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

by John A. Camp and Gary M. Pappas

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 Lilly & 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 practitioners despite West Virginia's (and possibly New Mexico's) suggestion that the LID no longer has a place in phar-

maceutical failure to warn jurisprudence.

Beale v. Biomet, Inc., 492 F. Supp. 2d 1360 (S.D. Fla. 2007), marked the first time a court sitting in Florida expressly considered several important issues relating to the application of the LID in the state: 1) whether the doctrine applied to medical devices; 2) whether the doctrine applied to consumer fraud claims under the Florida Deceptive and Unfair Trade Practices Act (FDUTPA)²⁶; 3) whether the Perez exception for DTC advertising applied; and (4) whether the "overpromotion" exception applied.

In *Beale*, the court consolidated two similar cases filed by individuals against Biomet, the manufacturer of a partial knee prosthetic device known as the Repicci II Unicodylar Knee²⁷ (the device).²⁸ Both plaintiffs had the device implanted by a board certified orthopedic surgeon with more than 35 years of experience, including an estimated 10,000 joint replacement surgeries.²⁹ The plaintiffs alleged that their weight and activity levels made them inappropriate candidates for the device and that in each case the device failed and needed to be replaced with a total knee prosthetic.³⁰ They sued Biomet for negligence, strict liability, violation of FDUTPA, and negligent misrepresentation, seeking damages for pain, suffering, and disfigurement for enduring two surgeries when only one procedure — the total knee replacement — should have been performed.³¹

Both plaintiffs had become aware of the device through newspaper advertisements for free seminars given by the surgeon's medical assistant at a local hospital. At the seminar, the medical assistant served refreshments, discussed osteoarthritis symptoms, displayed before-and-after x-rays, and handed out a brochure produced by Biomet for distribution in physicians' offices.³² The brochure contained basic information about the device and a series of frequently asked questions with Biomet's answers. The same type of information was on Biomet's Web page.³³ Biomet did not dispute that it engaged in these and other marketing efforts to promote the device, including sales visits to

physician's offices, advertisements in orthopedic journals, presentations at meetings of orthopedic surgeons, and video demonstrations of the surgical procedure.³⁴

Biomet moved for summary judgment on the basis of the LID, arguing that it discharged its duty to warn by providing adequate warnings to the medical profession relating to the device through its package insert and promotional materials. Additionally, Biomet argued that the chain of causation was broken because the surgeon had independent knowledge of the risks and complications associated with knee replacement surgery that an adequate warning should have been communicated.

The court began with a detailed discussion of the LID, including the *Buckner* court's first application of the doctrine in Florida and its ultimate adoption by the Florida Supreme Court in *Felix*. Noting the absence of controlling state precedent on whether a medical device falls within the LID, the court reasoned that the rationale behind the LID — that patients do not have access to prescription medicines without the intervention of a learned intermediary — made even more sense in the context of medical devices. The court went on to note that "[w]hile some individuals could conceivably gain access to prescription drugs without their doctor's assistance, it is not reasonably conceivable that an individual could obtain and implant a device that requires a surgeon without the intervention of a physician."³⁵ The court concluded, therefore, that the LID applies to medical devices under Florida law.³⁶

The court then analyzed the adequacy of Biomet's warning to the treating surgeon in the face of the plaintiffs' claims that they were improper candidates based on their weight and activity level. The court recited extensively from the package insert,³⁷ finding Biomet's warnings clear and unambiguous on the weight and activity issues, and held that the warnings were adequate as a matter of law.³⁸ Additionally, the court found that the plaintiffs had failed to introduce evidence contradicting

the surgeon's independent knowledge of the appropriate patient selection criteria for the device and risks associated with its implantation, and thus the chain of causation was broken as a matter of law.³⁹ The court rejected the plaintiffs' unsupported contentions that Biomet had colluded with, influenced, or misled the surgeon about the device through its marketing efforts.⁴⁰

Next, the court confronted another issue of first impression in Florida: whether the LID applied to the plaintiffs' consumer fraud claims brought under FDUTPA.⁴¹ The plaintiffs' pointed to Biomet's Web site and promotional brochure as the source of their alleged deception.⁴² The court recognized that federal courts in jurisdictions across the country, including Florida, had held the LID encompasses all claims based on a pharmaceutical manufacturer's failure to warn, including fraud, misrepresentation, and violation of state consumer protection laws.⁴³ The rationale behind these decisions was that the gravamen of all such claims is the defendant's alleged failure to adequately warn or disclose risks of using its product. "If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action, such as a violation of [the state consumer protection act] or a claim of misrepresentation, then the doctrine would be rendered meaningless."⁴⁴ The court held that the same result was warranted in Florida and that the plaintiffs' FDUTPA claim, which was ultimately based on Biomet's alleged failure to warn, was barred by the LID.⁴⁵

The court next addressed the plaintiffs' argument that Florida should adopt the DTC advertising exception to the LID created by the New Jersey Supreme Court in *Perez*.⁴⁶ The court fully explored the *Perez* court's reasoning in adopting the exception where drug companies market their products directly to consumers via broadcast and print media. Yet, the court observed that in the eight years following *Perez*, no court had joined New Jersey and several courts had expressly rejected an exception to the LID.⁴⁷ The court concluded, therefore,

that the Florida Supreme Court would be unlikely to recognize the DTC exception and declined to create such an exception in the plaintiffs' case.⁴⁸

Finally, the court confronted the plaintiffs' argument that "overpromotion" of a product creates an exception to the LID and negates any of the manufacturer's warnings. Once again, the court observed that this was an issue of first impression as no Florida court had recognized overpromotion as an exception to the LID.⁴⁹ The court then observed that the majority of cases cited by plaintiffs were factually distinguishable because the drug at issue in each was heavily promoted by "detail men" who visited the physicians' offices, encouraged them to prescribe the drug, and provided them with information which contradicted the package insert warnings. Moreover, the physicians in those cases testified that they were influenced by the salesmen's representations and prescribed the drugs more freely than they would have without their representations.⁵⁰ Assessing the facts before it, the court found no comparable evidence of overpromotion or influence and concluded the plaintiffs had failed to raise a genuine issue to defeat summary judgment.⁵¹

In conclusion, the court stated that the LID "is firmly established under Florida law, and no Florida courts have recognized the exceptions urged by Plaintiffs."⁵²

Analysis

The *Perez* opinion marked the first time a state recognized a DTC advertising exception to the LID. Until the West Virginia Supreme Court's opinion in *Karl*, however, no court had followed *Perez*, and several courts specifically declined to follow it. Thus, it appeared that *Perez* was an anomaly and that the LID would remain a viable defense in pharmaceutical failure to warn cases, even those involving direct-to-consumer advertising. The *Karl* opinion goes much further than *Perez*, however, and rejects the LID altogether, albeit against the backdrop of DTC advertising. The *Rimbert* opinion predicts that the New Mexico Supreme Court would do the same.

The *Karl* court found that "a mere

twenty-one states have expressly adopted the learned intermediary doctrine."⁵³ The use of the adjective "mere" to describe nearly half the states signals the *Karl* court's direction. Additionally, the court failed to acknowledge that while it may be the case that only 21 state supreme courts have expressly adopted the LID, courts in virtually every jurisdiction have recognized the doctrine, and the supreme courts of the remaining states have not specifically rejected it.

More significantly, the *Karl* court found the justifications for the LID "to be largely outdated and unpersuasive." Thus, the court raised and dismantled the justifications traditionally articulated in support of the LID. In the end, the *Karl* court ruled that manufacturers of prescription drugs are subject to the same duty to warn consumers directly about the risks associated with their products as other manufacturers. Thus, the *Karl* court departed from 70 years of jurisprudence and appears to have been more influenced by the current state of healthcare delivery than by the uniqueness of the doctor-patient relationship that underpins the LID.

In refusing to adopt the LID, the *Karl* court ignored the policy favoring the socially redeeming value to consumers of readily available information about prescription drugs and devices. Similarly, the *Rimbert* court cited increased patient awareness and information as a justification for doing away with the LID on the theory that providing information directly to patients makes the notion of warning patients by warning their doctors outdated. On the other hand, pharmaceutical companies argue that patients are better off today than they were during the Norman Rockwell era of "doctor knows best" because they have easy access to free content on manufacturers' Web pages, other Internet sites, and printed brochures about their medical conditions and prescription drugs or devices that their treating doctors may prescribe. Such information, they contend, allows patients to enter their treating doctors' offices with more focused questions about their conditions that allow the doctors to make better-in-

formed and efficient diagnoses and prescriptions for care. If the delivery of such information imposes a greater duty to warn, manufacturers would likely be forced to pull down their Web content and shut off the stream of information about their products, whether by printed brochures or DTC advertising.

Most people would agree that a world in which patients have direct access to information about their health and treatment is a good thing. While pharmaceutical companies certainly benefit from DTC advertising, so do patients. The LID is predicated on the notion, however, that it is doctors, not patients, who have to make ultimate decisions about the treatment of their patients. Arming patients with additional information may take the doctor-patient relationship out of the realm of the paternalistic, but patients must still rely on their doctors to prescribe courses of treatment and drugs or devices best suited for them. The LID encourages drug and device manufacturers to provide adequate information about their products to physicians, knowing that those physicians are in the best position to pass that information on to their patients in the context of their medical histories, courses of treatment, etc.

The *Beale* court was faced with the very same landscape as the *Karl* court, one of DTC advertising, readily available information about the prescription device via the Internet and printed brochures, and promotion of the product by sales representatives and the doctor's seminars. Nevertheless, the *Beale* court rejected every theory of recovery raised by the plaintiffs. The court acknowledged that direct-to-consumer advertising played a part in the plaintiffs' decisions to proceed with the surgery at issue, via print advertisements, patient brochures, the Biomet Web site, and patient seminars. That notwithstanding, the court refused to back away from Florida's "longstanding recognition of the learned intermediary doctrine."⁵⁴

The court in *Beale* pointed out that the rationale behind the LID makes even more sense in the context of medical devices. This reasoning

completely embraces the traditional justifications for the LID and appears to make a strong case for application of the doctrine in the case of medical devices notwithstanding the acknowledged changes in the world of pharmaceutical product sales. That said, there is nothing in the *Beale* opinion to suggest that the court would have ruled any differently had the product at issue been a prescription drug rather than a medical device.

The *Beale* court implicitly understood the policy issues at play in refusing to recognize the proposed exceptions to the LID. The outcome in *Beale* might have been different, though, had the underlying facts establishing the duty and causation elements of the LID not been so compelling. First, the court found that the information in Biomet's patient brochures and package insert and on its Web site was clear and unambiguous, and the plaintiffs did not present expert testimony to the contrary. Thus, the court concluded that Biomet had not misled or deceived the plaintiffs about the efficacy and appropriateness of the device and had fully disclosed the risks about which they complained in the litigation. Additionally, the treating physician in *Beale* was a highly experienced orthopedic surgeon with a good reputation, whose testimony about his independent knowledge of the risks associated with the device was undisputed. The physician was unwavering in his testimony that the plaintiffs were, and continued to be, appropriate candidates for the device based on his own independent medical judgment. There was no direct evidence of collusion with or undue influence on the physician by Biomet or any of its sales representatives. In fact, the *Beale* plaintiffs failed to present any evidence from the Biomet sales representatives on their role in promoting the device to the physician. Had any one or more of these evidentiary aspects of the case been different, the court might have found that a question of fact existed on the elements of the LID and denied Biomet's summary judgment.

Conclusion

In the time since *Beale* was decided, no Florida court has specifically addressed the continued validity of the LID as a defense in pharmaceutical failure to warn cases.⁵⁵ Plaintiffs' lawyers continue to press for limitations on the LID by pleading alternative common law and statutory causes of action and asserting the DTC and overpromotion exceptions to the doctrine. *Karl* signals a complete adoption of arguments plaintiffs have been making for years in an effort to peel back and discard the LID altogether. *Beale*, on the other hand, is a wholesale rejection of those same arguments and makes a compelling case that the LID remains a viable defense in Florida. The Florida practitioner should always be aware that each new drug or device case will present specific circumstances that may create questions of fact on the underlying LID elements or support new arguments by plaintiffs to circumvent the doctrine or convince a court to adopt a novel exception. □

¹ *Sterling Drug, Inc. v. Cornish*, 370 F.2d at 85 (1966) (emphasis added).

² *See In re: Norplant Contraceptive Products Liability Litigation*, 215 F. Supp. 2d 795, 806-08 (E.D. Tex. 2002) (finding that the learned intermediary doctrine applies or is recognized, without exception, in 48 states, District of Columbia, and Puerto Rico).

³ *Sterling*, 370 F.2d at 85 (1966).

⁴ *See Baker v. Danek Medical*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998). Even where there is a factual dispute as to the adequacy of the manufacturer's warning, if the prescribing physician either understood the warnings or had independent information about the risks, then the chain of causation is broken.

⁵ For a detailed discussion of the development of the LID in Florida, *see Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1366 (S.D. Fla. 2007).

⁶ *Felix*, 540 So. 2d at 104 (1989).

⁷ *See Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978).

⁸ *Perez*, 734 A.2d 1245 (N.J. 1999).

⁹ *Id.* at 1249.

¹⁰ *Id.*

¹¹ *Id.* at 1247.

¹² *Id.* at 1263.

¹³ *Id.*

¹⁴ *Id.* at 1256.

¹⁵ *Id.* at 1246.

¹⁶ *See, e.g., Cowley v. Abbott Laboratories, Inc.*, ___ F. Supp. 2d 514, 545 (E.D. Pa. 2006); *In re: Meridia Products Liability*

Litigation, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004).

¹⁷ *See, e.g., Banner v. Hoffman-LaRoche, Inc.*, 891 A.2d 1229 (N.J. Super. 2006) ("[t]he placement of informational brochures in a physician's office cannot fairly be equated with a course of mass advertising or be deemed direct-to-consumer advertising so as to remove the predicates of the learned intermediary doctrine").

¹⁸ *Karl*, 647 S.E. 2d at 910-11 (quoting *Perez v. Wyeth Labs, Inc.*, 734 A.2d 1245, 1255-56 (N.J. 1999)).

¹⁹ *Id.* at 914.

²⁰ *Id.* at 907.

²¹ *Id.* at 914.

²² *Id.*

²³ *See id.* at 910-11.

²⁴ *See Rhode v. Smiths Medical*, 165 P.3d 433 (Wyo. 2007).

²⁵ At virtually the same as *Rimbert*, the U.S. District Court for the District of Puerto Rico, applying Puerto Rico law, granted summary judgment to a pharmaceutical manufacturer on traditional LID grounds. *See Mendez Montes de Oca v. Aventis Pharma.*, ___ F. Supp. 2d ___, 2008 WL 4405311 (D. Puerto Rico Sept. 30, 2008).

²⁶ *See generally* FLA. STAT. §§501.201-203 (2007).

²⁷ Dr. John Repicci of Buffalo, New York, adapted the device from prior designs that had proven relatively unsuccessful in the late 1970s. Dr. Repicci, who is both an orthopedic surgeon and a dentist, drew upon his dental training and experience in developing the minimally invasive surgical technique used to implant the device.

²⁸ *Beale*, 492 F. Supp. 2d at 1362 (2007). The device resurfaces either the medial or lateral femoral condyle. In a total knee replacement, both condyles as well as the patella, or knee cap, are replaced.

²⁹ *Id.* at 1363. Dr. Robert Diaz received his medical degree in 1957 and was board certified in 1971. He performed an estimated 150 to 400 joint replacement surgeries per year in the West Palm Beach area through 2006.

³⁰ *Id.* at 1364.

³¹ *Id.*

³² The medical assistant also signed up patients for consultations with Dr. Diaz.

³³ *See id.* at 1363, 1373, where the court quotes some of the questions, answers, and Web content.

³⁴ *Id.* at 1363. Plaintiffs did not prove, however, that they saw or relied on the Biomet Web page or other forms of Biomet marketing. Plaintiffs also alleged that Biomet sponsored ghost-written articles extolling the virtues of the device, but they did not prove that their surgeon was influenced by the ghost-written articles. *Id.* at 1371. The court ultimately found these allegations immaterial, even if true. *Id.* at 1364 n.4.

³⁵ *Beale*, 492 F. Supp. 2d at 1368.

³⁶ *Id.*

³⁷ *Id.* at 1368-69.

³⁸ *Id.* at 1369, citing *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989) (holding that where warnings are accurate, clear, and unambiguous, the adequacy of

the warning may be decided as a question of law). The court also noted that the plaintiffs did not provide any expert testimony that the warnings were inadequate or not applicable to their weight and activity level allegations. *Id.*

³⁹ *Id.* at 1370-71, citing *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002).

⁴⁰ *Id.* at 1370-71.

⁴¹ *Id.* at 1372. See FLA. STAT. §§501.201-213 (2007) (protecting the consuming public from unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of trade or commerce).

⁴² *Id.* at 1373.

⁴³ *Id.* at 1372, citing *Edgar v. Danek Med., Inc.*, 1999 WL 1054864 (M.D. Fla. 1999) (LID precluded fraud based on underlying failure to warn of "off label" use of pedicle screws); *Catlett v. Wyeth, Inc.*, 379 F. Supp.2d 1374 (M.D. Ga. 2004) (LID encompasses any fraud, misrepresentation, concealment); *Doe v. Solvay*, 350 F. Supp. 2d 257 (D. Maine 2004) (applying LID to deceptive and unfair trade practices act and fraud); *In re Norplant*, 955 F. Supp. 700 (E.D. Tex. 1997).

⁴⁴ *Id.* at 1373, quoting *In re Norplant*, 955 F. Supp at 709.

⁴⁵ *Id.* at 1373.

⁴⁶ *Id.* at 1375.

⁴⁷ *Id.* at 1375-76, citing *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa 2006),

and *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791 (N.D. Ohio 2004). The *Beale* opinion predated the West Virginia Supreme Court's *Karl* opinion by 12 days.

⁴⁸ *Id.* at 1376-77.

⁴⁹ *Id.* at 1377.

⁵⁰ *Id.*, citing numerous cases involving a wide-spectrum antibiotic known as Chloromycetin. See, e.g., *Love v. Wolf*, 226 Cal.App.2d 378 (Cal. Ct. App. 1964); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal.1973); see also *Baldino v. Castanga*, 308 Pa. Super. 506, 454 A.2d 1012 (1983).

⁵¹ *Id.* at 1377-78. The court did not decide whether the Florida Supreme Court would recognize the exception, however.

⁵² *Id.* at 1378.

⁵³ *Karl*, 647 S.E. 2d at 903.

⁵⁴ *Beale*, 492 F. Supp. 2d at 1376-77.

⁵⁵ The U. S. District Court for the Northern District of Florida, in *Colville v. Pharmacia & Upjohn Co.*, 565 F.Supp.2d 1314, 1321 (N.D. Fla. 2008), recently acknowledged, without discussion, the LID standard articulated in *Buckner* in a case addressing the adequacy of the warning accompanying Depo-Provera, a prescription birth control drug. The *Colville* court granted summary judgment in favor of the manufacturer, finding that the warnings in the Depo-Provera label were adequate and concluding that because the prescriber was aware of the risk of the injury claimed by the plaintiff but failed to share that information with the plaintiff, any alleged

inadequacy in the warnings could not have been the proximate cause of the plaintiff's injury in any event. The *Colville* court's analysis was predicated on the notion that a drug manufacturer's duty to warn is fulfilled by an adequate warning given to the prescribing doctor.

Gary M. Pappas is a shareholder in the Miami office of Carlton Fields. His practice includes commercial litigation, products liability, insurance coverage, intellectual property, and environmental law. He received his J.D., with high honors, from the University of Florida College of Law.

John A. Camp is a shareholder in the Miami office of Carlton Fields and is a member of the firm's products and toxic tort liability and business litigation and trade regulation practice groups. He has extensive experience in product liability and personal injury defense, and the primary focus of his practice is the defense of prescription drug and medical device manufacturers. He is a graduate of the University of Florida College of Law.