Defending Failure-to-Warn Claims

Combatting "If You Had Known" Hypotheticals

By Sarah L. Bunce and Madeline Dennis

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By now, we are all familiar with the common tactics in medical device and pharmaceutical product liability litigation for eliciting favorable physician testimony at deposition to defend against failure-to-warn claims: confirm that the product insert included all of the alleged risks; confirm that the physician did not read the product insert; and establish that the physician was independently aware of the alleged risks. But far too often, even in the face of good physician testimony, summary judgment is defeated by the response to four little words: "if you had known." Plaintiffs' counsel commonly employ hypothetical "if you had known" scenarios to convince treating physicians that yes, had they known of a certain injury or increased risk, they would not have prescribed the treatment in the first instance. Many courts find this testimony sufficient to create a fact question for a failure-to-warn claim. But if you can anticipate the questions to be asked, and be prepared to debunk them, you will be well positioned to avoid the "if you had known" trap.

The Learned Intermediary Doctrine

Under the learned intermediary doctrine, a prescription drug or medical device manufacturer may discharge its duty to warn consumers directly regarding the risks associated with use of a drug or device by warning a learned intermediary, generally the prescribing or the implanting physician. *See* Restatement (Third) of Torts: Prod. Liab. §6 cmts. d–e (1998); *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1279–80 (11th Cir. 2002). Thus, the manufacturer has no legal duty to warn consumers of the risks associated with the drug or device at issue as long as it adequately informs the prescribing physician of the material risks, and the manufacturer is not responsible even if the doctor does not pass the warnings on to the patient. *See Metz v. Wyeth*, 872 F. Supp. 2d 1335, 1344 (M.D. Fla. 2012), *aff'd*, 525 Fed. Appx. 893 (11th Cir. 2013). The learned intermediary doctrine provides defendant manufacturers with protection from failure-to-warn-based claims, including, in many jurisdictions, claims for fraud, misrepresentation, and breach

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of warranty. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 744 (S.D. W. Va. 2014) (collecting cases); *Beale v. Biomet,* 492 F. Supp. 2d 1360, (S.D. Fla. 2007) (similar).

Every state has either adopted the learned intermediary doctrine or has predicted that the doctrine would apply in some context, and every state that has considered application of the doctrine in the prescription drug or device setting has applied it. *Tyree v. Boston Sci. Corp.*, 56 F. Supp. 3d 826, 829 n.3 (S.D.W. Va. 2014) (confirming that 35 states, including the District of Columbia, have adopted the learned intermediary doctrine in the prescription drug product liability context and identifying 13 other states that have applied the learned intermediary doctrine or have predicted that the highest court would apply it); *Estate of Baker v. Univ. of Vermont*, 2005 WL 6280644 (Vt. Super. May 5, 2005) (applying the learned intermediary doctrine under Vermont law); *Silva v. SmithKlineBeecham Corp.*, 2013 WL 4516160, at *2–3 (N.M. App. Feb. 7, 2013) (same, under New Mexico law); *Centocor Inc. v. Hamilton*, 372 S.W.3d 140, 157–59 (Tex. 2012) (noting that only one state—West Virginia—had rejected the learned intermediary doctrine in the prescription drug context altogether); W. Va. Senate Bill 15 (adopting the learned intermediary doctrine, §55-7-30, as it would apply to manufacturers of prescription drugs and medical devices, passed Feb 16, 2016); *Headcount: Who's Adopted the Learned Intermediary Rule?*, Drug & Device L. Blog (Jul. 5, 2007), https://www.druganddevicelawblog.com (listing which states have applied the learned intermediary doctrine and explaining that no state has rejected the doctrine in the prescription medical product context).

In most jurisdictions, the learned intermediary doctrine is not an affirmative defense that shifts the burden of proof to the defendant, but rather, it "delineates to whom a defendant [] owes the duty to warn."

The rationale behind the doctrine is self-explanatory: the physician, as a "learned" intermediary, is in the best position to assess the risks and the benefits pertaining to a course of treatment for the particular patient. *See, e.g.*, *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162–63 (4th Cir. 1999) (explaining that "[a]s a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient" and that the "choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative" (internal citations omitted)). This is because patients most often rely on physicians' expertise, not on information in labeling or packaging, in deciding which product to use. *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 811 (N.D. Ohio 2004). Indeed, risks information regarding prescription drugs and devices "is often too technical for a patient to make a reasonable choice." *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989). Likewise, courts recognize that manufacturers' provision of warnings directly to consumers could impair the doctor–patient relationship. *Ellis*, 311 F.3d at 1280. Other "practical realities" support the learned intermediary doctrine; specifically, it would be impossible for manufacturers to warn every patient directly. *Id.* at 163 (citing *Hill*, 884 F.2d at 1070).

Courts have recognized various exceptions to the learned intermediary doctrine, including for mass immunization programs, contraceptive drugs and devices, drugs that have been withdrawn from the market, direct-to-consumer advertising, and overpromotion to physicians. *See, e.g.*, *Centocor*, 372 S.W.3d at 159-60; *Vitanza v. Upjohn Co.*, 778 A.2d 829, 847 (Conn. 2001). Only the exception for mass immunizations programs, however, is generally accepted, and even that exception is not applied often. *Mazur v. Merck & Co.*, 742 F. Supp. 239, 255 (E.D. Pa. 1990); *Beale*, 492 F. Supp. 2d at 1376–77 (predicting that Florida would not recognize the DTC exception and declining to apply it). While two Texas federal districts court have applied an "emoluments" exception—rejecting application of the doctrine when a manufacturer compensates or incentivizes the prescribing or implanting physician—the decisions contradict Texas Supreme Court jurisprudence regarding the doctrine and have not been followed by any other state or federal court. *See How Not to Create an Exception to the Learned Intermediary Rule*, Drug & Device L. Blog (Aug. 3, 2017), https://www.druganddevicelawblog.com (discussing *Murthy v. Abbott Laboratories*, 847 F. Supp. 2d 958 (S.D. Tex. 2011), and *Depuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation*, Nos. 3:11-MD-2244-K, 3:11-cv-1941-K, 3:11-cv-2800-K, 3:12-cv-1672-K, 3:13-cv-1071-K, 3:14-cv-1994-K, 2016 WL 6268090 (N.D. Tex. Jan. 5, 2016)).

In most jurisdictions, the learned intermediary doctrine is not an affirmative defense that shifts the burden of proof to the defendant, but rather, it "delineates to whom a defendant [] owes the duty to warn." *Centocor*, 372 S.W.3d at 164–65 (stating that in the prescription drug context, the doctrine is "more akin to a common-law rule rather than an affirmative defense"); *Calisi v. Abbott Labs.*, No. 11-10671-DJC, 2013 WL 5441355, at *16 (D. Mass. Sep. 27, 2013) (explaining that it is "the plaintiff's burden in a failure to warn case involving prescriptive evidence applying the learned intermediary doctrine [] to produce evidence that demonstrates that the warning was not appropriate to educate the reasonable physician"); *A.B. v. Ortho-McNeil-Janssen Pharms.*, No. 100100649, 2013 WL 2917651, at *26 (Pa. Com. Pl. Apr. 5, 2013) ("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."); *In re Vioxx Cases*, No. JCCP 4247, 2006 WL 6305292 (Cal. Sup. Ct. Dec. 19, 2006) (similar). *But see Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467, 1482 (M.D. Fla. 1993) (explaining that "[b]ecause [defendant] raises the "learned intermediary doctrine" as an affirmative defense, [defendant] bears the burden of proof on this issue").

When the learned intermediary doctrine applies, plaintiffs must show that (1) the warnings provided to the prescribing or implanting physician were inadequate; and

(2) had the prescribing or implanting physician received the proposed different or additional warnings, the physician would not have used the drug or device. *See, e.g.*, *Bock v. Novartis Pharms. Corp.*, 661 F. App'x 227 (3rd Cir. 2016) (upholding summary judgment on a failure-to-warn claim where there was no prima facie showing that different warnings to the prescribing physician would have altered plaintiffs' treatment course); *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) ("[T]he 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 have not used or prescribed the product." (internal citations omitted)); *Higgins v. Ethicon*, No. 2:12-cv-01365, 2017 WL 2813144, at *2 (S.D. W.Va. Mar. 30, 2017) (granting summary judgment in manufacturer's favor on failure-to-warn claim where the plaintiffs "failed to present any testimonial or other evidence that [plaintiff's physician] would not have used or prescribed the [device] to treat [plaintiff] had he received a different warning").

Plaintiffs' counsel go to great lengths to obtain admissions that "had the physician known [insert outcome]," the physician would have altered his or her treatment, knowing that this is the magic language that courts are looking for.

A lack of proximate cause is fatal to plaintiffs' claims, and there are several routes to getting there. Proximate cause is lacking when a physician testifies that he or she was aware of the possible risks involved but decided to use the product anyway. *See Higgins*, 2017 WL 2813144, at *2; *Olmo v. Davol, Inc.*, No. 13-62260-CIV-COHN/SELTZER, 2017 WL 1367231, at *6 (S.D. Fla. Apr. 10, 2017) (finding that the plaintiff could not demonstrate that the alleged failure to warn proximately caused her injuries where the "[plaintiff's physician] had independent knowledge of the [alleged risk]" and "elected to implant [the device] anyway" (citing *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995))). Likewise, many courts find testimony that the prescribing or implanting physician has not read the product insert fatal to failure-to-warn claims. *See, e.g., In re Zimmer*, 218 F. Supp. 3d 700, 728 (N.D. Ill. 2016) (reasoning that because the physician "did not read or rely upon the warnings Zimmer actually provided, Plaintiffs cannot prove that an improved warning—whether about the risks of high flexion activities or about proper surgical technique—would have led to a different outcome in [plaintiff's] case"); *Avendt v. Covidien*, No. 11-cv-15538, 2017 WL 2868487, at *28 (E.D. Mich. Jul. 5, 2017) (similar). Similarly, courts grant summary judgment in manufacturers' favor on failure-to-warn claims when the label contains a warning regarding the injury alleged. *See Vakil v. Bayer Health Care*, No. 13-00080, 2016 WL 7175638, at *6 (D.N.J. Dec. 7, 2016) (emphasizing that "[b]y providing warnings to Plaintiff's physicians of the exact harm eventually suffered by Plaintiff, Defendants discharged their duty owed to Plaintiff and are protected from liability pursuant to the learned intermediary doctrine"). Finally, plaintiffs cannot sustain a failure-to-warn claim based on injuries that they have not experienced. *See id.* ("Defendants cannot be held accountable for failing to warn Plaintiff of a symptom he never experienced").

Manufacturing a Fact Issue with Improper Hypotheticals

Plaintiffs' primary strategy for defeating summary judgment on failure-to-warn claims in the learned intermediary doctrine context has been to manufacture fact issues during physician depositions by focusing on whether the physician would have prescribed the drug or device if the physician had received a different warning. This is largely accomplished by posing hypothetical questions based on assumed, yet often wholly unsupported negative facts that no reasonable physician could disagree would have affected his or her decision to use the drug or device in question. Plaintiffs' counsel go to great lengths to obtain admissions that "had the physician known [insert outcome]," the physician would have altered his or her treatment, knowing that this is the magic language that courts are looking for.

However, courts have started to see through this tactic and require more than testimony in response to plaintiffs' counsels' hypothetical questions to defeat summary judgment on failure-to-warn claims. For example, in *Boehm v. Eli Lilly & Co.*, No. 4:10-cv-159-DPM, 2012 WL 12848432 (E.D. Ark. Oct. 4, 2012), *aff'd*, 747 F.3d 501 (8th Cir. 2014), the court rejected precisely this sort of attempt by the plaintiff to defeat summary judgment with improper hypotheticals. There, Dr. Forrest Miller started prescribing Zyprexa to the plaintiff in January 2003, to treat his bipolar disorder. 747 F.3d at 503. Dr. Gregory Kaczenski, who treated the plaintiff during a later hospitalization, also prescribed Zyprexa to him. Dr. Kaczenski stopped prescribing Zyprexa to the plaintiff in March 2007, however, when he concluded that it was likely causing tardive dyskinesia (TD). *Id.* While the package insert included a warning about TD, the plaintiff alleged that Eli Lilly failed to warn him sufficiently that the risk of TD increased over time. *Id.* at 505. Both doctors testified that they were aware of the risk of TD with Zyprexa, both from the package insert and from clinical experience, and significantly, that an alternative warning regarding TD would not have changed their decisions to prescribe Zyprexa to the plaintiff. *Id.*

Thus, based on Arkansas' learned intermediary doctrine, Eli Lilly moved for summary judgment on the plaintiff's failure-to-warn claim. In opposition, the plaintiff relied on testimony that his counsel elicited during Dr. Miller's deposition, which involved having Dr. Miller assume that there was a 15 percent risk of TD with Zyprexa if it was used for three years. Dr. Miller indicated that he would not have prescribed Zyprexa to the plaintiff for as long as he did had he known about that hypothetical rate. 2012 WL 12848432, at *2. In deciding the issue, the court reasoned that Dr. Miller's testimony "*if supported*, *could* create a triable issue," but the court concluded that "nothing in the record, other than a fact witness's response to a question containing the em-

bedded percentage, supported the number." *Id*. at *2. Thus, the court required the parties to further brief the issue of "whether the 15 percent risk had sufficient roots in scientific fact, whether, that is, the alleged 15 percent risk was supported by evidence that would be admissible under *Daubert*." *Id*.

On further briefing, to support the 15 percent figure, the plaintiff presented his expert's report, which cited a blog post, a website advertising the services of another expert, and one peer-reviewed study. 2012 WL 12848432, at *2. However, the court quickly rejected both the blog post and the website as deficient foundation. Likewise, the court found that the study was insufficient support because it addressed only the class of drugs, and if anything, it suggested that Zyprexa had a lower risk of TD in the circumstances. *Id*. The court concluded, "There is too great an analytical gap to extract from [the study] the 15 percent incidence rate Dr. Miller said would have changed his prescribing decision," and as a result, the court excluded the 15 percent risk figure and corresponding testimony from its summary judgment analysis. *Id*.

In granting summary judgment in Eli Lilly's favor on the failure-to-warn claim, the court emphasized that "a duty to warn differently only arises if that figure is grounded in scientific fact" and noted that the record contained no evidence that it was. *Id*. at *3. Indeed, the court recognized that "no reliable clinical evidence indicated that Zyprexa's risks regarding [TD] could have been quantified and particularized in a risk percentage/duration fashion in a more specific warning to [the plaintiff's] doctors" because "[t]hat data did not and does not exist insofar as the record discloses." *Id*. at *4.

The Eighth Circuit affirmed the trial court's decision to exclude the testimony regarding the 15 percent figure and to grant summary judgment in Eli Lilly's favor, noting:

> On appeal, Boehm places great emphasis on the testimony in which Dr. Miller agreed that prescribing Zyprexa for three years was "too long" given the 15 percent risk of developing TD. But that testimony was based on Boehm's counsel instructing Dr. Miller that a 15 percent risk factor for Zyprexa users had been established… *which was untrue*.

747 F.3d at 508 (emphasis added).

Both courts likewise rejected the plaintiff's argument that the overpromotion exception to the learned intermediary doctrine precluded summary judgment on the failure-to-warn claim. Initially, the trial court voiced its doubt that Arkansas would recognize the overpromotion exception at all. 2012 WL 12848432, at *4. In addition, the court explained that there was no evidence in the record that any representation by an Eli Lilly salesperson affected the prescribing physicians' decisions to prescribe Zyprexa to the plaintiff. *Id*. The court emphasized that Dr. Miller did not remember whether any sales representatives discussed risks with him, and although Dr. Kaczenski recalled marketing contacts and documents from Eli Lilly, that did not undermine his status as a learned intermediary. *Boehm*, 2012 WL 12848432, at *4–5.

Similarly, in *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014), the court refused to consider deposition testimony based on an unfounded hypothetical in determining whether to grant summary judgment on the plaintiff's failure-to-warn claim. In opposition to the defendant's motion, the plaintiff cited deposition testimony from his prescribing nurse practitioner indicating that she would have altered her treatment decision if she had been made aware that Cymbalta's discontinuation adverse effects were as severe as Effexor's. *Id*. at 409–10. But the court emphasized that there was no evidence in the record that suggested that to be true. The court noted that defense counsel "properly objected to the line of questioning as lacking foundation and calling for speculation due to absence in the record of any support for the claim," and "the inadmissibility of [the] testimony is a separate, stand-alone ground for rejecting it as a basis for denying summary judgment." *Id*. at 410.

These decisions recognize the central tenet that courts should not consider inadmissible evidence in ruling on motions for summary judgment. *McDowell*, 58 F. Supp. 3d at 410 ("Only admissible evidence need be considered by the trial court in ruling on a motion for summary judgment.") (citing *Presbyterian Church*, 582 F.3d 244, 264 (2d Cir. 2009)); *Bock*, 661 F. App'x at 233–34 (emphasizing that "speculation cannot stave off summary judgment"). Other courts have likewise required reliable evidence to defeat summary judgment on failure-to-warn claims. For example, in *Avendt v. Covidien,* No. 11-cv-15538, 2017 WL 2868487 (E.D. Mich. Jul. 5, 2017), the court reasoned that "Plaintiffs offer insufficient evidence on which a reasonable juror could conclude exactly *what more* the [device IFU] *should* have said that would have dissuaded [plaintiff's doctor] from implanting it" and that "[i]n short, Plaintiffs have proffered no scientifically reliable peer-reviewed opinion that the [manufacturer's] IFU should have directed practitioners to remove [the product] in the face of a seroma or an infection." *Id*. at *26 (emphasis in original). Similarly, in *Beale*, the court reasoned that while the plaintiffs contended that the physician "was misled [by the manufacturer] into believing that the product worked better than it actually did," they "ha[d] not substantiated this assertion with any evidence in the record to create an issue of material fact as to whether [the physician] was so misled." 492 F. Supp. 2d at 1370.

Exposing and Defeating Improper Hypotheticals

There are several steps that defendant drug and device manufacturers can take to prevent deposition testimony based on improper hypotheticals from defeating summary judgment in the defendants' favor on failure-to-warn claims.

Initially, during plaintiffs' counsel's direct examinations of implanting or prescribing physicians, remember to object to the improper hypothetical questions as based on a lack of foundation. This both preserves the argument that the testimony should be inadmissible to oppose summary judgment and can also signal to more savvy (and sometimes pro-defense) physicians to question the proposed premise. Be sure also to take note of the hypotheticals presented so that you are prepared to debunk them on cross-examination.

During cross-examination, there are several ways to combat the hypothetical questions and the typically unfavorable physician testimony offered in response. Your approach to debunking the hypotheticals will depend on the type of questions asked. Two general categories of hypothetical questions that are often asked include (1) questions about whether the drug or device would have been prescribed

if the physician had known that a specific injury would result, or (2) questions about whether the drug or device would have been prescribed if the physician had known that the risk of a specific injury was higher than that of competitor products (or higher than warned by the defendant).

With the first category of hypotheticals, your questions should focus on the plaintiff's injuries and the known risks. More often than not, plaintiffs' counsel will ask hypotheticals based on injuries that were *not* suffered by the plaintiff. In that case, you should confirm with the physician the full extent of the injuries suffered by the plaintiff and emphasize that the plaintiff did not suffer the injuries asked about in the hypothetical. You should also be prepared to challenge the premise that the defendant manufacturer was aware of any risk of the hypothetical injury. Because the duty to warn includes only known risks, you can either produce evidence or use the exhibits offered by plaintiffs' counsel (if any) to demonstrate that the manufacturer was not aware of a risk of the hypothetical injury.

With the second category of hypotheticals, it is again important to focus on the plaintiff's injury and to confirm (if possible) that the hypothetical involved an injury that was not suffered by the plaintiff. In addition, in the vein of *Boehm*, it is critical to try to debunk the "fact" of an increased risk or greater risk of injury. Many times the hypothetical questions are based on anecdotal company documents regarding certain complaints, or on hand-picked articles about negative outcomes that say nothing about an overall risk of injury. You should first confirm with the physician that none of the exhibits offered by plaintiffs' counsel actually included any evidence of an overall risk of injury. Physicians will often readily admit that anecdotal reports of complaints and articles are not representative of every physician's or patient's experience with a certain drug or device, and thus they cannot be used as a proxy for the overall risk of injury. You should then offer rebuttal evidence—to the extent that such evidence exists—that demonstrates that the overall risk of injury was, in fact, *not* what the plaintiff had asked the physician to assume.

Conclusion

It can be easy to become discouraged at physicians' depositions to hear the inevitable "if you had known" questions and answers and feel your failure-to-warn defenses slipping away. But with preparation, you can successfully anticipate the hypothetical questions that you can expect and establish a solid record to expose the shaky factual premises on which they are based and preserve your defenses. FD