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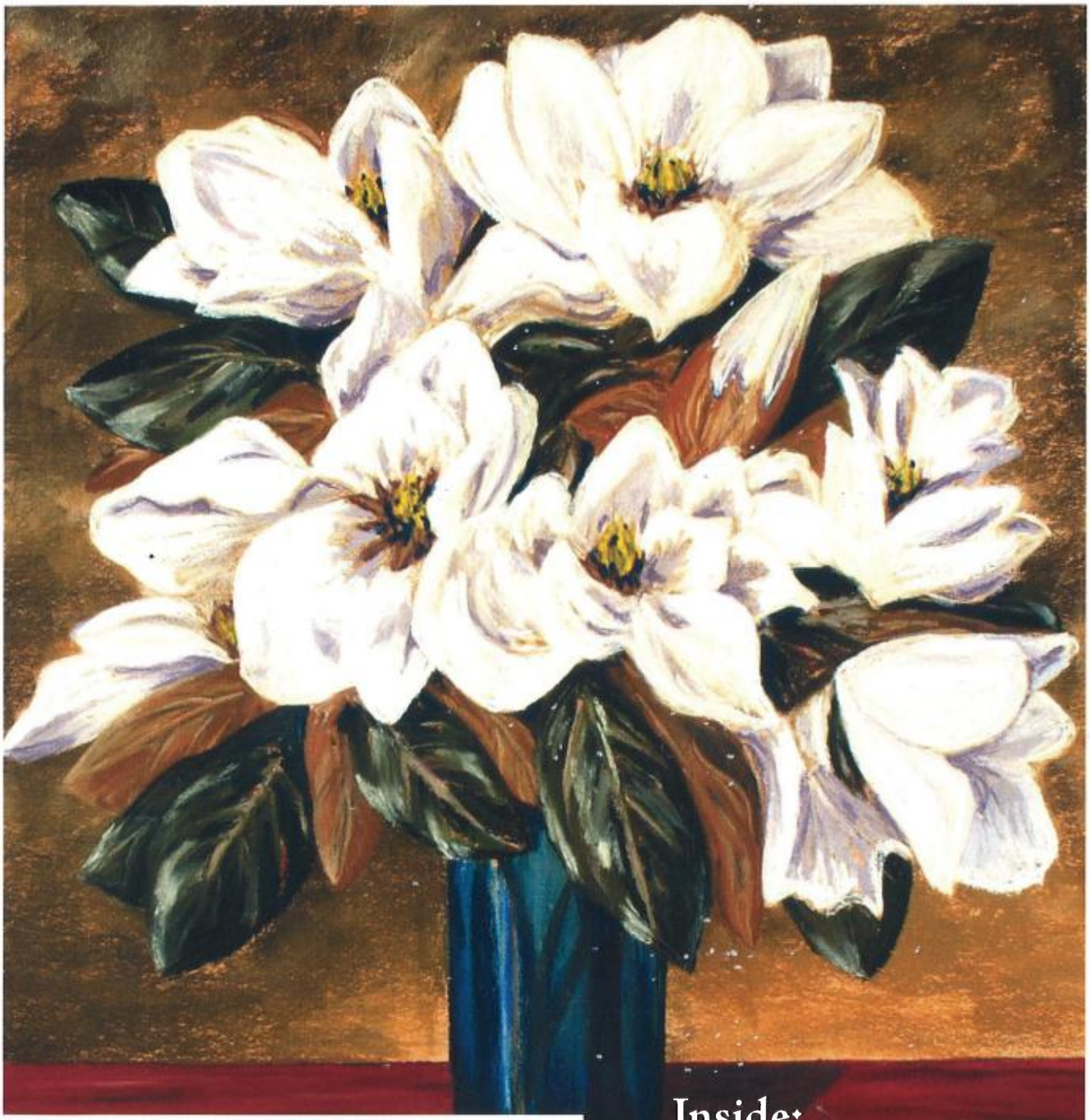

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The Learned Intermediary Doctrine in Florida: Courts Wrestle with Claimed Exceptions to the Doctrine in Drug and Device Litigation

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The learned intermediary doctrine (LID) is a widely recognized defense in pharmaceutical failure-to-warn litigation. Under the LID, a pharmaceutical manufacturer has a duty to warn the learned intermediary — the patient's prescribing physician—of risks associated with its product. The manufacturer does not have a duty to warn the patient directly. Virtually every state recognizes the LID in prescription drug litigation, and many courts have applied the LID in medical device litigation as well. Plaintiffs have sought to circumvent the LID by advancing alternative theories of recovery against manufacturers in addition to the traditional negligent failure to warn cause of action, including common law negligent misrepresentation and fraud claims as well as claims based on statutory consumer protection legislation. Additionally, plaintiffs in a variety of contexts have advocated for courts to recognize exceptions to the doctrine, including an "overpromotion" exception and a "direct-to-consumer" (DTC) advertising exception.

Two opinions issued in June 2007 addressed theories advanced by plaintiffs seeking to avoid the application of the LID. In one, the West Virginia Supreme Court rejected the LID in its entirety. In the other, the U.S. District Court for the Southern District of Florida reaffirmed the LID under Florida law and resolved in the manufacturer's favor several issues of first impression in this state, including whether the LID applies to medical devices and whether it applies to Florida's consumer fraud statute. Additionally, this court examined whether the overpromotion or DTC advertising exceptions applied to the case before it under Florida's LID framework.

This article traces the evolution of the LID generally and tracks its adoption and implementation in Florida. The authors then discuss the national trends in LID jurisprudence based on a landmark 1999 New Jersey Supreme Court opinion and the recent West Virginia Supreme Court opinion. Finally, in the wake of these decisions, the authors examine the June 2007 LID opinion from the Southern District of Florida and analyze the impact of this case on future LID cases in Florida.

Evolution of the Doctrine

The term "learned intermediary" was coined in 1966 in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966). The *Sterling* court articulated the doctrine as follows: "[W]e are dealing with prescription drugs rather than a normal consumer item. In such a case the purchaser's doctor is the *learned intermediary* between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect, there is an excellent chance that injury to the patient can be avoided."[1] Virtually every jurisdiction now recognizes the LID essentially as the *Sterling* court articulated it 40 years ago.[2]

The LID creates an exception to the general rule that a manufacturer owes its consumers a duty to warn of the risks associated with its products. Under the LID, a drug or medical device manufacturer's duty to warn consumers of the dangers associated with its prescription product extends only to the prescribing physician who acts as a "learned intermediary" between the manufacturer and the ultimate consumer and assumes responsibility for advising individual patients of the risks associated with the drug.[3] As long as adequate information has been provided to the patient's physician, the manufacturer will be deemed to

have discharged its duty to warn and will not be held liable if the physician fails to pass that information on to the patient.[4]

The Learned Intermediary Doctrine in Florida

The LID developed in Florida in the context of prescription drug failure-to-warn cases. It was first recognized by the Fifth District Court of Appeal in *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So. 2d 820 (Fla. 5th DCA 1981). The Florida Supreme Court adopted the LID eight years later in *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989).[5] In *Felix*, a mother sued the manufacturer of a prescription acne drug, Accutane, for the wrongful death of her son, which she attributed to her ingestion of the drug while she was pregnant. Her child was born with severe birth defects, which led to his early death. At issue in *Felix* was whether the manufacturer furnished adequate warnings of the dangers of using Accutane during pregnancy.

The court stated that the manufacturer's duty to warn of the risks associated with Accutane was directed to the physician, not to the patient, because "the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." Thus, the court concluded, the drug manufacturer had discharged its duty to warn and could not be penalized if the physician failed to impart his knowledge of the dangers of the drug to his patient.[6]

Rationale

Courts have articulated a number of rationales for the LID, all of which are based on the concept of the traditional doctor-patient relationship. First is the notion that the physician, not the patient, is in the best position to weigh the risks and benefits of a particular drug, taking into account the patient's presentation, medical history, and the like. It is the physician, after all, who exercises his or her independent professional judgment in selecting the appropriate drug for the patient. Second, the physician is in a better position than the manufacturer to provide the appropriate warning to his or her patient of the risks associated with the drug. As a practical matter, because the manufacturer lacks effective means to communicate directly with consumers of its product, it would be virtually impossible for a drug manufacturer to warn each patient. Third, requiring manufacturers to provide warnings directly to the ultimate consumers would interfere with doctors' relationships with their patients.

Critics of the LID have suggested that these rationales may have made sense in the era of the "Norman Rockwell image of the family doctor," when pharmaceutical companies directed their sales efforts entirely to physicians, and patients relied entirely on their doctors to choose and prescribe the drugs best suited for their needs. But, these critics argue, that world no longer exists, and the LID no longer applies in today's healthcare environment.

Advocates for the continued viability of the LID argue that the basic rationale for the doctrine still applies, even in the face of the changing healthcare landscape. For example, they maintain, whether a drug is advertised directly to a consumer or not, the physician who prescribes the drug is still the intermediary between the manufacturer and the consumer. It is the physician's duty after all to become informed about the qualities and characteristics of those products he or she prescribes and to exercise independent judgment, taking into account his or her knowledge of the patient and the product. The patient is expected to and, presumably, does place primary reliance upon that judgment. Even if information about a drug is readily available to the patient, it is the doctor who must make the final decision as to the appropriateness of that drug for the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the risks involved, the manufacturer can reasonably assume that the physician will exercise his or her informed judgment that information in conjunction with his or her own independent learning, in the best interest of the patient.[7] Even in the current healthcare environment, where product labels are set forth in their entirety in print advertisements, where drug companies tout the benefits of their products on radio and television, and where the Internet allows patients to thoroughly research the benefits and risks of drugs, patients still must rely on their physician to make decisions regarding the safety, efficacy, and appropriateness of the drugs they prescribed.

Challenges to the Application of the LID

In 1999, the New Jersey Supreme Court recognized for the first time an exception to the LID in the case of drugs that are advertised directly to consumers. In *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d at 1248 (N.J. 1999), the plaintiffs claimed that Wyeth failed to properly warn consumers about the side effects of the contraceptive Norplant. The plaintiffs alleged, among other things, that Wyeth undertook a widespread advertising campaign directed at consumers rather than at their doctors, including advertisements on television and in magazines, but did not directly warn consumers of the side effects associated with Norplant.[8] Wyeth moved for summary judgment, invoking the LID.[9] The trial judge granted summary judgment in Wyeth's favor, finding that the LID required Wyeth to warn only the plaintiffs' treating physicians of the risks associated with the product, not the plaintiffs themselves.[10] The intermediate appellate court affirmed the trial court's decision.

The New Jersey Supreme Court reversed and remanded the case to the trial court, finding that although New Jersey recognizes the LID, the doctrine did not apply in the arena of direct-to-consumer advertising. The court reasoned that "when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product

should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product."[11] The direct marketing of drugs to consumers, the court found, carries with it a corresponding duty requiring manufacturers to warn the consumers, rather than their doctors, of defects in the product.[12]

Central to the *Perez* court's decision was its conclusion that healthcare today is far different than it was when the LID evolved as a defense in pharmaceutical litigation. The court found that consumers today actively participate in their healthcare decisions, including whether particular drugs or devices should be used. Direct-to-consumer advertising, the court determined, "alters the calculus of the learned intermediary doctrine," making it inapplicable to drugs marketed directly to consumers.[13] In fact, the court concluded, "[c]onsumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests."[14] In short, the court determined that "[o]ur medical-legal jurisprudence is based on images of healthcare that no longer exist."[15]

Given the dramatic increase in direct-to-consumer advertising of drugs and medical devices in the past 10 to 15 years, it was generally believed that the *Perez* decision signaled a broad-ranging exception to the LID, and plaintiffs sought the application of *Perez* in a wide array of pharmaceutical cases across the country. In fact, plaintiffs have argued in a variety of contexts that *Perez* stands for the proposition that the LID is not applicable at all in cases involving direct-to-consumer (DTC) advertising.[16]

In the years following the *Perez* decision, however, the New Jersey Supreme Court's opinion does not appear to have had the impact practitioners and commentators on both sides of the debate thought it would have. Until 2007, no court chose to follow the *Perez* holding, and, in fact, courts in a number of jurisdictions specifically rejected the notion that DTC advertising creates an exception to the LID. Additionally, even New Jersey courts have held that *Perez* should not be read too broadly and refused to find a DTC exception even though information was provided by the manufacturer directly to patients.[17]

In June 2007, the West Virginia Supreme Court, in *State ex. rel. Johnson & Johnson Corp. v. Karl,* 647 S.E. 2d 899 (W.Va. 2007), refused altogether to adopt the LID. The *Karl* decision was based in part on the court's recognition of the rise of managed healthcare and DTC advertising both on television and via the Internet. The *Karl* court reasoned that the world of healthcare that underlies the development of the LID no longer exists and that the current model of managed care is not based on a focus on patient counseling or education about the risks and benefits of different pharmaceutical options.[18] At the same time, the pharmaceutical industry itself has changed, with drug manufacturers "pushing their products onto the general public like never before."[19] These conditions, the court opined, mark "[s]ignificant changes in the drug industry [that] post-dated the adoption of the learned intermediary doctrine in the majority of states in which it is followed."[20] Finding that drug companies now spend millions of dollars marketing their products to consumers (both through advertising and company and product web sites), the *Karl* court determined that the manufacturer, not the physician, is the one best suited to advise patients of the risks and benefits of its drugs.[21] Thus, the court held that "under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers."[22]

Focusing largely on the scope and effect of DTC advertising, the *Karl* court dispensed with the traditionally accepted rationales for the LID. The court refused to take into account the generally accepted view that the doctor is in a better position than the drug manufacturer to warn the patient about the risks associated with a drug. Additionally, the court ignored the rationale that it is the doctor, not the manufacturer, who is in the best position to decide which drug is appropriate for the patient, and that it would be difficult, if not impossible, for a manufacturer to provide warnings to ultimate users (beyond information already contained on product labels and in package inserts).[23]

Shortly after the *Karl* decision, the Wyoming Supreme Court added Wyoming to the list of states recognizing/adopting the LID.[24] Given the fact that the overwhelming majority of states have adopted the LID, most commentators concluded that *Karl* was an anomaly and would not change the pharmaceutical failure-to-warn landscape outside of West Virginia. Then, in August 2008, in *Rimbert v. Eli Lily & Co.,* No. Civ. 06-0874, slip op. (D.N.M. Aug. 22, 2008), the U. S. District Court for the District of New Mexico predicted that the New Mexico Supreme Court would also reject the LID.

The *Rimbert* court sounded many of the same themes as those articulated by the *Karl* court including, inter alia, dramatically increased DTC marketing, the changed healthcare delivery system, consumers' increased ability to get information about drugs. Additionally, it reasoned that New Mexico's strict liability jurisprudence is inconsistent with the LID, which the court determined shifts the risk of loss to the physician and patient. Citing the policy concerns upon which New Mexico's strict liability doctrine is based, the court concluded that, if presented with the issue, the New Mexico Supreme Court would reject the LID and refused to recognize it as a defense in the case before it.[25]

Beale v. Biomet

At the same time the West Virginia Supreme Court was rejecting the LID as a vestige of an earlier — no longer relevant — era, a federal district court interpreting the LID under Florida law embraced the traditional LID notions articulated by the Florida Supreme Court in *Felix* and rejected numerous attempts by the plaintiffs to avoid its application or to create exceptions. This opinion strongly suggests the continued viability of the doctrine for Florida practioners despite West Virginia's (and possibly New Mexico's) suggestion that the LID no longer has a place in phar-