Published on *The National Law Review* https://natlawreview.com

A Tried and True Summary Judgment Option in Pharmaceutical and Medical Device Failure to Warn Cases

Article By:

William A. Hanssen

Summary judgment is a manufacturer's goal in almost every case. Often, it's an uphill battle. For example, a recent Supreme Court decision has made summary judgment more difficult to obtain in prescription drug cases that allege a failure to adequately warn, by limiting the scope of the federal preemption defense.[1] Thus, a Food and Drug Administration ("FDA") decision that a particular risk need not be identified in the labeling is rarely a basis to preclude Plaintiffs from proceeding with litigation criticizing the FDA-approved labeling. Additionally, courts are reluctant to adjudicate, at the summary judgment stage, that labeling adequately warns of the risks at issue because this is perceived by many courts as a question for the jury.[2] Moreover, Plaintiffs' lawyers can easily find "experts" to criticize labeling and to offer opinions that the labeling, albeit FDA-approved, should have disclosed additional or different risks, or disclosed them in a different manner. These expert opinions, even when weakly supported, are often enough to thwart a defense summary judgment motion in most state court actions.

But even when the alleged risk is not mentioned in the labeling, prescription drug and medical device manufacturers may still have a defense available in failure to warn cases. As set forth in a seminal California case on this subject, *Plenger v. Alza Corporation*, 11 Cal.App.4th 349 (1992), a manufacturer has no duty to warn of a risk that is well-known and wellappreciated by the medical community. Id. at 362. The manufacturer's duty to warn runs to the physician under the learned intermediary doctrine[3] and there is no duty to warn where the intended audience for the warning is already aware of the risk or should have known of the risk. In addition, if the Plaintiff's physician is already aware of the risk (or is professionally obligated to be aware of it as common knowledge in the profession), a manufacturer's failure to warn of such a risk cannot be the proximate cause of any alleged injuries. *Id*.[4] If the physician actually knew of the risk, then the absence of warning on the label would not have prevented the physician's use of the product. If the physician should have known of the risk but did not, then the proximate cause of the Plaintiffs' injury was the physician's failure to know about the risk, not the absence of a warning. In other words, no harm can be caused by failure to warn of a risk already known.[5]

Courts outside of California have also recognized these defenses.[6] For example, as explained in *Stanback v. Parke, Davis and Co.*, 657 F.2d 642 (4th Cir. 1981), there is no evidence of causation when it is firmly established that a more complete warning would not have changed the physician's course of action in prescribing or administering a prescription drug. *Id*. at 645-46. In *Stanback*,

Plaintiff brought suit against a pharmaceutical manufacturer for its alleged failure to warn of the risk of Guillain-Barre Syndrome allegedly associated with its influenza vaccine. The lower court granted the manufacturer's motion for summary judgment holding that its alleged failure to warn was not the cause in fact of Plaintiff's illness, given the administering physician's testimony that he independently knew of the risk but chose to administer the vaccine anyway, without communicating the risk to the Plaintiff. *Id*. at 644. The appellate court affirmed, reasoning that the physician's testimony conclusively demonstrated that his decisions and actions would not have been affected in the least by the communication of a different warning, therefore breaking the chain of causation that Plaintiff needed to prove in order to survive summary judgment. *Id*. at 646.

The no duty to warn and the lack of proximate cause defenses are available in several contexts. First, in cases involving older products and established classes of medication, where the risk profile of the medications is well-known, both prescribers and experts are likely to concede this point, especially when confronted at deposition with ample medical literature reporting the risk.[7] Likewise, manufacturers may have success with this defense in cases involving off-label pediatric use of a product with a well-appreciated risk profile in adult patients. This defense may also be useful in cases where the alleged undisclosed risk had been the subject of regulatory action or media attention, yet the risk had not yet been inserted in the labeling or did not appear as a Warning/Precaution at the time of use.[8]

Similarly, the no duty to warn defense is also appropriate in cases where the risk is ever-present (for example, infection followed by death as a result of a surgical procedure) as was the case in *Plenger*. In *Plenger*, Plaintiffs filed an action for wrongful death, alleging that the decedent died as a result of an infection caused by her use of an Intrauterine Device ("IUD") that was manufactured by Defendant. The trial court ruled that the IUD was a prescription device and that the warnings Defendant had given to the decedent's physician were adequate to preclude liability. The trial court granted summary judgment and entered judgment in Defendant's favor. The Court of Appeal affirmed, holding that although Defendant did not specifically advise of the risk of death that can result from a pelvic infection, the court held that there was no triable issue of fact on the adequacy of Defendant's warning, since a manufacturer need not warn of a risk which is readily known and apparent to the consumer—in the case of prescription drugs, the prescriber. The Court explained:

> We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the consumer, in this case the physician. Further, if the risk of death from untreated infection is universally known in the medical profession, the failure to warn the physician of that risk cannot be the legal cause of the decedent's death.

Plenger, 11 Cal. App. 4th at 362 (citing Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671-672 (8th Cir. 1985)).

Manufacturers should not shy away from this defense in off-label cases. In *Huntman v. Danek Medical, Inc.*, No. 97-2155-IEG RBB, 1998 WL 663362 (S.D. Cal. July 24, 1998), the Defendant obtained summary judgment in a case involving an alleged off-label use of bone screws. Plaintiff alleged the manufacturer improperly marketed and promoted its bone screws for pedicle fixation even though FDA had only approved the use of these screws for anterior fixation. Plaintiff alleged that "but for" the manufacturer's illegal marketing, she would not have had the screws implanted. In support of its motion for summary judgment, the Defendant manufacturer provided the following evidence

regarding the prior knowledge of Plaintiff's surgeon, Dr. Thompson:

> [P]rior to plaintiff's surgery, Dr. Thompson had been a physician for over 30 years and had performed between 50–70 spinal fusions with pedicle screws. Dr. Thompson testified that he was aware of the risks involved in these procedures based on his independent research which involved (a) speaking with other physicians who were performing the procedure; (b) reading physician-authored articles concerning the procedure; and, (c) attending symposiums and conferences at which the pedicle screw techniques were presented. Dr. Thompson further testified that (a) he was generally aware of the lack of FDA approval for pedicle fixation from other doctors and (b) defendant's representative specifically informed him there was no FDA approval for pedicle fixation.

Id. at *5 (citations omitted).

The District Court found that the uncontroverted testimony of Dr. Thompson demonstrated he had independent knowledge of the risks of pedicle fixation. Thus, the Court granted Defendant's motion for summary judgment holding that the adequacy of the warnings is immaterial where the doctor knows of the specific risks.

Conclusion

In summary, armed with medical literature and case reports in a failure to warn case involving a prescription medication or medical device with a long history of use, welldefined risks, or recent publicity and/or regulatory action, Defense counsel may well be able to elicit deposition testimony from the prescriber which not only concedes that the relevant risk is well-known in the medical community but also that he or she was specifically aware of the risk. In those situations, the chance of obtaining summary judgment based on lack of duty or proximate cause is increased. Likewise, if the prescriber is not available for deposition or if a summary judgment motion can be filed without prescriber testimony, a manufacturer may use expert testimony, medical literature, and medical texts to demonstrate to a court's satisfaction that a risk was well-known in the medical community, thus negating any legal obligation for the manufacturer to warn of the risk at issue.

---

1 See generally Wyeth v. Levine, 555 U.S. 555 (2009).

2 Eiser v. Feldman, 507 N.Y.S.2d 386, 388 (N.Y. App. Div. 1986) (Except in rare cases, "the adequacy of warnings is often properly left for jury determination."); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 71 (Mass. 1985)("[W]hether a particular warning measures up to this standard is almost always an issue to be resolved by a jury…"); Gurski v. Wyeth-Ayerst Div. of Am. Home Prods. Corp., 953 F. Supp. 412, 417 (D. Mass. 1996) (Although a court can find that a particular warning is adequate as a matter of law, adequacy "is almost always an issue to be resolved by a jury.")

3 Carlin v. Super. Ct. (Upjohn Co.), 13 Cal. 4th 1104, 1126 (1996).

4 Plenger, 11 Cal. App. 4th at 362 ("We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the consumer, in this case the physician."); see also Carlin, 13 Cal. 4th at 1116 (1996).

5 See Rosburg v. Minn. Mining & Mfg. Co., 181 Cal. App. 3d 726, 735 (1986). Plaintiff complained that the manufacturer of breast implants failed to adequately warn of the risk of spontaneous deflation. The Plaintiff's physician testified that he already knew of the danger. The trial court concluded that

"no harm could have been caused by failure to warn of a risk already known." Judgment for the manufacturer was affirmed on appeal.

6 See generally Proctor v. Davis, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997); Wooten v. Johnson & Johnson Products, Inc., 635 F. Supp.799, 803 (N.D. Ill. 1986) ("[C]ourts have consistently held that a drug manufacturer is entitled to summary judgment where the prescribing physician is aware of the

risks associated with a drug."); Sacher v. Long Island Jewish-Hillside Med. Ctr., 530 N.Y.S.2d 232, 232 (App. Div. N.Y. 1988) (Generally no duty to warn

users of products who are fully aware of the risks attendant to their use.); Tatum v. Schering Corp., 795 F.2d 925, 927 (11th Cir. 1986)) ("Since the

manufacturer's goal in warning is to provide the physician with knowledge, when that physician has such knowledge, either from the manufacturer or

independently, there can be no causal link between a failure to advise a physician of what he already well knows…"); Kirsch v. Picker, 753 F.2d 670, 671

the cancer risks associated with radiation therapy."); Strong v. E.I. DuPont de Nemours Co., 667 F.2d 682, 687 (8th Cir. 1981) ("In the realm of strict liability there is a … principle providing that a manufacturer has no duty to warn when the dangers of a product are within the professional knowledge of the user"); Jones v. Minn. Mining & Mfg. Co., 669 P.2d 744, 748 (N.M. Ct. App. 1983) (No duty to warn of dangers actually known to the user of the product; in the case of prescription drugs and devices, this rule applies to a manufacturer's duty to warn a prescribing physician.); Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 92 (2d Cir.1980) ("No one needs notice of that which he already knows.")

7 Physician co-defendants are also better served by acknowledging awareness of the benefits and risks of a medication and standing behind their prescribing decision and counseling strategy as opposed to claiming they were unaware of a well-known risk.

8 According to FDA "[t]he WARNINGS AND PRECAUTIONS section is intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are serious or are otherwise clinically significant because they have implications for prescribing decisions or patient management. To include an adverse event in the section, there should be reasonable evidence of causal association between the drug and the adverse event, but a causal relationship need not have been definitively established." See FDA GUIDANCE FOR INDUSTRY, Warnings and Precautions, Contraindication, and Boxed Warnings Sections of Labeling for Human Prescription Drugs and Biological Products – Content and Format (2011), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf (emphasis in original).

National Law Review, Volume II, Number 135

Source URL:https://natlawreview.com/article/tried-and-true-summary-judgment-option-

pharmaceutical-and-medical-device-failure-to-