*, No. 4:20-CV-00694, 2021 WL 4302252, at *4 (E.D. Ark. Sept. 21, 2021) ("To prove causation, plaintiffs must show that a proper warning would have changed the decision of [the prescribing physician], *i.e.*, that but for the inadequate warning, [the physician] would not have prescribed the [device].").

3. **Colorado**: *Lynch v. Olympus Am., Inc.*, No. 18-CV-00512, 2018 WL 5619327, at *11 (D. Colo. Oct. 30, 2018) (plaintiff must prove that "had the warning been adequate, the treating physician would not have prescribed that drug or used that device").

4. **Delaware**: *Green v. Janssen Pharms., Inc.*, No. 1:15-CV-00401, 2019 WL 1567841, at *3 (D. Del. Apr. 11, 2019) (granting summary judgment where prescribing physician "testified that additional information on the risks associated with [medicine] would not have impacted his decision to prescribe Plaintiff the drug").

5. **Florida**: *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009) (no proximate causation where physician "would still have prescribed the medication for Appellee").

6. **Georgia**: *Hubbard v. Bayer HealthCare Pharms. Inc.*, 983 F.3d 1223, 1232, 1236 (11th Cir. 2020) ("[t]o establish proximate cause, the plaintiff must prove a causal link between the inadequate warning and the prescription decision," and "a change in communication practices" is irrelevant to the inquiry).

7. **Illinois**: *Muhammad v. Abbott Lab'ys, Inc.*, No. 1-21-0478, 2022 WL 2253517, at *11 (Ill. App. Ct. June 23, 2022) ("To prevail, [Plaintiff] must establish that greater warnings would have prevented [Plaintiff's] injuries; that is, whether greater warnings would have led the physicians to make different

prescribing decisions such that [Plaintiff] would not have been exposed to [the medicine].").

8. **Indiana**: *Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978–79 (N.D. Ind. 1999) ("[A] plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff.").

9. **Iowa**: *Kelly v. Ethicon, Inc.*, No. 20-CV-2036, 2020 WL 4572348, at *4 (N.D. Iowa Aug. 7, 2020) ("[T]o establish proximate causation, 'the plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.*, that but for the inadequate warning, the treating physician would not have used or prescribed the product.'").

10. **Kansas**: *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 977 (10th Cir. 2001) (affirming summary judgment where a different warning "would have made no difference in [physician's] decision to use" medical device).

11. **Louisiana**: *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 994 F.3d 704, 708–09 & n.4 (5th Cir. 2021) ("causation analysis in a failure-to-warn claim asserted against a drug's manufacturer . . . is focused on the prescribing physician's

decision to prescribe," and not on "whether and how the doctor would have advised the patient").

12. **Maryland**: *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006) (granting summary judgment where physician "testified that the warnings advocated by the plaintiffs would not have altered his decision to prescribe").

13. **Massachusetts**: *Liu v. Boehringer Ingelheim Pharms., Inc.*, 230 F. Supp. 3d 3, 9 (D. Mass. 2017) (plaintiff required "to prove causation by showing that if the proper warning and information had been provided, [his physician] would not have prescribed [the medicine]").

14. **Minnesota**: *Dolan v. Bos. Sci. Corp.*, No. 20-CV-1827, 2021 WL 698777, at *3 (D. Minn. Feb. 23, 2021) ("[Plaintiff] has not alleged that her prescribing physician would not have used the [device] if he or she had been properly apprised of the risks. Therefore, [Plaintiff's] failure to warn claim must be dismissed.").

15. **Mississippi**: *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31, 58 (Miss. 2004) ("The Plaintiffs bear the burden of establishing that [the medicine] was the cause of their injuries

and that 'an adequate warning would have convinced the treating physician not to prescribe the product for the Plaintiffs.'").

16. **Missouri**: *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) ("Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.* that *but for* the inadequate warning, the treating physician would not have used or prescribed the product.").

17. **Nebraska**: *McElroy v. Eli Lilly & Co.*, 495 F. App'x 166, 168 (2d Cir. 2012) ("[W]e conclude that [Plaintiff] failed to demonstrate the existence of any genuine dispute as to any material fact on the question of causation because he adduced no evidence permitting an inference that his treating psychiatrists would have altered their prescription decisions if [Defendant] had provided different warnings.").

18. **New Mexico**: *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1197 (D.N.M. 2008) ("Courts have also held that a prescription-drug manufacturer's alleged failure to warn a prescribing physician cannot be the proximate cause of injury unless the plaintiff can establish that a different warning would have changed the physician's decision to prescribe the drug, *i.e.*,

that, but for the alleged inadequate warning, the physician would not have prescribed the product.").

19. **New Jersey**: *Strumph v. Schering Corp.*, 626 A.2d 1090 (N.J. 1993) (adopting dissent below); *Strumph v. Schering Corp.*, 606 A.2d 1140, 1148 (N.J. App. Div. 1992) (Skillman, J., dissenting) ("Plaintiff has the burden of proving that defendant's alleged inadequate warnings were a proximate cause of her injuries. To satisfy this burden, plaintiff must show that adequate warnings would have altered her doctors' decision to prescribe [the medicine]." (citation omitted)); *see also Gaghan v. Hoffman-La Roche Inc.*, Nos. A-3211-11T2, A-3217-11T2, A-2717-11T2, 2014 WL 3798338, at *13 (N.J. Super. Ct. App. Div. Aug. 4, 2014) (rejecting argument that "an inadequate warning is a proximate cause of the injury if the patient would decline to use the medication upon learning of the potential side effect that should be disclosed to her by her doctor," and noting under both California and New Jersey law that "[s]ince the warning is directed to the doctor, adequacy of the warning must be measured from the doctor's point of view").

20. **New York**: *Mulhall v. Hannafin*, 45 A.D.3d 55, 61 (N.Y. App. Div. 2007) ("[P]laintiffs had to show that had the

warning been different, [their physician] would have departed from her normal practice and used another device.").

21. **Ohio**: *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 838–39 (Ohio 1981) ("Where, as here, an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter, . . . the required element of proximate cause between the warning and ingestion of the drug is lacking.").

22. **Oklahoma**: *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001) (proximate causation "requires that the plaintiff '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'").

23. **Oregon**: *Pearson v. Ethicon, Inc.*, No. 3:20-CV-01905, 2021 WL 4498562, at *10 (D. Or. Aug. 16, 2021) ("[Plaintiff] has failed to establish a genuine issue of material fact that had [the prescribing physician] received 'adequate warnings,' he would have changed his treatment recommendations or decisions for [Plaintiff]. Accordingly, [Plaintiff's] negligence-based failure to warn claim fails because she has not established a genuine issue of fact on causation."), *R.*

& R. adopted in relevant part, 2021 WL 4494188 (D. Or. Sept. 30, 2021).

24. **Pennsylvania**: *Lineberger v. Wyeth*, 894 A.2d 141, 151 (Pa. Super. Ct. 2006) (no causation where physician "would still have prescribed the drug for Appellant"); *see also In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 639 F. App'x 874, 878 (3d Cir. 2016) ("To prove a failure to warn claim, a plaintiff must establish proximate cause by showing that had the manufacturer issued a proper warning to the plaintiff's prescribing physician, the physician would not have prescribed the drug to the plaintiff and the injury would have been avoided.").

25. **Rhode Island**: *In re Zyprexa Prods. Liab. Litig.*, 277 F.R.D. 243, 251 (E.D.N.Y. 2011) ("Because there is no evidence that plaintiff's doctor would have altered his prescription decision had he been provided additional information, summary judgment against the plaintiff is granted."), *aff'd sub nom. Greaves v. Eli Lilly & Co.*, 503 F. App'x 70 (2d Cir. 2012).

26. **South Carolina**: *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1002 (4th Cir. 1992) ("We agree that plaintiff has failed to show that her doctor would not have prescribed the

[device] if [Defendant] had phrased its warning differently. We thus affirm the judgment of the district court.").

27. **South Dakota**: *Schilf v. Eli Lilly & Co.*, No. 07-CV-4015, 2010 WL 4024922, at *4 n.3 (D.S.D. Oct. 13, 2010) ("Plaintiffs are required to show that a different warning would have changed [the prescribing physician's] decision to prescribe [the medicine] to [Plaintiff]."), *rev'd on other grounds*, 687 F.3d 947 (8th Cir. 2012).

28. **Tennessee**: *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 577 (6th Cir. 2012) ("[Plaintiff] has not presented any evidence that a warning on [Defendant's device] would have caused [the prescribing physician] not to use the device in [Plaintiff's] joint space, thus preventing his injury. [Plaintiff] has failed as a matter of law to establish a triable issue of fact over causation on his failure-to-warn claim.").

29. **Texas**: *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 172 (Tex. 2012) ("[T]he fact that [the prescribing physician] would have considered [additional] information, if included in the package insert, does not prove that the presence of such information would have changed his decision to prescribe [the

medicine] to [Plaintiff]—a critical element of the [Plaintiffs'] claims.").

30. **Utah**: *Stewart v. Bos. Sci. Corp.*, No. 2:12-CV-03686, 2015 WL 5842762, at *6 (S.D. W. Va. Oct. 6, 2015) (no causation where "the record does not show that [prescribing physician] would have altered his decision to prescribe the product had he known of additional warnings"; argument that physician would have "informed" plaintiff of additional warnings had he known of them "misses the point").

31. **Virginia**: *Knapp v. Zoetis Inc.*, No. 3:20-CV-00191, 2022 WL 989015, at *6 (E.D. Va. Mar. 31, 2022) ("A plaintiff must also allege that adequate warnings would have altered the physician's decision to prescribe the drug.").

32. **Washington**: *Sherman v. Pfizer, Inc.*, 440 P.3d 1016, 1023 (Wash. Ct. App. 2019) (no proximate causation where "package inserts for [medicine] did not impact [physician's] prescription decision"); *see also Luttrell v. Novartis Pharms. Corp.*, 894 F. Supp. 2d 1324, 1345 (E.D. Wash. 2012) (rejecting as irrelevant under the learned intermediary doctrine Plaintiff's argument that "if [Defendant] had adequately warned [Plaintiff]

of the risk, he simply would not have taken the drug"), *aff'd*, 555 F. App'x 710 (9th Cir. 2014).

33. **West Virginia**: *Mullins v. Ethicon, Inc.*, No. 2:12-CV-02952, 2017 WL 4384937, at *2 (S.D. W. Va. Jan. 19, 2017) ("the operation of the learned intermediary doctrine stymies the plaintiffs' failure to warn claims against [Defendant]" where evidence showed that "any other warning would not have altered [physician's] decision to perform the surgery").

34. **Wisconsin**: *Hanson v. Bos. Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *5 (S.D. W. Va. Apr. 12, 2016) ("[T]he plaintiff must show that [the prescribing physician] would not have prescribed the device but for the inadequate warnings or instructions.").

CERTIFICATE OF WORD COUNT

This brief complies with the type-volume limitations of Appellate Rule 8.520(c)(1) because it contains 8,596 words, as counted by the Microsoft Word word-processing program used to prepare the brief, excluding the parts of the brief exempted by Appellate Rule 8.520(c)(3).

/s/ Ashley M. Simonsen
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Dated: November 18, 2022

PROOF OF SERVICE

I, Mark S. Shuttlesworth, am a resident of the State of California and over the age of 18 years. Neither I, nor my client, the Pharmaceutical Research and Manufacturers of America, are a party to this action. My business address is Covington & Burling LLP, 1999 Avenue of the Stars, Los Angeles, CA 90067.

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Executed in Los Angeles, California, November 18, 2022.

/s/ Mark S. Shuttlesworth
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STATE OF CALIFORNIA
Supreme Court of California

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

11/18/2022

Date

/s/Ashley Simonsen

Signature

Simonsen, Ashley (08355)

Last Name, First Name (PNum)

Covington & Burling, LLP

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