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Using the Learned Intermediary Doctrine at Each Stage of the Litigation

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This article presents options for addressing the LID at each stage of drug and medical device litigation.

The learned intermediary doctrine ("LID") is an important defense for pharmaceutical and medical device manufacturers facing failure-to-warn claims and it should be considered by defense counsel seeking to challenge whether a plaintiff met his or her burden on proximate causation. Prescribing physicians evaluate the benefits and risks of any given drug (or device) for each specific patient based on the U.S. Food and Drug Administration (FDA)-approved labeling, as well as on their own independent knowledge from multiple sources, including their medical education, training, and experience, peer-reviewed scientific literature, and clinical studies. When deciding whether to prescribe a certain treatment, physicians typically consider, among other factors, whether the drug or device is the best treatment option available for that patient, the extent to which the patient's medical condition merits treatment, the patient's medical history, including previous treatment attempts, and the risk of the patient suffering any adverse events as a result of the chosen treatment.

Patients appropriately rely on their physicians to understand and communicate in lay terms the highly regulated and technical, medical, and scientific language about drug risk and proper use that appear on the drug's prescribing information. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3961 cmt. 112 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) ("Requiring that language used in prescription drug labeling be tailored to a lay audience would result in a loss of the clarity and precision needed to effectively communicate to practitioners a product's benefits and risks."). The physician acts as the *intermediary* between a pharmaceutical company—which develops, studies, and markets a prescription drug or medical device in conjunction with the FDA—and the patient who uses the drug or device.

Recognizing the substantial and unique role of prescribing physicians, federal and state courts across the country have adopted an exception to the general rule that manufacturers have a duty to warn consumers about the risks of their products: in pharmaceutical product liability litigation, a manufacturer fulfills its duty to warn by directing warnings about a product's risks to the prescribing physician, who acts as a "learned intermediary" between the manufacturer and patient. *E.g.*, Restatement (Third) of Torts: Product Liability § 6(d) & cmt. D (A.L.I. 1998); Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 Brook. L. Rev. 839, 890-91 (2009) (explaining the several rationales for the learned intermediary doctrine and collecting cases).

Coined in 1966 by the Eighth Circuit in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966), the term "learned intermediary" has developed into a fundamental doctrine of pharmaceutical litigation: the learned intermediary doctrine. The LID is recognized by nearly every state across the United States. Cf. Aaron D. Twerski, *A Quarter Century After the Products Liability Restatement: Reflections*, 90 Brook. L. Rev. 1027, 1033-34 (2025) (citing

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In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002) (laying out jurisdictions that have applied or recognized LID)).

This article presents options for addressing the LID at each stage of drug and medical device litigation, including by closely scrutinizing the complaint and assessing whether to challenge proximate causation and raising the LID at the pleadings stage; advocating for multidistrict litigation (MDL) courts to prioritize case-specific discovery of prescribing physicians in the discovery schedule; and addressing LID issues with prescribing physicians during their depositions. The article also considers plaintiffs' evolving strategies to counter the LID and potential defense responses.

Consider Raising the LID Defense at the Pleading Stage

The pleadings stage presents the earliest opportunity to challenge plaintiffs' failure-to-warn claims on causation, which, depending on the law of the relevant jurisdiction, typically requires allegations to support a finding that, but for the inadequacy of the label, a prescribing physician would not have prescribed the drug or device (warnings causation) and the drug or device would not have caused plaintiff's injury (proximate causation). It also presents a good opportunity to preview the defendant's case, including informing the court of the benefits and social value of the drug or device, the relevant FDA regulatory scheme, and, critically, here, the importance of prescriber testimony. Depending on the allegations and facts of the case, it can be important to introduce LID early in the litigation.

Defense counsel can preview LID arguments at the motion to dismiss stage, particularly if the alleged facts regarding warnings and proximate causation are merely boilerplate. A boilerplate allegation that the manufacturer failed to warn cannot suffice under *Twombly* and *Iqbal*. *E.g., Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 608-09 (11th Cir. 2008) (affirming dismissal of failure-to-warn claims because the complaint pled the inadequacy of warnings to doctors "in only one conclusory sentence,... without explaining either the information available to [plaintiff's] physician at the time of the administration of the drug or how the contents of the label were inadequate"); *Harrison v. Medtronic, Inc.*, No. 22-10201, 2022 WL 17443711, at *3 (5th Cir. Dec. 6, 2022) (per curium) (affirming dismissal of failure-to-warn claim because "general allegations—such as that the 'warnings failed to inform the user of the nature of the danger'—do not meet the pleading standard"); *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1161 (E.D. Cal. 2019) ("Merely stating that the Defendants failed to 'adequately warn' of potentially fatal lung conditions is a bare legal conclusion.").

To be sufficiently pled, a plaintiff must provide the following types of information:

- Identifying the prescribing physician, *see Fearrington v. Bos. Sci. Corp.*, 410 F. Supp. 3d 794, 801-02 (S.D. Tex. 2019); *Acevedo v. Johnson & Johnson*, No. 16-CV-11977, 2018 WL 4693958, at *4 (D. Mass. Sept. 30, 2018);
- Stating "whether plaintiff's physician had adequate warning of the resulting injury," *Dye v. Covidien* LP, 470 F. Supp. 3d 1329, 1341 (S.D. Fla. 2020);
- Providing "the contents of defendants' warnings," *Gioia v. Janssen Pharms.*, Nos. 19-CV-04629, 19-CV-05377, 2021 WL 602683, at *3 (E.D.N.Y. Feb. 16, 2021); *Bailey*, 288 F. App'x at 608-09; and
- Identifying "what information was missing from Defendant's warnings or how and why the warnings were inadequate," *Foge, McKeever LLC v. Zoetis, Inc.*, 565 F. Supp. 3d 647, 653-54 (W.D. Pa. 2021); *Jones v. Angiodynamics, Inc.*, No. 6:23-cv-1554, 2024 WL 4430671, at *2 (M.D. Fla. Sept. 9, 2024).

Moving to dismiss on the issue of causation may be proper where the complaint fails to allege facts sufficient to state a failure-to-warn claim under the law of the relevant jurisdiction—typically that the warning was inadequate and, but for the inadequacy of the label, the prescribing physician would not have prescribed the drug or device. *E.g., Stephens v. Teva Pharms., U.S.A., Inc.*, 70 F. Supp. 3d 1246, 1254 (N.D. Ala. 2014) ("plaintiffs' failure to allege [that the] prescribing physician was not adequately informed about the risks of [the drug]... is fatal to plaintiffs' claims"); *Cubbage v. Novartis Pharms. Corp.*, No. 5:16-cv-129-Oc-30PRL, 2016 WL 3595747, at *5 (M.D. Fla. July 5, 2016) ("Because of the learned intermediary doctrine, however, causation must be demonstrated

by establishing that a treating physician would not have prescribed or would have recommended that the patient cease taking the drug if a different, adequate warning had been provided."); *Doyle v. Bayer Corp.,* No. C24-1973, 2025 WL 1666261, at *3 (W.D. Wash. June 12, 2025) (dismissing failure-to-warn claim because complaint did not include allegations that manufacturer failed to warn prescribing physician and that an adequate warning would have altered the physician's decision to prescribe).

Where appropriate based on plaintiffs' complaint, moving to dismiss on the issue of proximate causation also may result in narrowing the scope of plaintiffs' claims. Complaints often include non-specific claims that the defendant failed to warn the plaintiff or "the general public" of the risks of a drug or device. Such claims are insufficient under the LID, where the critical inquiry is whether the defendant manufacturer failed to warn *plaintiff's prescribing physician* of the risks. Because the manufacturer's duty runs only to the prescribing physician, claims premised on a failure to warn the *plaintiff* or the *general public* may well be ripe for dismissal at the motions to dismiss stage. *See, e.g., Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 440 (W.D. Ark. 2020) ("Plaintiffs' claims fail as a matter of law to the extent that they seek to impose on Defendant a duty to directly warn the ultimate drug consumers of the risks of taking Defendant's drugs. Plaintiffs' claims should be dismissed to the extent that they are premised on Defendant's failure to directly warn [plaintiff], or the general public, of the risks of taking [the drug]."); *cf. Summers v. Medtronic, Inc.*, No. 1:24-cv-11793, 2025 WL 2201110 (D. Mass. Aug. 1, 2025) (holding that allegations that device manufacturer failed to warn had failed to state a claim because the manufacturer had no duty to warn plaintiff). Moving to dismiss on this basis can also highlight for the court that although the plaintiff's failure-to-warn claims focus on what the plaintiff knew at time of use, what truly matters is the prescriber's knowledge.

Where appropriate, counsel can use publicly available documents—such as the FDA-approved drug label, clinical trial results or protocols, and FDA guidance and regulations—to demonstrate that the allegedly inadequate warning does, in fact, warn of plaintiff's exact injury. Courts across the country have dismissed failure-to-warn claims after taking judicial notice of public documents. *See, e.g., Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575-76 (E.D.N.Y. 2012) (dismissing claims after taking judicial notice of the FDA-approved label because the drug's "FDA-approved warning labels warn of the very injuries plaintiffs have pled"); *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 755-56 (11th Cir. 2011) (affirming dismissal because biologic's package insert "expressly and clearly warned [plaintiff's prescriber] about how to identify... patients and about the risk of the exact injury of which [plaintiff] now complains"); *Krulewich v. Covidien*, LP, 498 F. Supp. 3d 566, 577 (S.D.N.Y. 2020) ("The warnings given noted the risks of the complications that [plaintiff] actually experienced...."); *Marroquin*, 367 F. Supp. 3d at 1162 ("More than once, [the risk] is clearly and expressly identified as the most dangerous toxicity/potential side effect."); *Tears v. Bos. Sci. Corp.*, 344 F. Supp. 3d 500, 512 (S.D.N.Y. 2018) (various FDA-approved labeling "all contain warnings regarding the possibility of [the relevant risk]").

Asserting LID-related defenses at the pleadings stage may result in the need for amended complaints, limiting the number of legal claims alleged, or even reducing the inventory of plaintiffs. Even if unsuccessful, the motion to dismiss will highlight the importance of the LID and other case facts, thereby helping to focus discovery on the key issues.

Prioritization of LID Discovery, Especially in MDLs

Failure-to-warn cases in the pharmaceutical context are often consolidated into MDLs, with hundreds or thousands of plaintiffs alleging a common drug or device caused the same or similar injury. *See* U.S. J.P.M.L., *MDL Statistics Report – Docket Type Summary* (Aug. 1, 2025), ***https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-1-2025.pdf*** (38 pharmaceutical or medical device MDLs pending as of August 2025). The MDL judge's role is to manage the litigation in a manner that "promote[s] the just and efficient conduct" of the MDL. 28 U.S.C. § 1407(a). The Judicial Panel for Multidistrict Litigation defers to the MDL court to use its overall knowledge of the issues to manage, evaluate, and dispose of the actions before it. *See, e.g., In re Bard Implanted Port Catheter Prods. Liab. Litig.*, 698 F. Supp. 3d 1381, 1383 (J.P.M.L. 2023) (stating that MDL courts may respond to the filing of meritless complaints by "commit[ing] to dispos[e] of spurious claims quickly" (quotation omitted)). To that end, the MDL judge has substantial discretion in managing the discovery schedule, see Manual for Complex Litigation (Fourth) § 10.1 (2004), including by implementing procedures that help the parties more quickly understand the strengths and weaknesses of their cases.

Some MDL courts have implemented phased discovery wherein prescribing physicians are deposed early in the discovery period. Early LID discovery may provide a vehicle for the prompt disposition of weak or meritless cases in an MDL. For example, the court in *In re BioZorb Device Products Liability Litigation* entered a case management order wherein the first phase of discovery focused on the LID, which resulted in dismissal of one of the four bellwether cases less than a year later. See No. 1:23-cv-10599-ADB (D. Mass. Apr. 25, 2024), Dkt. No. 11 (CMO limiting first phase of discovery to core document discovery and depositions of plaintiffs and their implanting physicians); No. 1:23-cv-10599-ADB, 2025 WL 509834, at *3-4 (D. Mass. Feb. 14, 2025) (granting summary judgment to defendants for failure to produce evidence that prescriber "would not have used BioZorb had the manufacturer provided adequate warnings").

Early plaintiff-specific discovery, including depositions of prescribing physicians, is essential to the parties' and the court's ability to assess the inventory value or validity of the claims. Early depositions of prescribing physicians tend to help both parties more fully comprehend the strengths and weaknesses of the inventory, which, in some cases, can help advance global MDL resolution. *See In re Taxotere Prods. Liab. Litig.*, 994 F.3d 704, 709 (5th Cir. 2021) (affirming summary judgment by MDL court where prescribing physician gave dispositive LID testimony); *Carlson v. Bos. Sci. Corp.*, 856 F.3d 320, 323 (4th Cir. 2017) (same).

Pursue Dispositive LID Testimony

Depositions of prescribing physicians in failure-to-warn cases can lead to testimony sufficient to break the chain of proximate causation under the LID. Courts have found that, depending on the relevant jurisdiction's standards, proximate causation may be broken under various scenarios:

1) **The prescriber does not typically read labels and did not read the label of the allegedly defective treatment.** *See, e.g., Gebhardt v. Mentor Corp.*, 15 F. App'x 540, 542 (9th Cir. 2001) (holding expert testimony on the warning label was not relevant to causation because evidence showed the prescriber did not read the label); *Fields v. Mylan Pharms., Inc.*, 751 F. Supp. 2d 1260, 1263 (N.D. Fla. 2009) (granting summary judgment because "[e]ven if the warnings were deficient,... [the prescriber's] testimony establishes that [the drug's] labeling and warnings played no role in the physician's decision to prescribe [the drug] to Plaintiff"); *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 648 (E.D. Pa. 2020) (granting summary judgment because prescriber testified he did not read the warning label in its entirety and could not recall reading it prior to plaintiff's surgery).
2) **The doctor knew of the risk of the exact injury alleged by plaintiff independent of the label.** *See, e.g., Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 452 (Tenn. Ct. App. 1998) (affirming summary judgment to manufacturer because prescriber stated he was fully aware of the risks involved in using the hardware in this type of surgery and did not rely on defendant's literature in making his determinations); *Silverstein v. CoolSculpting – Zeltiq Aesthetics, Inc.*, 235 A.D.3d 604, 606 (N.Y. App. Div. 2025) (affirming summary judgment to manufacturer because prescriber testified that the claimed warning was "obvious" to pretty much anyone and that "through his education and training, he was aware of and knew the dangers of placing ice on bare skin, and that those dangers were basic medical knowledge"); *Fields*, 751 F. Supp. 2d at 1263 (granting summary judgment where prescriber relied on his own background, training, and expertise, rather than the label and plaintiff thus failed to establish proximate causation); *Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 104-05 (D. Md. 2020) (granting summary judgment because physician testified that he placed little weight on the device's warnings because he understood the risk through independent research, reading peer-reviewed literature, and the metal-on-metal community).
3) **The prescriber would have still prescribed the drug or device, even with knowledge of the risks of plaintiff's alleged injury or with the warnings requested by plaintiff.** *See, e.g., Chase v. Novartis Pharm. Corp.*, 740 F. Supp. 2d 1295, 1298 (M.D. Fla. 2006) (granting summary judgment because prescriber "unequivocally states that he would not have changed his prescription decision for Plaintiff in 2000, even with the addition of the language now found in the package insert"); *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 286 F. Supp. 3d 667, 671-72 (E.D. Pa. 2017) (granting summary judgment because prescriber testified that if the current package insert were in place when he prescribed the drug to plaintiff, he still would have prescribed the drug); *Wheeler v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 1344, 1353-54 (S.D. Ga. 2013) (granting summary judgment because prescriber testified the risks were well known in the medical community, he was aware of the risks, "and, most significantly, that he continues to prescribe Zometa in the same manner today as he did for" plaintiff).

The Impact of Plaintiff's Subjective Testimony on the LID Is Legally Irrelevant

At deposition, a plaintiff may testify that he or she would not have taken the drug or used the device at issue if a warning about the risk of plaintiff's alleged injury had been provided. Similar testimony often is offered in the form of an affidavit or declaration attached to an opposition to a motion for summary judgment, in the hope of creating a "genuine dispute as to [a] material fact." Fed. R. Civ. P. 56.

Some courts have held that such plaintiff testimony should be considered in conjunction with the LID, emphasizing the role of the patient in the doctor-patient relationship. *See, e.g., Himes v. Somatics, LLC*, 549 P.3d 916, 926 (Cal. 2024) (stating that "the learned intermediary doctrine affirms patient autonomy in medical treatment decisions"). Those decisions are inconsistent with the LID's purpose. *See Luttrell v. Novartis Pharms. Corp.*, 555 F. App'x 710, 712 (9th Cir. 2014) ("the learned intermediary doctrine requires a showing that the prescribing physician, not the patient, would have taken a different course of action if better warnings had been issued"); *Dearinger v. Eli Lilly & Co.*, 510 P.3d 326, 329 (Wash. 2022) ("a manufacturer satisfies its duty to warn patients of product risks by warning the prescribing physician, who then takes on the responsibility of communicating those warnings to the patient"); *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, 953 (E.D. Cal. 2013) (explaining that among the rationales for the LID is the concept that if a patient is "given the complete and highly technical information on the adverse possibility associated with the use of the drug," the patient 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"). The focus of causation in a pharmaceutical failure-to-warn case must be on the prescriber's decision, not the hindsight subjective testimony of the plaintiff.

To avoid improper reliance on a plaintiff's testimony, it is important to highlight for the court the rationale underlying the LID, which requires the rejection of subjective testimony at the summary judgment stage. *E.g., Arnold v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 1268, 1272 (M.D. Fla. 2014) (holding evidence that plaintiff would not have taken the drug if she had been warned of the risk was inadmissible because the manufacturer's duty to warn runs to the physician, not the patient). Comprehensive plaintiff testimony regarding the circumstances surrounding his or her treatment also may impact the court's assessment of any subsequent plaintiff testimony or affidavit. *See Leavitt v. Ethicon, Inc.*, 524 F. Supp. 3d 360, 370 (D. Vt. 2021) (finding LID rationale "persuasive especially where, as here, a plaintiff claims she relied exclusively on her physician's warn-

ings regarding the risks and benefits of" the medical device).

Know Your Jurisdiction When Assessing the Risks of Not Deposing the Prescribing Physician

It is the plaintiff's, not the defendant's, burden to prove causation and, therefore, one could argue that there is no need for a defendant to initiate efforts to depose a prescriber regarding proximate causation testimony. In a number of jurisdictions, if there is no prescriber testimony related to LID, then plaintiffs cannot show causation. For example, in *Greaves v. Eli Lilly & Co.*, the Second Circuit considered the plaintiff's appeal of a pharmaceutical manufacturer's summary judgment win under the LID. 503 F. App'x 70, 72 (2d Cir. 2012). The court affirmed summary judgment for lack of proximate causation, specifically noting that the plaintiff elected not to depose one of the prescribing physicians and, as such, the plaintiff "adduced no evidence showing that [the prescribing physician] was unaware of the... risk." *Id.* The court concluded: "In sum, because [the plaintiff] would have the burden of establishing proximate cause at trial, the absence of any record evidence that [the prescriber] was unaware of the risk... associated with [the drug] warrants granting summary judgment in favor of [defendant] under the learned intermediary doctrine." *Id.*

Other courts have similarly dismissed failure-to-warn claims where the prescriber was unavailable, not properly questioned, or dead. *See Pustejovsky v. PLIVA, Inc.*, 623 F.3d 271, 277 (5th Cir. 2010) (holding the plaintiff could not meet her burden on causation where the prescriber could not recall anything about her prescribing decision); *In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 3596982, at *9, 11 (E.D.N.Y. Oct. 20, 2009) (granting summary judgment because, as the plaintiff's prescribing physicians were not located and thus not deposed, the plaintiff failed to offer evidence that a different warning would have altered the prescriber's conduct, as required under California's LID); *Sauls v. Wyeth Pharms, Inc.*, 846 F. Supp. 2d 499, 502-503 (D.S.C. 2012) (holding that because the plaintiff bears the burden of proof, the prescriber's death prior to being deposed required dismissal of the plaintiff's failure-to-warn claims, where the plaintiff could not locate the prescriber's medical records and failed to preserve any testimony prior to the prescriber's death).

In contrast, some jurisdictions apply a "heeding presumption" to warnings causation, which puts the onus on the defendant to produce affirmative proof of the lack of causation—i.e., that the physician would not have heeded an allegedly adequate warning not to prescribe the medication for the plaintiff. *E.g., Wooderson v. Ortho Pharm. Corp.*, 235 Kan. 387, 410 (1984). In these jurisdictions, failure to depose the prescribing physician may impede the defendant's ability to succeed on summary judgment.

Deciding whether to depose a prescribing physician is both case and jurisdiction specific. Most doctors stand by their decision to prescribe—often due to the severity of the plaintiff's medical condition and the inferiority of available alternative treatments—and "normally they will testify that they understood the warnings provided by the company." Lars Noah, *supra*, at 893. Depositions of prescribing and treating physicians can play an important role in the outcome of pharmaceutical cases and whether to take them is a strategy decision that should be determined by the facts of each case.

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The LID's applicability is an important consideration in any pharmaceutical failure-to-warn based case. Counsel should fully assess its application to a specific case and use that information to inform interactions with opposing parties and the court at all stages of the litigation.