Natali Shabani
PRESTIGE LAW FIRM

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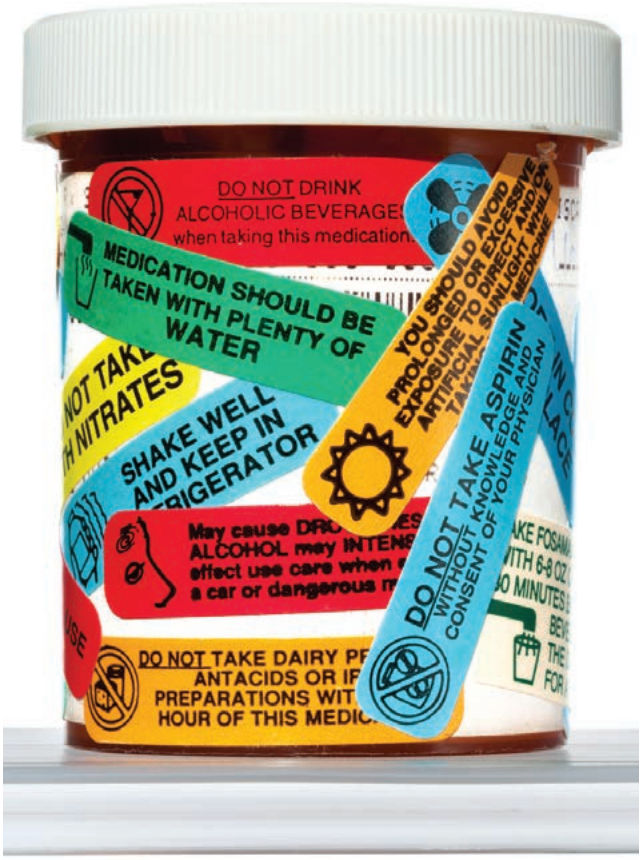
When that which is supposed to heal, does more harm than good

AN OVERVIEW OF THE DOCTRINAL FRAMEWORK OF WARNING DEFECTS AS APPLIED TO PHARMACEUTICAL-INJURY CASES



Pharmaceutical-related products-liability claims come in three basic categories, which parallel those of defective-product claims in general: claims based on defectively manufactured pharmaceutical drugs, claims based on defectively designed drugs (even though properly manufactured), and claims based on inadequate warnings or improperly marketed pharmaceutical drugs. The focus of this article is this last category: where the pharmaceutical manufacturer fails to issue proper or adequate warnings regarding the dangers or side effects of a drug it manufactured.

As early as 1980, California courts recognized that that when it comes to choosing whether the cost of an injury involving prescription medication should be borne by an innocent plaintiff or a negligent defendant, the latter should bear the cost. (*Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, 610-611.) Significant moral blame attaches where a brand-name drug manufacturer fails to warn about the unsafe effects of its drug, when those unsafe effects are known or reasonably should have been known to the manufacturer. (See *Peterson v. San Francisco Community College Dist.* (1984) 36 Cal.3d 799, 814.) A brand-name drug manufacturer is in the best position to discover and cure deficiencies in its warning label, to bear the cost of injury resulting from its failure to update and maintain the warning label, to ensure against the risk of liability, and to spread any increased cost widely among the public. After all, the fault (if any) for a deficient label lies with the brand-name manufacturer alone. (*Groll v. Shell Oil Co.* (1983) 148 Cal.App.3d 444, 449.)

In 2008, in *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, the court recognized warning-label liability in both brand-name and generic drugs. In *Conte*, the court decided that a brand-name drug manufacturer's common-law duty of care when warning of the dangers of its drug extended not only to consumers of the brand-name drug, "but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug." (*Id.* at 94.) The court's holding predated by approximately three years the United States Supreme Court's ruling requiring generic drug manufacturers to conform their warning label to the brand-name manufacturer's label. (*PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604.)

Adequacy of warning

Imposition of liability requires a showing that the pharmaceutical manufacturer did not adequately warn

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of a known or reasonably knowable risk. There is no duty to warn against every conceivable health problem associated with the use of a product or to warn of risks that are "merely speculative or conjectural, or so remote and insignificant as to be negligible." (*Carlin v. The Superior Court of Sutter County* (1996) 13 Cal.4th 1104, 1116.) "Knowledge of a potential side effect which is based on a single isolated report of a possible link between a prescription drug and an injury may not require a warning." (*Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 701.) However, the more severe the consequences from exposure, the greater the need to warn of significant health risks. Thus, the warning must be commensurate with the risk of harm. (*Schwoerer v. Union Oil Co.* (1993) 14 Cal. App.4th 103.) State-of-the-art evidence is admissible on the issue of whether the defendant knew or should have known of the particular risk involved. (*Anderson v. Owens-Corning Fiberglass Corp.* (1991) 53 Cal.3d 987.)

Where the manufacturer does issue a warning, the warning must be sufficient to apprise the reader of the dangers of the product. If the warning is clear, understandable, and unambiguous, the manufacturer cannot be held liable for a breach of the duty to warn. (*Temple v. Velcro USA, Inc.* (1983) 148 Cal.App.3d 1090.)

Warnings need only be in English, the official language of the State of California. (Cal. Const. Art. 3 Section 6.) Thus, a drug manufacturer may not be held liable in tort for failing to label a drug with warnings in a language other than English. (*Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539.)

Learned-intermediary doctrine: Was the doctor warned?

California courts have consistently followed the learned-intermediary doctrine, which provides that, in context of prescription drugs, the duty to warn is satisfied if the manufacturer gives adequate warning to the prescribing physician. (See *Finn v. G. D. Searle & Co.*, 35 Cal.3d at p. 691.) Therefore, if the manufacturer provides adequate warning to the prescribing physician, it need not communicate the warning directly to the patient; its duty to warn is discharged when it provides proper warnings to the prescribing physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient. (*Carlin v. Superior Court*, 3 Cal.4th at pp. 1112-13.) The rationale for this rule is that the prescribing physician, as a "learned intermediary" standing between the patient and the pharmaceutical manufacturer, is generally in the best position to evaluate the potential risks of the medication and its benefits to the patient, and to decide and advise the patient accordingly. (*Garside v. Osco Drugs, Inc.* (1st Cir. 1992) 976 F.2d 77, 80.) "In essence, the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant. Thus, the duty to warn in these cases runs to the physician, not the patient." (*Valentine v. Baxter Healthcare Corp*. (1999) 68 Cal.App.4th 1467, 1483.)

As discussed in more detail below, the law further provides that a plaintiff asserting a claim on the basis of inadequate or improper warnings must prove proximate causation. (*Motus v. Pfizer, Inc.* (C.D. Cal. 2001) 196 F.Supp.2d 984.) In the context of the learned-intermediary doctrine, this means that the plaintiff must establish not only that manufacturer's warnings were inadequate, but also that adequate warnings would have prompted the prescribing physician to alter the course of treatment in a way that would have prevented plaintiff's injury. Therefore, and as elaborated below, more often than not, it is the prescribing physician's testimony that is the determining factor in whether the defendant manufacturer's motion for summary judgment is granted or denied.

Moreover, often, the effect of a successful learned-intermediary defense by a drug manufacturer is to shift the responsibility for warning the patient about the potential risks of the medication from the pharmaceutical manufacturer to the prescribing physician. This may result in the prescribing physician becoming the main or perhaps the sole defendant in the lawsuit. After all, as the learned intermediary who "stands in the shoes of the ordinary user," the prescribing physician becomes responsible for any harm caused by the drug if he or she "was aware of the possible risks involved in the use of the product but decided to use it anyway." (*Pustejovsky v. PLIVA* (5th Cir. 2010) 623 F.3d 271, 276; *Valentine v. Baxter Healthcare Corp*, *supra*, 68 Cal.App.4th 1467, 1483.) It is undisputed that shifting the responsibility from the manufacturer to the physician will often have the unfortunate effect of limiting the amount available for recovery to plaintiff.

Proximate causation

"The application of the failure-to-warn theory to pharmaceuticals requires determination of whether available evidence established a causal link between an alleged side effect and a prescription drug, whether any warning should have been given, and, if so, whether the warning was adequate." (*Carlin v. Superior Court*, *supra*, 13 Cal.4th at p.1116.)

"There is no requirement that a manufacturer must give a warning which could not possibly be effective in lessening the plaintiff's risk of harm." (*Rosburg v. Minnesota Mining & Mfg. Co.* (1986) 181 Cal.App.3d 726, 735.) To prevail, plaintiff must prove that the manufacturer's alleged failure to provide adequate warning was a substantial factor in bringing about the injury (*Rutherford v. Owens-Illinois, Inc.* (1997) 16 Cal.4th 953, 968.) A products-liability defendant is therefore liable only for those injuries *proximately caused* by breach of its duty to communicate adequate product warnings. (*Carlin v. Superior Court supra*,13 Cal.4th at p. 1104.)

Ramirez v. Plough, Inc. (1993) 6 Cal.4th 539, is one of the earlier cases recognizing the proximate-causation

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requirement in failure-to-warn cases pertaining to pharmaceutical drugs. In *Ramirez*, an infant sued a drug manufacturer, alleging that he contracted Reyes Syndrome as a result of ingesting aspirin. The product label, which was entirely in English, contained a warning that aspirin has been associated with Reyes Syndrome and stated that the dosage for a child under two should be "as directed by doctor." The plaintiff's mother, who was literate only in Spanish, did not consult a doctor before giving him aspirin. The mother did not ask anyone to translate the label or package insert into Spanish, even though other members of her household could have done so. The primary question in *Ramirez* was whether the drug manufacturer had a duty to provide warnings in Spanish. The court concluded that it did not. After losing on this ground, the plaintiff asserted an alternative ground of liability: that, lack of Spanish warnings aside, the English label provided defective warnings. The court also rejected this argument, reasoning that the plaintiff's mother "neither read nor obtained translation of the product labeling. Thus, there was no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury." (*Id.* at pp. 555-556.)

As it currently stands, in products-liability failure-to-warn actions, California does not recognize a rebuttable presumption in favor of the plaintiff: that had adequate warning been provided by the manufacturer, it would have been read and heeded by the injured plaintiff. (*Huitt v. Southern California Gas Co.* (2010) 188 Cal.App.4th 1586, 1603.) California courts have decided that a defendant manufacturer "may assume that [its warnings] will be read and heeded." (*Carmichael v. Reitz* (1971) 17 Cal.App.3d 958, 991; also see *Oakes v. E.I. DuPont de Nemours & Co.* (1969) 272 Cal.App.2d 645.) Similarly, in *Ramirez, supra,* the court did not apply or even mention any rebuttable presumption that the plaintiff's mother would have read and heeded an adequate warning.

In *Motus v. Pfizer, Inc.* (C.D. Cal. 2001) 196 F.Supp.2d 984, the district court, relying on California law, held that it would not apply the rebuttable presumption that a warning would have been heeded had proper and adequate warnings been given. The court, as in *Huitt*, held that the plaintiff was required to prove, with affirmative evidence, that the failure to warn was a substantial factor in causing plaintiff's injuries.

Motus involved a lawsuit brought by a widow against manufacturers of an antidepressant drug, Zoloft, claiming that her husband suffered from an adverse reaction to the drug, which caused him to commit suicide. Plaintiff argued that the manufacturer was liable because it failed to provide adequate warnings to doctors of alleged and possibly lethal side effects associated with the drug.

At the prescribing physician's deposition, plaintiff's counsel asked him: "[i]f you had been told that Zoloft can cause an increased risk in suicide during the first few weeks of drug treatment, is that the kind of information you would pass on to your patients?" The physician responded, "Yes." Despite the doctor's testimony, the court granted the summary judgment in favor of defendant, stating that the appropriate question would have been: "[i]f Zoloft's package insert had contained a warning that Zoloft can cause an increased risk in suicide during the first few weeks of drug treatment, would you have prescribed Zoloft to [decedent]?" The court concluded that given the physician's testimony, there was not enough evidence presented to establish causation under a failure-to-warn theory. Pursuant to *Motus*, a "plaintiff is required to offer competent evidence that answers the question: What difference would a warning have made in this case?" (*Id.* at 998.)

Therefore, to prove causation, plaintiffs must present "ex post facto" testimony establishing not only that they would have read, understood and remembered the warning, but also that the warning would have resulted in the plaintiff and/or the prescribing physician altering their course of conduct to avoid injury to plaintiff.

Innovator liability: the brand-name manufacturer

California courts have long held that a brand-name drug manufacturer is in the best position to warn of a drug's harmful effects. (*Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, 611.) As such, it is the brand-name manufacturer that bears responsibility for the accuracy and adequacy of its label "as long as the drug is on the market." (*Wyeth v. Levine* (2009) 555 U.S. 555, 570-571.) It is also the brand-name drug manufacturer's duty to update the warning label to disclose risks as they become known, and to ensure that the warnings remain adequate.

In *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, the court found that a brand-name manufacturer was liable for inadequate warnings about the potential risks of the drug, regardless of whether the consumer received the brand-name drug or a generic version of the drug, and that the liability did not end at the moment that the brand-name manufacturer sold its rights to the brand-name drug to a generic manufacturer. (*Ibid.*) However, the Court clarified that the brand-name drug manufacturer would not be liable where the injury resulted from a manufacturing defect, where the generic manufacturer's label did not conform to the brand-name drug's label, or where the generic manufacturer advertised a use of the drug that was inconsistent with the FDA-approved label. (*Id.* at 170.) Under warning label liability, the brand-name drug manufacturer is liable for injuries arising from the generic drug only where the "deficiencies in its label foreseeably and proximately caused injury." (*Id.* at 171.)

The generic manufacturer, on the other hand, has an ongoing duty to ensure that its warning label is the same as the brand-name manufacturer's warning label, and may only change its labels "to match an updated brand-name label or to follow the FDA's instructions."

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(*PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613.)

Federal preemption

Since its enactment in 1938, the federal Food, Drug, and Cosmetic Act (FDCA) has governed the entry of prescription drugs on the market. A drug manufacturer seeking to market its prescription medication is required to file a new drug application (NDA) with the FDA. (See 21 U.S.C. § 355(a).)

From 2002 through 2008, each of the nation's key federal health and safety regulatory agencies, including the Food and Drug Administration (FDA), took the position and asserted that virtually any regulatory action taken by the agency effectively wiped away the governing state law such that only the federal law governed.

The Supreme Court's 2009 ruling in *Wyeth v. Levine*, 129 S.Ct. 1187, emphatically rejected the assertion that the FDA's approval of a brand-name prescription drug's label preempts the state's failure-to-warn claims.

In *Wyeth*, plaintiff filed a personal injury action against Wyeth, the drug manufacturer, asserting that Wyeth had failed to include a warning label describing the possible injuries that could occur from negligent injection of the drug. Wyeth argued that because their warning label had been deemed acceptable by the FDA, a federal agency, any state regulations making the label insufficient were preempted by the federal approval. The lower court found in favor of Plaintiff and denied Wyeth's motion for a new trial.

Relying on *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d, which recognized that federal warning-label regulations alone may be insufficient to protect patient safety, the Supreme Court affirmed the lower court's ruling that federal law did not preempt plaintiff's claim based on the state law's warning requirements. In reaching this conclusion, the Supreme Court majority reasoned that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." (*Ibid*. at 579.)

Therefore, with respect to brand-name drugs, the FDA requirements merely provide a floor, not a ceiling, for state regulations, and the states are free to create more stringent labeling requirements than federal law provides.

However, *Wyeth*'s decision seems to be applicable only to brand-name drugs, and not to generic medications. In a later decision, *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, the Supreme Court held that federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, these same state law claims. The Supreme Court conceded that state law places a duty directly on all drug manufacturers to adequately and safely label their products. (*Id.* at 2573.) However, federal drug regulations prevent generic manufacturers from independently changing their drugs' safety labels. (*Id.* at 2581.) The Court distinguished this case from *Wyeth* because federal law does allow brand manufacturers to change their drugs' safety labels; therefore, it is possible for a brand-name drug manufacturer to comply with both state and federal law. In contrast, where the state law mandates the generic manufacturers to maintain and update their drug safety labels, the state law conflicts with federal law barring the generic manufacturers from taking that very action. Where such conflict exists, with respect to generic drugs, the federal law preempts the state law. (*Ibid*.)

Conclusion

Failure-to-warn is often the primary theory used against pharmaceutical manufacturers. While a full explication of the theories, definitions and defenses involved with pharmaceutical product-liability law is complex, this article has provided a brief overview of the doctrinal framework of warning defects as applied to pharmaceutical-injury cases. This area of law is ever evolving as the courts aim to reach a difficult-to-attain balance between deterring irresponsible drug manufacturing and encouraging beneficial drug development.

Natali Shabani is an associate at Prestige Law Firm, *where she litigates complex personal injury, wrongful death and medical malpractice cases. She is a graduate of Loyola Law School and UCLA.*