Combating Evidence of Off-Label Promotion in Pharmaceutical and Medical Device Products Liability Actions with the Learned Intermediary Doctrine

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I. Introduction

Allegations of off-label promotion—i.e., that a drug or medical device manufacturer has improperly marketed its product for an unapproved use—have become increasingly common in drug and device products liability cases in recent years as both the FDA and FTC have undertaken high-profile enforcement efforts in this area. Indeed, the plaintiffs’ bar now frequently argues that off-label marketing constitutes per se evidence of a manufacturer’s failure to warn whenever a plaintiff was injured from an off-label use.

Fortunately for defendants, however, a prescriber’s decision to use a drug or device off-label is entirely legal, and the learned intermediary doctrine—which remains alive and well across the country—can be an effective tool for combatting such claims.

At core, whether a defendant's alleged off-label marketing caused a plaintiff’s injury is a question of proximate cause. If the off-label marketing in question cannot be shown to have influenced a treating physician's decision to recommend the drug or device in question, it cannot be said that the drug or device manufacturer's marketing efforts—whether or not they were otherwise permissible—had any effect on the plaintiff’s alleged injury.

This article examines recent developments in the law of off-label promotion and the learned intermediary doctrine, and provides strategies for setting the stage for summary judgment with effective discovery.

II. What Is Off-Label Marketing, and Why Does It Matter?

A. Off-Label Marketing: An Overview

Under the Federal Food Drug and Cosmetic Act (“FDCA”) and implementing regulations, drugs and medical devices may only be labeled and marketed by their manufacturers for particular uses that have been previously approved by the FDA. If a manufacturer deviates from this requirement, they will be considered to be selling a “misbranded” product in violation of Section 352 of the FDCA. See 21 U.S.C. §502. For many years, FDA has construed this statute to prohibit drug and device manufacturers from promoting unapproved uses of their products, even if such unapproved uses are supported by efficacy and safety data. See, e.g., 65 Fed. Reg. 14,286, 14,286 (March 16, 2000) (“an approved new drug that is marketed for a ‘new use’ becomes an unapproved new drug with respect to that use.”)

Nevertheless, the FDA has no authority to regulate the practice of medicine, and it is widely accepted in the medical community that doctors may prescribe drugs or devices for any medically appropriate purpose, even if that purpose has not been previously approved by the FDA. When a doctor makes such a choice, it is commonly referred to as an “off-label” use. See, e.g., https://www.fda.gov/ForPatients/Other/OffLabel/uscm20041767.htm. Indeed, the FDA has acknowledged that “[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment.” See https://www.fda.gov/RegulatoryInformation/Guidances/uscm126486.htm.

The conflict between these two principles becomes obvious when a drug or device manufacturer seeks to disseminate information about its product for a purpose that may have gained acceptance in the
medical community, but has not yet been approved by the FDA. Such activities are commonly referred to as “off-label promotion,” and generally speaking, they are viewed as prohibited by federal law.

Over the years, the FDA—and its counterparts at the FTC and DOJ who enforce off-label promotion under the False Claims Act—have shifted their position on what type of activity by manufacturers constitutes off-label promotion, while simultaneously stepping up their efforts to enforce what they deem to be improper marketing.

For example, in the past decade, DOJ has initiated dozens civil and criminal actions against pharmaceutical and medical device companies for alleged off-label promotion. Many of these actions were brought with the assistance of states’ attorneys general and styled as fraud actions, alleging at core that the manufacturers in question misled Medicaid and Medicare into paying for drugs and devices that were not approved by the FDA. See, e.g. https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf. The majority of these actions resulted in guilty pleas and civil settlements, many of them in excess of $1 Billion. See, e.g., https://www.justice.gov/opa/press-release/file/918366/download.

Meanwhile, the FDA has also issued seemingly-contradictory industry guidance suggesting that manufacturers may nevertheless disseminate medical journal articles and scientific literature to prescribers that discuss off-label use of their products. See, e.g., https://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm; see also https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf (setting up framework for responding to prescriber requests for off-label information). This has left manufacturers in a tenuous position, trying to balance the benefit of providing the medical community with as much information as possible about their products with the risk of running afoul of the general prohibition on off-label promotion.

Recognizing this inherent conflict, courts have begun to clarify that manufacturers have a First Amendment right to disseminate truthful and non-misleading information about their products, even if such information relates to uses unapproved by the FDA. In 2012, for example, the United States Court of Appeals for the Second Circuit reversed the criminal conviction of a sales representative accused of communicating with physicians about off-label applications for the narcolepsy drug Xyrem, finding his truthful statements regarding other uses of the medicine were protected speech. See generally United States v. Caronia, 703 F.3d 149 (2d Cir. 2012). Writing for the majority, Judge Denny Chin reasoned that because “off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government’s goals of preserving the efficacy and integrity of the FDA’s drug approval process and reducing patient exposure to unsafe and ineffective drugs.” Id. at 166. Thus, the Second Circuit held, “we construe the FDCA as not criminalizing the simple promotion of a drug’s off-label use because such a construction would raise First Amendment concerns.” Id. at 168.

More recently, in 2015, Judge Paul Engelmayer of the United States District Court for the Southern District of New York took Caronia’s logic a step further, granting a preliminary injunction to the manufacturer of the triglyceride-lowering drug Vascepa after finding that the threat of an FDA enforcement action would have a chilling effect on its right to disseminate truthful scientific information about alternative uses for the drug. See Amarin Pharma, Inc. v. United States FDA, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). While FDA vigorously contested Amarin’s initial claim, the case settled shortly thereafter, with FDA conceding that Amarin was permitted to “engage in truthful and non-misleading speech promoting the off-label use of Vascepa . . . and that under Caronia, such speech may not form the basis of a prosecution for misbranding.” See id., No. 1:15-cv-3588-PAE, ECF No. 84 at 2 (March 8, 2016).
In light of the Amarin settlement, it appears that the FDA has begun to recognize the inherent conflict between the First Amendment and its desire to limit manufacturers’ ability to promote their products off-label. Indeed, many were expecting a major change in FDA policy when the agency held a public hearing on off-label promotion this past fall. Nevertheless, as of this writing, the FDA still takes the view that the First Amendment does not prevent the enforcement of off-label promotion, and has expressed its intent to continue to pursue such cases. See, e.g., https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537371.htm.

In sum, the law in this area remains in flux, and is likely to continue to evolve in the coming months as the debate about access to affordable healthcare—and pharmaceuticals and medical devices in particular—moves to the forefront of public consciousness. Against this backdrop, the plaintiff’s personal injury bar has gone to great lengths to incorporate evidence of allegedly nefarious off-label promotion into related products liability claims.

B. Off-Label Marketing as a Products Liability Claim

In products liability cases, plaintiffs often argue that by promoting off-label, manufacturers fail to sufficiently warn of potential side effects associated with off-label uses that do not appear in the approved labeling.

In the device context—where claims for PMA-approved devices are generally preempted—plaintiffs have successfully argued that evidence of off-label promotion is sufficient to establish a parallel claim. See, e.g., Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1179-80 (C.D. Cal. 2013) (finding that because off-label promotion is prohibited under federal law, “[p]laintiff’s fraud claims are parallel or ‘genuinely equivalent’ to federal law because there is no likelihood that Defendants could be held liable under state law without having violated the federal law.”); Schouest v. Medtronic, Inc., 13 F. Supp. 3d 692, 704 (S.D. Tex. 2014) (finding that “Schouest’s state law fraud claims based on false off-label promotion would, if proven, also amount to a violation of federal law, and thus such claims could survive preemption.”); Shuker v. Smith & Nephew PLC, 2015 U.S. Dist. LEXIS 43141, at *51 (E.D. Pa. Mar. 31, 2015)(“[O]ff-label promotion can be a basis for a non-preempted parallel claim in some circumstances, as federal law has generally been interpreted to prohibit off-label promotion.”).

In the drug context—where preemption is generally unavailable as a defense—plaintiffs have successfully argued that promoting medicines for off-label uses without also communicating off-label risks is tantamount to negligence per se. See, e.g., Miles Laboratories, Inc. v. Superior Court, 133 Cal. App. 3d 587, 595 (Cal. App. 4th Dist. 1982) (finding liability could lie where the manufacturer (a) knew or should have known that its drug was being used for an off-label use; (b) benefited from that use; and (c) failed to warn of risks associated with that off-label use); McNeil v. Wyeth, 462 F.3d 364 (5th Cir. 2006) (holding that manufacturers who substantially profit from off-label use of their products must warn physicians of the risks associated with that off-label use); Dellinger v. Pfizer, 2006 WL 2057654 (W.D.N.C. July 19, 2006) (finding that it was unreasonable for Pfizer not to warn of risks because Pfizer fraudulently promoted off-label use of the drug); Smith v. Pfizer, 714 F. Supp. 2d 845 (M.D. Tenn. 2010) (holding that Pfizer’s unauthorized promotion of Neurontin for off-label use made it more likely that use was foreseeable, thereby triggering duty to warn physicians of risks associated with off-label use).

III. Evidence of Off-Label Promotion Does Not Diminish a Plaintiff’s Burden to Establish Proximate Cause

When faced with allegations of off-label promotion in the context of a failure to warn claim in either the drug or device context, defendants may initially be tempted to argue that it would have been impossible
for them to warn of the risks associated with off-label uses because the FDA’s regulations prohibit such conduct. And in some cases, depending on the facts, such a defense may be appropriate. But often times, such an argument is too clever by half: if a manufacturer is prohibited from disclosing the risks, shouldn’t it also be prohibited from selling the product?

Rather, defense attorneys may be better served by zeroing in on causation: In order to establish that a manufacturer is liable for failing to warn, it must be shown that said failure to warn the proximate cause of the plaintiff’s individual harm. Thus, rather than focusing on the propriety of the allegedly improper off-label promotion in general, in many cases it is better to focus on what role—if any—the alleged off-label promotion in question actually played in the plaintiff’s decision use the medicine or device that they claim gave rise to their injury.

A. The Learned Intermediary Doctrine Is Alive and Well

The “learned intermediary” doctrine is an exception to the general rule that manufacturers have a duty to warn consumers of foreseeable risks associated with the use of their products. See Restatement (Third) of Torts: Prods. Liab. §2(c). For prescription drug and medical device manufacturers, that duty is satisfied by providing a warning to the prescribing physician, who stands as a “learned intermediary” between the manufacturer and the end-user of the product. See Restatement (Third) of Torts: Prods. Liab. §6 cmt. d. “The rationale supporting this ‘learned intermediary’ rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.” Restatement (Third) of Torts: Prods. Liab. §6(d)(1) cmt. b.

Courts have also recognized other policy reasons for the learned intermediary doctrine, including (1) prescribing physicians are “in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient”; (2) manufacturers lack the means to provide warnings directly to patients; and (3) direct warnings to patients would interfere with the doctor-patient relationship. See Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (Ky. 2004). Some form of the learned intermediary doctrine has been adopted in all fifty states, the District of Columbia, and Puerto Rico, either by statute or through common law.2

The rule is not without exceptions, however. For example, many courts have concluded that the learned intermediary doctrine doesn’t discharge manufacturers from liability for warning of the risks associated with vaccines, which are often administered as part of a mass-vaccination program with little physician involvement. See, e.g., Reyes v. Wyeth, 498 F. 2d 1264 (5th Cir. 1974). Other courts have refused to apply the learned intermediary doctrine in cases involving oral contraceptives for the same reason. See, e.g., MacDonald v. Ortho Pharmaceutical Corp., 475 N.E. 65, 67 (Mass. 1985) (because “the pill” is often used as “a convenience, rather than a traditional medication,” the physician plays a less-active role in prescribing decisions); see also Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1148 (D. Or. 1989). And New Jersey has recognized an exception to the learned intermediary doctrine where manufacturers engage in substantial direct-to-consumer advertising of prescription medicines. See Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1263 (N.J. 1999). The Perez ruling generated substantial controversy and has not been widely followed. See, e.g., Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (“While the Perez court found that the law should be changing in response to changes in marketing strategies by drug manufacturers, New Jersey is the only state to have done so. It is now eight years since Perez was decided, and no other state has followed suit.”); Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 163 (Tex. 2012) (“Even so, we must believe that patients who seek prescription drugs based solely on DTC advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient.”)
Finally, while the learned intermediary doctrine clearly applies to physicians, Courts have also concluded in some contexts that other intermediaries, such as nurses and physicians’ assistants, might qualify as “intermediaries” as well, especially if they make prescribing decisions. See e.g., Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1281 (11th Cir. 2002) (nurses); Stevens v. Novartis Pharmaceuticals Corp., 247 P.3d 244 (Mont. 2010) (physicians assistants). The same cannot be said, however, for optometrists and pharmacists, who have generally been found to lack the training or experience to make patient care decisions. See, e.g., Prager v. Allergan, Inc., 1990 WL 70875, at *4 (N.D. Ill. May 2, 1990); Bukowski v. CooperVision Inc., 592 N.Y.S.2d 807, 809 (N.Y. App. Div. 1993); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1387 (Pa. 1991).

B. The Learned Intermediary Doctrine and Proximate Cause

In order to establish that a manufacturer’s alleged failure to warn was the proximate cause of their claimed injury, it is the plaintiff’s burden to establish that their physician would have made a different prescribing decision had they received different information from the company. But “where the treating physician is independently aware” of potential adverse events, that knowledge is “an intervening event relieving the manufacturer of any liability to a patient under the failure to warn theory.” Banker v. Hoehn, 278 A.D.2d 720, 722, 718 N.Y.S.2d 438, 440-41 (3d Dept. N.Y. 2000); see also Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 286 (S.D.N.Y. 2009) (granting summary judgment, finding “[t]he Plaintiff has not shown that a failure to warn . . . was the proximate cause of his injuries, as his physicians were aware of the risks . . .”). Put another way, a physician’s existing awareness of a potential risk or side effect “sever[s] the causal [chain]” between an allegedly inadequate warning and a plaintiff’s injury. Glucksman v. Halsey Drug Co., 160 A.D.2d 305, 308, 553 N.Y.S.2d 724, 726 (1st Dept. 1990).

Thus, by focusing discovery efforts on the learned intermediary’s knowledge of the risks associated with a drug or device, defendants can often muster strong evidence supporting a summary judgment motion based on proximate cause (or lack thereof). See, e.g., Bee v. Novartis Pharm. Corp., 18 F. Supp. 3d 268, 284 (E.D.N.Y. 2014) (“where a defendant can show, via ‘specific facts,’ that any given warning would have been futile—either because any such warnings would not have been heeded or because the injury would have occurred, regardless of the given warnings—a defendant will have successfully rebutted the general presumption that a user would have heeded warnings if they had been given, and that the injury would not have occurred”).

Indeed in some jurisdictions, Courts have concluded that a plaintiff can only defeat summary judgment with testimony from their prescriber that the prescriber would have acted differently had a different warning been provided. See e.g., In re Mentor Corp. ObTape Transobdurator Sling Prods. Liab. Litig., No. 4:13-cv-229, 2016 WL 4611572 (M.D. Ga. Sept. 2, 2016) (excluding expert testimony regarding what a “reasonable doctor” would do, holding that for purposes of causation, the question is not what a reasonable doctor would do, but what the patient’s particular doctor would do); In re Accutane Litigation, 2016 WL 5958374 (New Jersey Super. Law. Div. Oct. 12, 2016) (granting summary judgment for defendants under 35 different state laws where death or disappearance of the actual prescriber precluded the affirmative testimony necessary to satisfy the plaintiff’s burden of proof).

IV. Strategies for Minimizing the Impact of Evidence of Off-Label Promotion

Because a manufacturer’s duty to warn extends only to prescribing physicians, and a prescribing physician’s independent knowledge of a risk severs the causal chain in a failure to warn case, whether off-label
promotion influenced the prescribing physician's medical judgment at all is a key fact for defendants to establish whenever allegations of off-label promotion are raised in a case. Simply put, if the prescribing physician was unaware that the drug or device was promoted off-label, or if the prescribing physician made a decision to use a drug or device off-label with full knowledge of the risks, then evidence of off-label promotion becomes largely irrelevant. Keeping these facts out of a case are important, as there can be little doubt that allegations about big-ticket off-label settlements that have no actual bearing on a prescriber's decision to use a particular medicine run the risk of prejudicing the fact finder. Attacking these issues early and efficiently in discovery is therefore crucial to a successful defense.

A. Elicit Beneficial Testimony from Prescribers

The first step to successfully defending any drug or device failure to warn claim is to identify the prescriber (or prescribers) who were involved in making treatment decisions for the plaintiff related to the product in question. This is often easier said than done, and requires substantial persistence. Most doctors have no interest in becoming involved in litigation, and different states have different rules on communicating with third-party treating physicians in the context of a personal injury case. While some states forbid defense attorneys from having ex parte communications with prescribers, other states, such as New York, have mechanisms to encourage it. Where it is possible to have ex parte communications with physicians, it is often much easier to approach them informally rather than subpoenaing them to ask for their cooperation in the form of a voluntary deposition or an affidavit. Many doctors will be startled to learn that their prescribing decision has become the focus of a lawsuit, and will want the opportunity to explain themselves.

Once you have an opportunity to sit down with a prescriber, either in a deposition or otherwise, it is important to direct your examination of them in a way that bolsters their credibility and confidence. When given the chance, most physicians will testify credibly that they make their own prescribing decisions, and that they don’t rely solely on information provided by pharmaceutical companies. Many will tell you they rely most on their own clinical experience, as well as continuing medical education classes, conferences, and conversations with their peers. The more that you can elicit testimony that physicians rely on information outside of a product’s labeling, the better position you will be in to argue that a different warning would not have changed their mind.

With regard to off-label allegations specifically, it is important to pin down physicians about their independent knowledge of off-label use for the product at issue. More often than not, unapproved uses are extensively discussed in the medical community, and most physicians make the decision to use a drug or device off-label based on conversations with their peers, not communications with the manufacturer. Indeed, prescribers consciously using medicines off-label often have a more sophisticated understanding of the unique risks and benefits attendant to that decision than those using medicines on-label.

Finally, while plaintiffs lawyers will often rely on hypothetical questions to establish what a doctor would have done differently with different information, if the prescriber is being offered as a fact witness as opposed to an expert, such hypothetical opinions should not be admissible. It is important to understand the rules in your jurisdiction to make sure the plaintiff’s lawyer is not allowed to elicit improper opinion testimony without properly disclosing the physician as an expert.

B. Understand the Reach of the Alleged Off-Label Promotion

In addition to understanding the extent to which off-label promotion influenced a prescriber from their perspective, it is also important to understand the scope of the alleged off-label promotion from the manufacturer’s perspective. If your client was involved in any kind of enforcement action with the FDA, FTC,
or DOJ, odds are that there is a substantial record to review, but much of this record may have little to do with the facts of the subsequent products liability case. In some cases, the alleged off-label promotion occurred in a different geographic area than where the prescriber treated the patient. In other cases, the alleged off-label promotion occurred during a different time period than when the prescriber was making treatment decisions about the patient. It is therefore important to look at your client’s records to determine as best as possible whether the off-label promotion in question ever reached the actual prescriber.

If there is evidence that the off-label promotion in question could have reached the prescriber in question, it may be helpful to locate the sales representatives involved. In many cases, sales representatives will remember particular physicians and may be in a position to offer beneficial testimony. For example, the representative may remember that the prescriber in question refused to take meetings with sales reps, which is not uncommon. Testimony to this effect can help militate against documentary evidence (such as call logs) that might suggest a sales rep had substantial contact with a particular prescriber.

C. Challenge the Relevance of Plaintiffs’ “Off-Label” Experts

Plaintiffs will often attempt to rely on regulatory and marketing “experts” to opine that off-label promotion efforts had a substantial effect on the medical community’s decision to use a particular drug or device for an off label use. Such experts will pore over company documents regarding off label promotion efforts, and attempt to correlate off label promotion to an effect on sales or internal knowledge of a risk. But these experts are rarely able to present this evidence in a way that is relevant to the actual case, particularly when confronted with testimony from a prescriber with factual knowledge. At the end of the day, an expert’s hypothetical statement about what a hypothetical doctor would have done at some point in the past had a different warning been given is far less helpful to the fact-finder than a prescriber’s testimony about what he or she actually knew and actually did.

Thus, when given the opportunity to depose plaintiff’s experts, it is always important to focus on how little they know about the actual case. Often, a plaintiff’s expert will have never seen or treated the plaintiff, and never spoken with the plaintiff’s treating doctors, and as such motions to exclude their hypothetical testimony can be a valuable tool.

V. Conclusion

Plaintiffs work hard to incorporate evidence of off-label promotion into their cases to paint pharmaceutical and medical device defendants as greedy wrongdoers, but such allegations are irrelevant under the learned intermediary doctrine if there is no evidence that off-label promotion reached the prescriber, or if there is no evidence that it had any effect on their prescribing decision. Focusing on breaking this causal chain early in discovery is the key to a successful defense of any products liability case concerning a drug or device that has been promoted off-label.
Appendix

State-by-State Recognition of the Learned Intermediary Rule

I. Adopted By Legislature or Highest Court in Prescription Medical Product Cases


19. **Mississippi**: Miss. Code §11-1-63(c)(ii); *Janssen Pharmaceuticals, Inc. v. Bailey*, 878 So.2d 31, 57 (Miss. 2004); *Moore v. Memorial Hospital*, 825 So.2d 658, 664 (Miss. 2002); *Bennett v. Madakasira*, 821 So.2d 794, 804 (Miss. 2002); *Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d 688, 691-92 (Miss. 1988).


II. Adopted By Highest Court In State in a Non-Prescription Medical Product Case


III. Jurisdictions In Which An Intermediate Appellate Court Has Adopted Learned Intermediary Doctrine in Prescription Medical Product Cases


III. Jurisdictions In Which An Intermediate Appellate Court Has Adopted Learned Intermediary Doctrine in Prescription Medical Product Cases


IV. Jurisdictions in Which a Trial Court Has Adopted Learned Intermediary Doctrine in Prescription Medical Product Cases


V. Jurisdictions in Which Federal Courts Have Predicted the Adoption of the Rule in Prescription Medical Product Cases Where the State Courts Are Silent


Endnotes

1 Whether a doctor's decision to use a drug or device off-label could subject them to potential liability for medical malpractice is different story for a different article.

2 In 36 states and the District of Columbia, the learned intermediary doctrine has been formally adopted by the legislature or the state's highest court, with West Virginia being the most recent in May 2016. In 2 states, Idaho and South Carolina, the learned intermediary doctrine has been recognized in a non-prescription medical product case. In 4 states, Colorado, Indiana, Louisiana, and New Mexico, the learned intermediary doctrine has been recognized by an intermediate appellate court. In Vermont, the learned intermediary doctrine has been recognized by a trial court. Finally, in 8 states and Puerto Rico, while the state courts have remained silent on the issue, the learned intermediary doctrine has been recognized by federal courts applying state law. A complete list of these states is attached as an Appendix to this article.