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Learning About the "Learned Intermediary" Doctrine and Its Application to Certain Product Liability Cases

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He Who Learns Must Suffer.[2]

There has been a large increase in product liability cases in the personal injury, mass tort arena. Most recently these cases involved vaginal and hernia mesh, numerous prescription drugs, artificial knees and hips, IVC filters[3] and more. New Jersey Federal and State Courts are often the site for these coordinated product liability actions. As the number of cases increases, jurisprudence concerning this area of practice has become much more complicated.

One such area is the "learned intermediary" doctrine and its application to these cases. Quite simply, the learned intermediary doctrine is an affirmative defense that where a manufacturer creates a product which is dispensed or provided to patients by doctors or healthcare providers rather than directly to the patients themselves - the manufacturer has only a duty to warn the doctor or healthcare provider of any known risks associated with the use of the product. It is then assumed that the doctors will convey the information contained in the warnings to the patient, so that the patient may make an informed decision to go forward with use of the product.

As noted above, the transvaginal and hernia mesh cases are a part of this mass tort compendium concerning cases filed around the country involving personal injury product liability allegations arising from severe and permanent injuries allegedly sustained by individuals who suffered from a pelvic organ prolapse or hernia. These individuals were surgically implanted with an allegedly defective and dangerous synthetic mesh device. Plaintiffs have asserted that the material used to make the mesh for implantation was a non-medical-grade, petroleum-based product. Plaintiffs often complain that as a result of the implantation of the device, they suffer chronic and debilitating pain and incontinence caused by a hardened and degrading implant device that they claim cannot be safely removed.

These plaintiffs often file claims alleging design defect and/or a failure to warn. The plaintiffs claim that the warnings omit multiple and significant relevant risks including but, not limited to: chronic and/or permanent nature of many mesh-related complications; failure to adequately warn about likelihood of risks occurring and nature and severity of the risks; the failure to warn physicians and patients about the risk of permanent pain as compared to alternative procedures; failure to warn that the pain may be so debilitating that removal of the device would be recommended for relief; and failure to warn that the pain may continue after removal.

Defendants vehemently oppose the plaintiffs' allegations. They contend that the warnings were more than sufficient and covered all possible contingencies. In addition, they argue

that the doctors were aware of any issues concerning the product and moreover, still utilized the mesh product regardless of any purported failure to warn.

A component or defense to these claims often involves the application of the learned intermediary doctrine. To adequately protect clients – whether representing a plaintiff or a defendant - it is incumbent on the attorney to determine whether and, if so, how the learned intermediary doctrine is applicable to a case. Indeed, in many jurisdictions the learned intermediary doctrine is an affirmative defense and applies *only if* the manufacturer's warning or instruction to the physician is "*adequate*." *See* N.C.G.S. §99B-5(c). No manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer *if an adequate warning* or instruction has been provided to the *physician* or other legally authorized person who prescribes or dispenses the prescription drug for the plaintiff.

In certain jurisdictions, such as North Carolina, while the learned intermediary doctrine may be codified, it may *not* cover all potential products. For example, North Carolina's statute applies the doctrine directly to prescription drugs, but does not specifically mention durable medical equipment. The doctrine is, however, extended to durable medical equipment by the relevant North Carolina case law, although this may still be an unsettled question.

If the warning to the physician or healthcare provider is inadequate, then proximate cause can be shown by proof other than the doctor's testimony, including that adequate warning communicated to the patient would have altered use of the product. In other words, the patient would not have used the product had *he or she* received an adequate warning. *See, e.g., Fussman v. Novartis Pharms. Corp.*, 2011 U.S. Dist. LEXIS 133950, *7 (M.D.N.C. Nov. 21, 2011) (upholding jury verdict for failure to provide an adequate warning despite prescribing physician's testimony she would have prescribed drug even with the proposed adequate warning where decedent testified that "she would not have taken [pharmaceuticals] if she knew then what she knows now").

A manufacturer's contention that a physician's "independent knowledge" of a drug's dangers relieves the manufacturer of any duty to provide further warnings was soundly rejected. *Holley v. Burroughs Wellcome Co.*, 348 S.E.2d 772 (N.C. 1986) (holding that even where the prescribing physician stated that he was independently aware of the risks, there were still genuine issues of fact precluding summary judgment on proximate cause, because the physician relied in part on the medical literature, which was potentially affected by the package inserts and promotional information from the drug manufacturer).

Thus, in many jurisdictions the learned intermediary doctrine applies only where the warnings are adequate, and the failure to provide adequate risks and warnings may run to the patient as well and the physician. The doctrine is not meant to absolve manufacturers of all liability simply because healthcare provider decided on their own volition to do something.

In New Jersey, the learned intermediary doctrine is codified in the New Jersey Product Liability Act, which reads, in relevant part, as follows:

> **In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, *or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.* If the warning or instruction given in connection with *a drug or device* or food or food additive has been approved or prescribed by the federal Food and Drug Administration**

> **under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. s. 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. s. 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."**

NJSA 2A:58C-4 (emphasis added). It is important to note that the New Jersey Statute specifically refers to *both* drugs and devices.

Moreover, under the relevant New Jersey authority, a prescription drug manufacturer's duty to provide adequate warnings is owed to prescribing physicians and healthcare providers and not necessarily to patients. "[A] pharmaceutical manufacturer generally discharges its duty to warn by supplying physicians with information about the drug's dangerous propensities". *Niemiera v. Schneider,* 114 N.J. 550, 559 (1989). To defeat a motion for summary judgment a "plaintiff must show that adequate warnings would have altered her doctors' decision to prescribe [medication]." *Strumph v. Schering Corp.*, 133 N.J. 33 (1993). To fully demonstrate that an inadequate warning proximately caused plaintiff's injury she "must show that [an] adequate warnings would have altered her doctors' decision to prescribe [the drug]." *Niemiera,* 114 N.J. at 559.

The New Jersey Supreme Court also recognizes that the plaintiff is entitled to a presumption that if properly warned, he or she would have "heeded" the warning. The "heeding presumption" doctrine. To rebut this presumption, the defendant need only produce inferential evidence that plaintiff would not have heeded an adequate warning. It is also important to note that the New Jersey Supreme Court has created another exception to the learned intermediary doctrine where a manufacturer engages in Direct To Consumer ("DTC") advertising. *Perez v. Wyeth Labs*, 161 N.J. 1, 24 (1999).

Often the court's analysis turns on whether the doctor or healthcare provider did in fact read and rely on the warning, whether it be the Directions for Use ("DFU"), package insert, warning label, or any other mechanism - however conveyed. If the doctor or healthcare provider does not read, nor rely on, the warning, courts are loathed to find that a plaintiff has established proximate causation between the injuries they sustained and the actual failure to warn. Moreover, a doctor's or healthcare provider's reliance on his or her own expertise may not constitute an intervening cause of injury to relieve the defendants of liability.

Inexorably intertwined in the courts' analysis of the learned intermediary doctrine is the review of the record developed during discovery for any evidence that would permit an inference that the doctor or healthcare provider read, was familiar with, and relied on the warning in prescribing the device for the patient. Such a review often rests on the treating or prescribing doctor's deposition testimony. This may also include evidence that the doctor would have altered his or her treatment regimen or recommendation had there been a different warning.

It is therefore crucial that the attorney prosecuting such an action establish, during discovery, the requisite evidence that the doctor read, was familiar with, and relied on the warning when prescribing the drug or durable medical equipment and that a different warning would or would not have made a difference in the course of treatment rendered to the patient-plaintiff. Alternatively, those attorneys defending against such a case can use the lack of such evidence as the basis for filing a motion for summary judgment at the close of discovery to assert that the plaintiff has failed to carry their burden.

As we see more and more mass tort product liability actions across the country, practioners are more frequently exposed to the legal authority associated with these actions. As the area becomes much more prevalent issues surface in a variety of contexts. Whether prosecuting or defending against these cases lawyers must be cognizant of the foregoing doctrine and resulting analyses to effectively represent their clients in these actions.

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[3] Temporary "filters" inserted into a vein carrying deoxygenated blood.

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