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...
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.

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

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.

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
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-La Roche, 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 the doctor’s decision to prescribe the drug. See Ackermann v. Wyeth Pharms., 526 F.3d 203, 215-16 (5th Cir. 2008) (Texas law); Rakitin 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).


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.
As a result, consider the following as potential lines of inquiry for prescribers. The very fact that the product was prescribed is a powerful indicator in depositions. However, the very fact that the product was prescribed is a powerful indicator in depositions. There are a variety of reasons to modify an approach to a prescriber deposition. 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 claim hinges on poking holes in specific labeling materials, as warning on a case-by-case basis (certain patients tolerate certain amounts of risk information). Nor should they settle for favorable, perhaps qualifying the prescriber as a pseudo-expert.

**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 prescribed 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 cause 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 a pending case 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.