THE FORGOTTEN ELEMENT?

WARNINGS PROXIMATE CAUSATION IN TRIAL PRACTICE

THE BEGINNING.

Everything should be made as simple as possible, but not simpler.
— Einstein

Stereotypes begin with a kernel of truth. Admit it, you've seen them within your virtual firm. Maybe it's the science wonk, convinced that no jury could award damages if they could only be made to *truly* understand the esoteric biological principle—the one that can only be described via acronym. Perhaps it's the detail-oriented associate or nurse analyst, uncovering the pivotal blip in the plaintiff's timeline that calls the entire injury claim into question. Then, of course, there's the

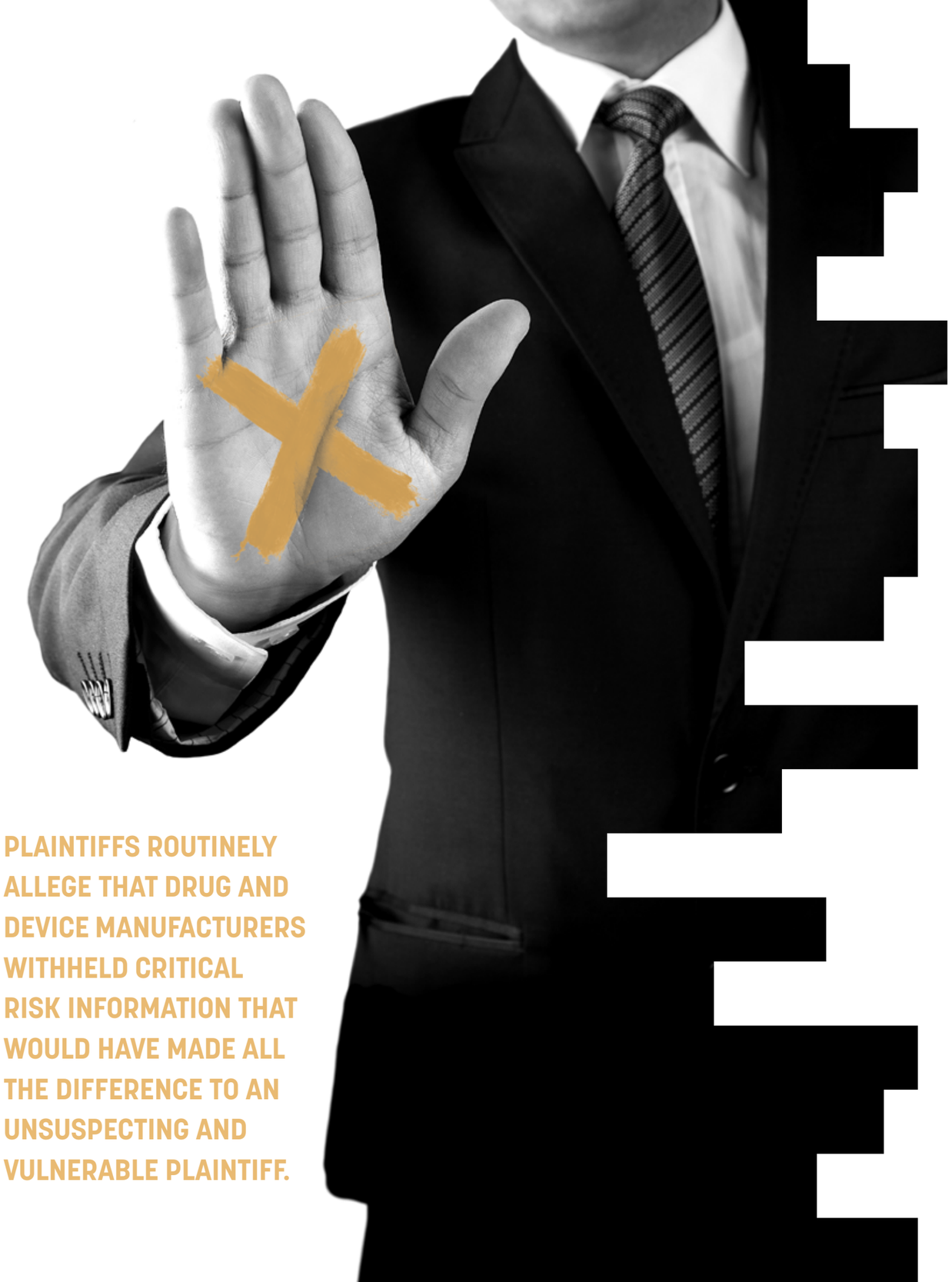
weary "handler," charged with preparing your company witness or regulatory expert. A handler's job is to anticipate any possible critique of the client's conduct from the time of its founding, and to defend a product warning against a myriad of attacks, like a careless internal email, an unfavorable—but isolated—scientific finding, or even so-called "common sense."

These stereotypes may ring familiar because the driver of so many drug and device products cases is the warnings claim. Plaintiffs routinely allege that drug and device manufacturers withheld critical risk information—information that, if properly shared, would have made all the difference to an unsuspecting and vulnerable plaintiff. And, while the substantive law on failure-to-warn across jurisdictions can vary—in some instances, widely—there is a prevailing pattern to the elements of proof in a warnings claim.

Using a matrix to illustrate a concept in a section touting simplicity is, admittedly, cringe-worthy. It is also valid. Virtually all failure-to-warn or inadequate warnings claims begin with four elements to be proven:

1. ***general medical causation*** *— can the offending product cause (or, in some jurisdictions, merely contribute to) the alleged injury;*
2. ***specific medical causation*** *— did the product cause this plaintiff's injury;*
3. ***warnings adequacy*** *— are the product warnings in effect at the time of the plaintiff's use consistent with reasonable practice; and*
4. ***proximate cause*** *— if the warnings are deemed inadequate or unreasonable, are those failings responsible for the outcome.*

	CAUSATION	WARNING
GENERAL	General Medical Causation	Warnings Adequacy
SPECIFIC	Specific Medical Causation	**"PROXIMATE CAUSE"**



PLAINTIFFS ROUTINELY ALLEGE THAT DRUG AND DEVICE MANUFACTURERS WITHHELD CRITICAL RISK INFORMATION THAT WOULD HAVE MADE ALL THE DIFFERENCE TO AN UNSUSPECTING AND VULNERABLE PLAINTIFF.

Plotted this way, the elements fall into two pairs of concepts: (1) causation and warnings along one axis; and (2) general and specific along the other. Now, look again at our stereotypes on the previous page. Three of these elements are described, but the fourth—proximate causation—is not. Why?

One possible explanation for this discrepancy is the nearly unconscious deference to an insurmountable piece of evidence. In every failure-to-warn claim, inevitably the plaintiff will be asked by her attorney: *if you had known that using **this** product would result in **this** injury, would you have ever used it?* It's a hindsight question, of course, and one loaded with assumptions, but the answer is typically automatic and emphatic. *Of course not.* If this ultimate question is so firmly within the direct control of the plaintiff, then it makes sense to marshal the defense elsewhere.

Advantage, plaintiff?

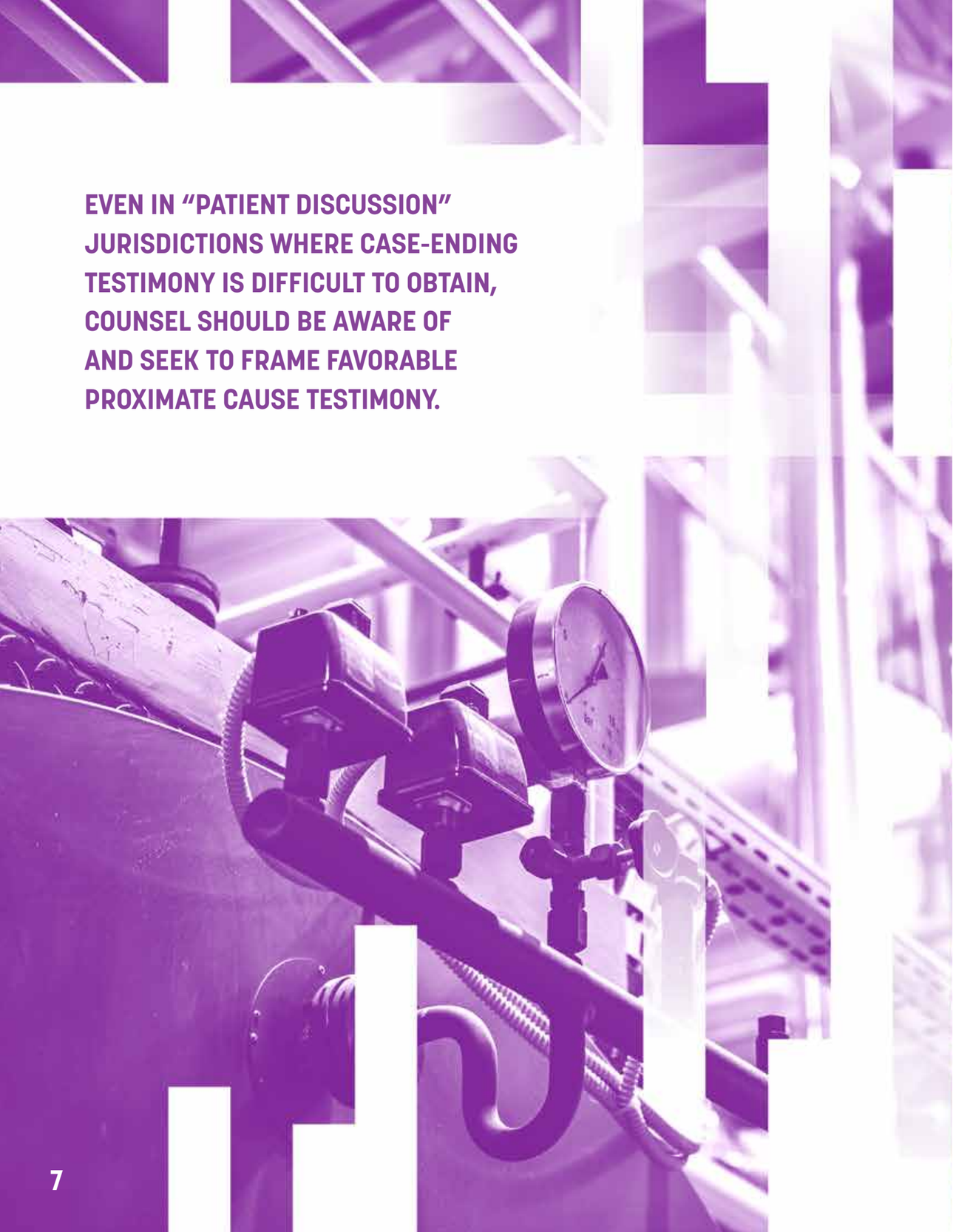
THE MIDDLE.

You keep using that word. I do not think it means what you think it means.

— Inigo Montoya, The Princess Bride

At the same time, attend any drug and device seminar, approach an attendee at random, and pose the question: What does the "learned intermediary" doctrine mean? The answer is rote: *Why, the manufacturer's duty to warn runs to the doctor, not the patient.* That is the undeniably correct answer. It is also, as a practical matter, incomplete. It doesn't mean what you think it means, at least, not entirely. From a trial defense perspective, the learned intermediary doctrine should mean that the proximate cause element of a failure-to-warn claim is properly satisfied not by the plaintiff, but by the prescriber. Because drug and device manufacturers warn these specialized-knowledge-wielding proxies, rather than the ultimate consumers of their products, then any

EVEN IN "PATIENT DISCUSSION" JURISDICTIONS WHERE CASE-ENDING TESTIMONY IS DIFFICULT TO OBTAIN, COUNSEL SHOULD BE AWARE OF AND SEEK TO FRAME FAVORABLE PROXIMATE CAUSE TESTIMONY.



failings in the product warnings are assessed against the prescriber's knowledge and decision to use, not the plaintiff's. Taken to its logical end, the application of the learned intermediary doctrine should render the plaintiff's ultimate question above ineffectual, even irrelevant.

This tension—between competing interpretations of proximate causation in the learned intermediary context—has played out in multiple jurisdictions. One effect is a distinction between the "prescribing decision" and the "patient discussion" as the determinative facts for a proximate causation analysis. That is, there are competing positions for what satisfies the elemental burden of proximate cause: whether the doctor (or other healthcare provider) would have continued to prescribe the product, or whether the interaction and discussion with the patient regarding the product would have changed. Plaintiffs prefer the latter, because any admission by a prescriber that different information would alter the interaction with the patient funnels the decision point toward the ultimate, plaintiff-controlled question. By contrast, defendants prefer the former, and not merely as an "anti-plaintiff" position. Prescribers are being asked to confirm and reinforce their own judgment regarding the decision they previously made with respect to this individual patient, i.e., the decision to use the product.

In *Gaghan v. Hoffmann-LaRoche, Inc., et al.*,[1] the New Jersey Appellate Division reversed a verdict awarded to an Accutane user on the basis of California's interpretation of the proper scope of the proximate cause inquiry:

> The question of law is whether the conduct of the doctor that would be altered by a stronger warning is limited to the doctor's prescribing decision or, as the trial court concluded here, also includes the doctor's decision to provide a stronger warning to the patient. In the absence of a decision by a California appellate court contradicting the holdings of the federal courts, we conclude that California law focuses on the **prescribing decision** of the doctor as the learned intermediary.
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> A number of other jurisdictions have held similarly that the relevant conduct that would be altered by a stronger warning is the **doctor's decision to prescribe** the drug. See *Ackermann v. Wyeth Pharms.,* 526 F.3d 203, 213-14 (5th Cir. 2008) (Texas law); *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 976-77 (10th Cir. 2001) (Kansas law); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (Louisiana law); *Hoffmann-La Roche, Inc. v. Mason*, 27 So.3d 75, 77 (Fla. Dist. Ct. App. 2009) (Florida law), *review denied*, 37 So.3d 848 (Fla. 2010).
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> Our own Supreme Court in New Jersey has reached the same conclusion. See *Strumph v. Schering Corp.*, 133 N.J. 33, 626 A.2d 1090 (1993), *rev'ing on dissent*, 256 N.J. 309, 323, 606 A.2d 1140 (App. Div. 1992) (Skillman, J.A.D., dissenting) (under New Jersey law, plaintiff must show adequate warnings would have altered physician's prescribing decision). *But cf. Niemiera v. Schneider*, 114 N.J. 550, 565-66, 555 A.2d 1112 (1989) (under New Jersey's learned intermediary doctrine, doctor's responsibility is to inform patient about information that enables patient to use product safely); *In re: Diet Drug Litig.*, 384 N.J. Super. 525, 541, 895 A.2d 480 (Law Div. 2005) (leaving prescribing decision solely in hands of learned intermediary runs afoul of New Jersey's public policy).
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> (emphasis added)

Other states, like Mississippi, Alabama, and Georgia, have also adopted the "prescribing decision" interpretation of warnings proximate causation.[2] However, the issue is not fully settled. "Patient discussion" advocates do find legal support, as some courts are reluctant to cede all decision-making authority to the prescribers, when the plaintiff ultimately decides to use a product now claimed to have caused harm.[3]

THE END.

Do, or do not. There is no try.
— Yoda, The Empire Strikes Back

The takeaway from all of this is the importance of the prescriber's testimony on this issue, which makes the available prescriber's deposition critical in any drug or device products case. Defense counsel should never approach a prescriber deposition seeking only to regurgitate a treatment

timeline. Nor should they settle for favorable, but ultimately derivative or cumulative proof on elements of medical causation. Even in "patient discussion" jurisdictions where case-ending testimony is difficult to obtain, counsel should be aware of and seek to frame favorable proximate cause testimony. A dispositive element of plaintiff's claim hinges on the results.

As this is a lawyerly piece, disclaimers apply. Rules beget exceptions, and individual judgment should always trump checklists in defending products cases. Perhaps the prescriber consults regularly for plaintiffs' lawyers, or has a known bias against manufacturers, or has suspect credentials or a vast litigation history. There are a variety of reasons to modify an approach to a prescriber deposition. However, the very fact that the product was prescribed is a powerful indicator in many cases that favorable testimony on proximate cause can be had.

As a result, consider the following as potential lines of inquiry for prescribers.

- **Establish "learned-ness."** As noted, in some cases, perhaps qualifying the prescriber as a pseudo-expert is not the preferred course. But where favorable testimony is anticipated, tracking the highlights of the prescriber's education, training, and experience reinforces the specialized knowledge the learned intermediary doctrine represents. As a corollary, determine whether the prescriber has contributed to key opinions for industry, participated in sponsored clinical trials, or developed new products in the field as an indicator of alignment.
- **Sources of information.** Plaintiffs' warnings claims hinge on poking holes in specific labeling materials, such as package inserts or instructions for use. Expect that opposing counsel will put before the prescriber some piece of information that is not set out in the labeling. As such, it is important to establish other sources of information, often ranging from experience to professional associations/discussions with colleagues to literature as a means of shoring up the prescriber's knowledge of either the potential for injury or its alleged relationship with the product.
- **Give the indication its due.** Plaintiffs tend to focus on one medical condition—the alleged injury. In fact, drug and device products cases always involve (at least) two. The underlying condition for which the product was prescribed should be explored, in part to establish the ramifications of non-treatment. Put another way: establish the benefits of the use of the product where available.
- **Product usage.** Similarly, look for opportunities to establish safe, effective use of the product with other patients both before the plaintiff's use and after, including present and ongoing use where possible. This is one of the signals of potential favorable testimony with the ultimate question.
- **Reinforce the prescriber's judgment.** A by-product of plaintiff's warnings claim is an inference that the prescriber's judgment was impaired by insufficient knowledge. Many prescribers inherently reject challenges to their medical judgment. Mine that tendency.
- **Establish "standard" and "case-by-case" warnings practice.** It may be the case that the prescriber did not warn the plaintiff of the specific alleged injury. And it is typical for prescribers to acknowledge that, as between less information and more information, they prefer the latter: they would "want to know." Plaintiffs' lawyers tend to pivot from these questions to low-risk, general questions like, *And if you had additional information, you would pass that on to your patients?* Prescribers often agree, leaving plaintiff's counsel one step away from setting up their ultimate question. One hedge against that is to test the notion that prescribers deliver certain "standard" warnings for products (most common side effects, e.g.) as well as warning on a case-by-case basis (certain patients tolerate certain amounts of risk information).
- **Test the alternate warning.** To the extent plaintiffs have developed a proposed alternate warning addressing the alleged deficiencies in the product warnings, consider directly confronting the prescriber with loaded questions: *E.g., plaintiff's expert has opined that if this warning had been available when you prescribed to the plaintiff, then your understanding of the risks and benefits of the product would have been so altered that you would not have prescribed. Is that true?* Recognize that these are high-risk, high-reward questions; judgment is critical.
- **Ultimate question.** Similarly, information obtained over the course of a deposition can signal whether to attempt a "prescribing decision" ultimate proximate cause question. If successful, consider a series of questions designed to satisfy the "patient discussion" prong as well, e.g., *if plaintiff presented to you in [original date of use], would your approach and course of treatment have been the same, with or without this additional information?"*

Warnings proximate causation is an essential element of a plaintiff's warnings claim. Under the learned intermediary doctrine, that proof comes from the prescriber's understanding of the warning and any alleged flaws, in conjunction with the prescriber's general knowledge as a physician. Defense counsel should recognize the parameters of the doctrine where an action is pending and should be deliberate in their approach to prescriber depositions.

And who knows? Perhaps with consistent and heightened attention to this element of proof, a new defense lawyer stereotype will emerge.

1. 2014 WL 3798338, *15 (N.J. App. Div. 2014).
2. *See, e.g., Janssen Pharmaceutia, Inc. v. Bailey*, 878 So.2d 31, 58 (Miss. 2004) ("The Plaintiffs bear the burden of establishing that Propulsid was the cause of their injuries and that 'an adequate warning would have convinced the treating physician **not to prescribe** the product for the [P]laintiff[s].'") (Miss. law); *Wyeth v. Weeks*, 159 So.3d 649, 673-74 (Ala. 2014) ("In short, the patient must show that, but for the false representation made in the warning, the prescribing physician **would not have prescribed** the medication to his patient.") (Ala. law); *Porter v. Eli Lilly & Co.*, 291 Fed. Appx. 963 (11th Cir. 2008) ("Under Georgia law, Porter was required to prove that, but for the alleged inadequate warning, Dr. Wolfberg, decedent's physician, **would not have prescribed** Prozac to decedent.") (Ga. law) (emphasis added).
3. *See, e.g., Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063 (S.D. Ill. 2007) (Ill. law); *Gilliland v. Novartis Pharmaceuticals Corp.*, 34 F. Supp.3d 960 (S.D. Iowa 2014) (Iowa law); *Rossitto v. Hoffmann-LaRoche, Inc., et al.*, 2016 WL 3943335, *24 (N.J. App. Div. 2016) ("'The 'prescribing decision'—insofar as it logically entails both a physician's recommendation and a patient's assent to follow that recommendation after being apprised of the pertinent risks—could have been affected by the absence of a stronger warning. Although a physician can function as a 'learned intermediary,' *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989), it should not be assumed that a doctor will issue a prescription to an informed patient who is unwilling to risk a drug's side effects.") (N.J. law).

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