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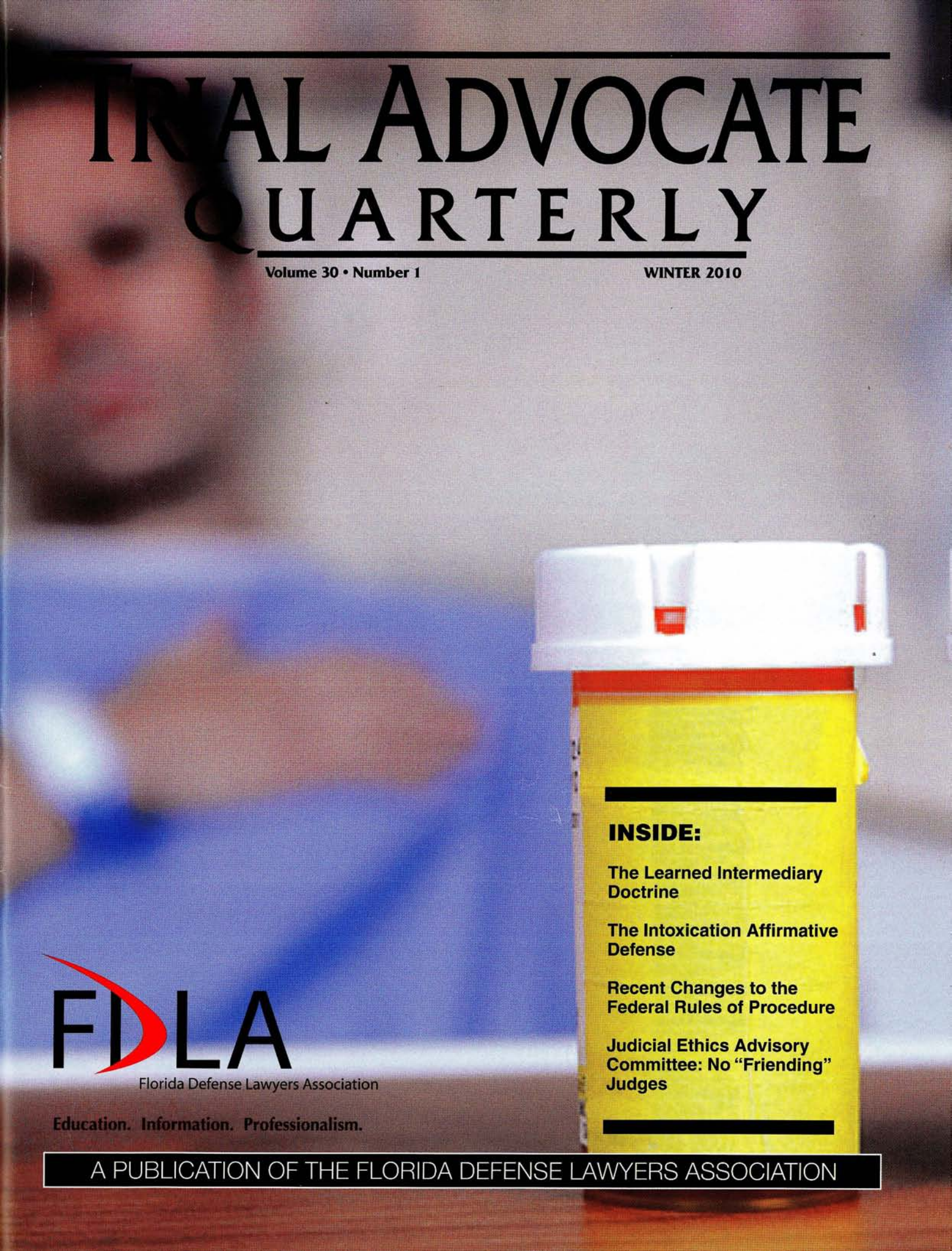

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The Learned Intermediary Doctrine: An Update

By Carol Rooney

The learned intermediary doctrine allows the manufacturers of prescription drugs or medical devices to defend against a claim of failure to warn brought by an injured patient by showing that they provided adequate warnings to the prescribing physician. Although the doctrine has vigorously been challenged and has been eliminated or limited in a few jurisdictions, it continues to be a viable defense in Florida.

Florida has long recognized the learned intermediary doctrine as a viable defense by manufacturers of prescription drugs to lawsuits alleging a failure to warn of the risks associated with the use of their products.[1] Florida has also extended the doctrine's application to prescription medical devices.[2] Notwithstanding the widespread recognition of the defense in Florida and most other jurisdictions that have considered the issue, new and creative attacks upon the defense continue to be asserted by litigants seeking recovery against the manufacturers of drugs and medical devices.[3] Nevertheless, recent federal and state court opinions have further solidified the doctrine in Florida jurisprudence. This article will briefly review the underpinnings of the doctrine in Florida and highlight recent opinions favoring, rejecting, or commenting on the defense throughout the country.

I. Significance of Learned Intermediary Doctrine as a Defense in Prescription Drug and Medical Device Litigation

Under Florida law, a product may be considered defective and liability established by virtue of a design defect, a manufacturing defect, or an inadequate warning.[4] Liability based upon an inadequate warning is founded on the duty owed by product manufacturers to sufficiently warn consumers of the dangers and risks associated with the use of these products. However, in the context of prescription drugs and medical devices, courts have recognized that the duty of manufacturers does not extend directly to the consumers. Rather, under the "learned intermediary" doctrine, a manufacturer's duty to provide an adequate warning extends only to the physician.[5]

The learned intermediary doctrine was first recognized in Florida by the Fifth District Court of Appeal in *Bucker v. Allergan Pharmaceuticals, Inc.*[6] In *Buckner*, the plaintiff appealed the dismissal of her complaint against manufacturers of prescription steroid drugs for failure to state a cause of action. The plaintiff alleged that various doctors prescribed corticosteroids for eye disorders without warning her of known dangerous side effects; that she took the drugs without knowledge of their danger; and that, as a result, she developed a condition known as one of the harmful side effects. The plaintiff alleged that the manufacturers knew of such dangerous effects and provided adequate warnings to the medical profession, but knew or should have known that the medical profession was not adequately relaying those warnings to the consuming public. The plaintiff argued that the manufacturers were required to convey fair and adequate warnings to the ultimate consumer pursuant to the doctrine of strict products liability as adopted in Florida.[7]

The appellate court affirmed the trial court's dismissal of the action, finding the complaint failed to state a cause of action. The court held that the manufacturer of a prescription drug fulfills its duty to warn by conveying an adequate

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warning to physicians and those authorized to prescribe the drugs to the consumer. Although Florida courts had not yet specifically addressed the issue, the appellate court noted numerous jurisdictions were in accord with this view.[8]

The *Buckner* court went to great lengths to set forth the rationale for the learned intermediary doctrine, noting that it applied even in actions for strict products liability:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.[9]

The application of the learned intermediary doctrine significantly impacts the plaintiff's burden of proof in prescription drug and medical device strict products liability claims. The plaintiff cannot state a valid cause of action by claiming that the drug manufacturer failed to provide an adequate warning to the ultimate consumer. Rather, the plaintiff must allege and prove that the manufacturer failed to provide an adequate warning to the physician. In this regard, the alleged inadequacy of a warning is not judged according to the knowledge of a layperson, but by the warning's effect on the prescribing physician. Except in the most obvious cases, this must be proved by expert testimony.[10] Finally, and most importantly, the Florida Supreme Court has ruled that the adequacy of the warning can be determined as a matter of law, rather than by a jury, where the warning is accurate, clear and unambiguous.[11]

The ability of manufacturers to obtain summary judgment and avoid jury trials in prescription drug and medical device litigation based upon the learned intermediary doctrine shows the critical import of the doctrine as a defense. In addition to obtaining summary judgment based upon the adequacy of the warning, manufacturers may also rely on the doctrine to show the plaintiff's inability to establish proximate cause. Even assuming that the plaintiff is able to avoid summary judgment on the adequacy of the warning, the plaintiff must prove that the lack of an adequate warning caused the treating physician to prescribe the drug or device.[12] If the warning, or lack thereof, had no effect on the treating physician's decision to prescribe the drug or device, the plaintiff cannot establish that the alleged inadequate warning caused his or her injuries and summary judgment for the manufacturer will be granted.[13]

The significance of the learned intermediary doctrine as a defense to strict products liability actions cannot be overstated.

In sum, the significance of the learned intermediary doctrine as a defense to strict products liability actions brought against manufacturers in the pharmaceutical industry cannot be overstated.

II. The Learned Intermediary Doctrine in Florida

In *Beale v. Biomet, Inc.*,[14] the United States District Court for the Southern District of Florida surveyed the history of the learned intermediary doctrine in Florida ruling against the plaintiffs in their efforts to limit or bar the application of the doctrine. Thedistrict court noted that, since the first Florida court applied the doctrine in the case of *Buckner v. Allergan Pharmaceuticals, Inc.*[15], the doctrine had been recognized by other Florida courts and expressly approved by the Florida Supreme Court. Thus, the learned intermediary doctrine was clearly "the law in the State of Florida."[16]

In *Biomet,* the plaintiffs filed suit against the manufacturer of a knee prosthetic device alleging multiple counts for negligence/gross negligence, strict products liability, violation of Florida's Deceptive and Unfair Trade Practices Act, and negligent misrepresentation. The plaintiffs alleged that they experienced severe pain and eventually needed revision surgery on their knees following implantation of the devices. Moreover, they claimed that they were improper candidates for the device and that they were not informed of the risks involved.

The manufacturer moved for summary judgment on the basis of the learned intermediary doctrine, contending that the warnings provided to the plaintiffs' physician regarding the implantation of the device were adequate. The district court noted that, although the learned intermediary doctrine had been adopted by Florida state courts in cases dealing with prescription drugs, the state courts had not yet addressed the application of the doctrine to medi-

cal devices. However, the district court noted that other federal district courts in Florida, as well as other jurisdictions, had applied the doctrine to prescription medical devices. Thus, given the rationale behind the doctrine, the court felt it made sense to further extend the doctrine to medical devices.[17] Accordingly, the district court found that the learned intermediary doctrine applied to the plaintiffs' claims.

Because the plaintiffs did not establish a genuine issue of material fact as to the adequacy of the warnings to the physician, the district court found the plaintiffs' claims were barred by the application of the doctrine.[18] The district court also found that the plaintiffs had failed to meet their burden of establishing proximate cause as the plaintiffs' treating physician testified that he was aware of all of the risks associated with the device and still believed that the plaintiffs were appropriate candidates for the device. As the treating physician's decision was not impacted by the alleged inadequate warning, the causal link was broken.[19]

As might be expected, the plaintiffs argued that their claims under Florida's Deceptive and Unfair Trade Practices Act and for negligent misrepresentation survived notwithstanding the application of the learned intermediary doctrine. In this regard, they asserted that the manufacturer's marketing activities constituted a "direct to consumer" or "over-promotion exception" to the doctrine.[20]

The district court acknowledged that no Florida state court had yet considered a claim relating to a prescription medical product under Florida's Deceptive and Unfair Trade Practices Act. However, federal courts in jurisdictions across the country, including Florida, had found that the learned intermediary doctrine encompassed all claims based upon a pharmaceutical manufacturer's failure to warn, including claims for fraud, misrepresentation, and violation of state consumer protection laws. The district court noted with approval the opinion of a Texas district court considering similar challenges to the doctrine's application, including claims made under Texas's Deceptive Trade Practices Act.[21] Florida's district court agreed with the Texas court and found that, no matter the labels used by the plaintiffs, their claims were ultimately based upon the manufacturer's alleged failure to warn and were thus barred by the learned intermediary doctrine. Further, plaintiffs' claims for negligent misrepresentation failed as a matter of law as plaintiffs could not point to a single false or misleading statement made by the manufacturer regardless of the application of the doctrine.[22]

The district court found plaintiffs' attempt to avoid the application of the doctrine based on a direct-to-consumer marketing or over-promotion exception equally unavailing. The plaintiffs had urged the district court to follow the ruling of the Supreme Court of New Jersey in *Perez v. Wyeth Laboratories, Inc.*[23] in which that court found that the learned intermediary doctrine did not apply when a manufacturer engages in a marketing campaign directly to consumers. In that case, the plaintiffs argued that the prosthetic knee device was over-promoted to consumers, thus negating any warnings provided, regardless of adequacy, and was an exception to the learned intermediary doctrine.[24]

The Florida district court acknowledged the *Perez* decision but considered it an anomaly given that no court, including any Florida court, had recognized a direct-to-consumer marketing exception to the learned intermediary doctrine. Noting Florida's "long-standing recognition" of the doctrine, the district court found it unlikely that the Florida Supreme Court would recognize the exception.[25] The district court rejected the plaintiffs' call for an over-promotion exception concluding that the cases cited by plaintiffs were factually distinguishable from the facts at hand.[26]

The *Biomet* opinion clearly establishes the strength of the learned intermediary doctrine as a defense in Florida. The district court found the doctrine appropriately applied in the context of prescription medical devices. Further, the doctrine was held to be broad enough to encompass all claims made by a plaintiff against a manufacturer regardless of the labels placed on the claims alleged by the plaintiff.

III. Recent Opinions Recognizing the Learned Intermediary Doctrine as a Valid Defense

Despite the *Perez* opinion, and a similar and an even more expansive rejection of the learned intermediary doctrine by the West Virginia Supreme Court in *State ex rel. Johnson & Johnson Corp. v. Karl*,[27] discussed below, the doctrine still appears firmly rooted in Florida, as well as in several other jurisdictions that have considered the issue.[28] In *Hoffman-La Roche Inc. v. Mason,*[29] for example, the manufacturer of the prescription drug Accutane sought reversal of a judgment for compensatory damages entered against it following a jury trial. The plaintiff was diagnosed with Crohn's Disease, a form of inflammatory bowel disease, after being prescribed Accutane to treat his severe acne. The plaintiff had filed suit against the manufacturer under theories of strict liability and negligent failure to warn, alleging that Accutane's warning label was inadequate to warn the patient's physicians about the risk of developing inflammatory bowel disease.

At trial, the plaintiff presented an expert who testified that the warning label for Accutane was inadequate in that the warning indicated only a temporal relationship between the use of Accutane and inflammatory bowel disease. However, the plaintiff's physician testified that he understood the language of the warning to mean that there was at least a possibility of a causal relationship between

Accutane and inflammatory bowel disease. Further, the physician testified that he would have prescribed Accutane for the plaintiff even if the label warned it could cause inflammatory bowel disease.

The doctrine continues to survive challenges in Florida and elsewhere.

At the close of the plaintiff's case, the manufacturer moved for a directed verdict arguing that the plaintiff had failed to establish that his injury was proximately caused by any alleged warning inadequacy. The trial court denied the motion after the jury returned its verdict in favor of the plaintiff. The manufacturer then appealed.

The appellate court noted that, in order for the plaintiff to prevail at trial on either of his claims, he was required to prove that the warning label was inadequate, that the inadequacy of the warning proximately caused his injury, and that he suffered an injury from using Accutane. The court noted that while drug companies have a duty to warn of a drug's dangerous side effects, the duty to warn is directed to physicians rather than patients pursuant to the learned intermediary doctrine. The appellate court then found that although the plaintiff had presented evidence that the warnings were inadequate to warn physicians generally, the plaintiff's prescribing physician's testimony indicated that he would have prescribed the medication even if all the information suggested by the plaintiff had been included in the warning. Accordingly, the appellate court found that the plaintiff failed to meet his burden of establishing proximate cause.

Although the *Hoffman-La Roche Inc.* opinion did not elaborate on the history or strength of the learned intermediary defense as did the district court in *Biomet*, it was the first Florida state appellate court decision to consider the issue in recent years.[30] In another recent Florida case, *Wolicki-Gables v. Arrow International, Inc.*,[31] the United States District Court for the Middle District of Florida found plaintiff's claims against the manufacturer and distributor of a allegedly defective drug delivery pump and catheter were expressly preempted by Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. In that case, the district court acknowledged that the learned intermediary doctrine would act to bar the plaintiff's claims even assuming they were not expressly preempted.

The doctrine continues to be recognized and survive challenges beyond Florida as well. In *In re Zyprexa Products Liability Litigation,*[32] the United States District Court for the Eastern District of New York considered the claims of a Plaintiff's estate against Eli Lilly & Company, the manufacturer of the drug, Zyprexa. Thousands of Zyprexa cases were transferred to the district court in New York pursuant to an order of the Judicial Panel on Multidistrict Litigation and the cases were administered as a quasi-class action.

In the estate's action, the plaintiff alleged negligence against the manufacturer based upon a failure to warn theory, claiming that the manufacturer had failed to warn of the dangers of the drug, and if it had then the drug would not have been prescribed. The manufacturer moved for summary judgment, arguing that the dangers asserted by the plaintiff were well known to the medical community and to prescribing physicians.

The district court found that the estate's claims could not survive the application of the learned intermediary doctrine under Illinois law.[33] As stated by the district court:

> The learned intermediary defense is an "aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians. The learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored."[34]

In so finding, the district court also noted the "strong trend in prescription drug failure to warn cases to reiterate and apply this well-established doctrine."[35] The district court found that the estate had offered no evidence to support a finding that the warning at issue was inadequate or that the alleged failure to warn had any effect on the physician's decision to prescribe the drug.[36]

The learned intermediary defense also continues to resist challenges to its application under Texas law. In *Pustejovsky v. Wyeth, Inc.*[37], the plaintiff sued the manufacturer of a generic drug used to treat gastroesophageal reflux disease ("GERD"). The plaintiff alleged claims sounding in negligence, fraud, misrepresentation, breach of warranty, and strict liability. All the claims focused on the manufacturer's alleged failure to adequately warn of the risk of developing a condition called tardive dyskinesia. The manufacturer of the generic drug moved for summary judgment based on the learned intermediary doctrine.

The United States District Court for the Northern District of Texas noted the doctrine applied to both strict liability and negligence claims. The district court determined that, under the doctrine, it is assumed that a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs,

assessing the risks and benefits of available drugs, prescribing and supervising their use. Thus, when a drug is marketed though a doctor, the doctor-patient relationship relieves the drug manufacturer of the obligation to warn the ultimate consumer of the risks associated with the product. The court held that the duty to warn extends only to the doctor, and the manufacturer may not be held liable to the ultimate consumer for failing to warn even if the doctor does not exercise independent professional judgment regarding the use of the drug.[38]

Accordingly, for the plaintiff to recover for failure to warn when the doctrine is applied, the plaintiff must show that the warning to the physician, i.e., the intermediary, was defective, and that the failure to warn was a producing cause of the injury. The district court found that the plaintiff could not show that there was a factual issue as to these matters, as her treating physician testified she had not read the package insert for the generic medication and did not rely on any warnings from the manufacturer in prescribing the medication. Thus, the district court granted summary judgment for the manufacturer of the generic drug.

IV. Rejection of the Learned Intermediary Doctrine — The Aftermath of *Karl*

The West Virginia Supreme Court, in *State ex rel. Johnson & Johnson Corp. v. Karl*,[39] reviewed the history and rationale of the learned intermediary doctrine but, unlike the district court in *Biomet*, found that changes in pharmaceutical marketing had rendered the doctrine obsolete. More specifically, the court found that the increase in marketing efforts of pharmaceutical companies directly to the consumer obviated the premises upon which the doctrine was based. There have been relatively few cases citing to *Karl* in any context since the West Virginia Supreme Court's ruling.

In *Rimbert v. Eli Lilly and Co.*,[40] the United States District Court for the District of New Mexico reviewed *Karl* in the context of determining whether the Supreme Court of New Mexico would adopt the learned intermediary doctrine. At issue were claims on behalf of the estate of a consumer of the prescription antidepressant Prozac who had killed his wife and committed suicide. The manufacturer of the drug sought summary judgment under New Mexico law on the basis of the learned intermediary doctrine. In a lengthy opinion, the district court denied the manufacturer's motion for summary judgment on the plaintiff's failure to warn claims, finding that there were issues of material fact regarding whether the warnings were adequate.[41] In denying summary judgment, the district court extensively reviewed the history and application of the learned intermediary doctrine in New Mexico as well as other jurisdictions.

The district court noted that New Mexico's state appellate courts had adopted the learned intermediary doctrine in opinions issued in the 1970s and 1980s. However, the district court predicted that the Supreme Court of New Mexico would not, in 2008, follow those opinions. The primary reason stated by the district court for its belief that the high court would not follow the earlier decisions was that the learned intermediary doctrine was "fundamentally inconsistent" with New Mexico's strict products liability jurisprudence.[42] According to the district court, if the Supreme Court of New Mexico adopted the doctrine, the risk of loss borne by suppliers of defective products under the traditional jurisprudence would be shifted to the physician and patient.

Further, the district court noted that New Mexico had adopted the doctrine of strict products liability to promote fairness by ensuring that plaintiffs injured by unreasonably dangerous products would be compensated for their injuries. The district court opined that adopting the learned intermediary doctrine would leave some plaintiffs uncompensated. The district court stated it did not believe the Supreme Court of New Mexico would choose a doctrine which would leave some plaintiffs uncompensated when there did not appear to be a compelling reason for them to be uncompensated.[43]

The district court also noted its approval and agreement with the findings of the *Karl* court in that the justifications for the learned intermediary doctrine were largely outdated and unpersuasive. The district court believed that the Supreme Court of New Mexico would make similar findings as the Supreme Court of West Virginia in *Karl* and, given the opportunity in 2008, would not adopt the doctrine given the changing dynamics between doctors and patients, patients' self-diagnosis, and direct-to-consumer advertising by drug manufacturers.[44]

More recently, in *Woodstock v. Mylan, Inc.*,[45] the United States District Court for the Southern District of West Virginia revisited *Karl* in a choice-of-law context in order to determine whether the *Karl* opinion rejected the learned intermediary doctrine on public policy grounds. In finding that West Virginia had rejected the doctrine on such grounds, the district court found that Alabama law, although applicable in every other instance, could not apply to the plaintiff's manufacturing defect claim. This was because West Virginia's choice-of-law rules, like many states, provided that a foreign state's law which contravened West Virginia's public policy could not be applied. The district court noted that its decision "almost certainly invited forum shopping by plaintiffs dissatisfied with their home state's products liability laws." Nevertheless, the district court concluded it was convinced that the West Virginia Supreme Court would hold that the application of the doctrine would violate West Virginia public policy.

Interestingly, in a different context, the same district court in West Virginia considered the *Karl* opinion

in determining whether West Virginia would refuse to accept any form of the sophisticated user doctrine. In *Roney v. Gencorp*,[46] the son of a worker who died from liver cancer allegedly caused by exposure to vinyl chloride monomer sued the supplier of the chemical to the plant where his father worked. The supplier defended on the grounds that it had no duty, as any alleged duty was obviated by the employer's own duty to warn.

The district court noted that the supplier's defense was commonly referred to as a "sophisticated user" defense and had not been explicitly adopted or rejected in West Virginia. The district court noted that the West Virginia Supreme Court had recently rejected a similar defense in *Karl*. The district court, however, found that the decision in *Karl* was very context-specific and based on reasoning not applicable to the facts presented. Further, an earlier opinion of the West Virginia Court signaled that the court would not entirely reject some form of the sophisticated user defense. Accordingly, the district court found that West Virginia courts would adopt the sophisticated user defense in their application of comment n to § 388 of the Restatement (Second) of Torts.[47]

In *Nye v. Bayer Cropscience, Inc.*[48], the Court of Appeals of Tennessee noted that the learned intermediary doctrine had not been extended beyond the realm of pharmaceutical and medical device liability cases in Tennessee. The plaintiff appealed a jury verdict in favor of the defendant seller/supplier for strict products liability and failure to warn related to exposure to asbestos. Although the appellate court found that the doctrine was applicable to cases involving highly skilled users, especially medical doctors, the same rationale would not fit sales of defective products to commercial users. Accordingly, the appellate court found that the trial court had erred in instructing the jury on a charge which incorporated the learned intermediary doctrine as well as the sophisticated buyer doctrine.[49]

Recently, the United States District Court for the Eastern District of Pennsylvania noted the learned intermediary doctrine's uncertain status in New Mexico. In *In re Avandia Marketing, Sales Practices and Products Liability Litigation*,[50] the doctrine was considered in the context of claim for fraudulent joinder. The district court found that New Mexico's law was too unsettled to find that the plaintiff's claims against a sales representative for a drug manufacturer were not viable according to the standard for fraudulent joinder.

In another Pennsylvania opinion, *In re Diet Drugs (Phentermine/FenFluramine/Dexfenfluramine) Products Liability Litigation*,[51] the United States District Court for the Eastern District of Pennsylvania reviewed the learned intermediary doctrine under Missouri law. The manufacturer moved for summary judgment on plaintiff's counts for negligence, negligence per se, design and manufacturing defects, failure to warn, inadequate and false warnings, misrepresentation and fraudulent misrepresentation, strict products liability and breach of implied warranty of merchantability on the basis of the learned intermediary doctrine. However, the district court found that the doctrine only applied to claims based upon a failure to warn theory.[52]

The district court characterized plaintiff's counts for negligence and negligence per se, design and marketing defects, misrepresentation and fraudulent misrepresentation, strict products liability and breach of implied warranty of merchantability as "independent" causes of action which did not appear to be premised on a failure to warn. Thus, according to the district court, the counts were subject to dismissal "only to the extent they are based on failure to warn."[53]

The district court's holding could be contrasted to the *Biomet* court holding, which found that the doctrine encompassed all claims based upon a pharmaceutical manufacturer's failure to warn, including claims for fraud, misrepresentation, and violation of state consumer protection laws.[54] The *Biomet* court found that, regardless of the various names used for the plaintiff's claims against the manufacturer, the claims were all ultimately based upon the manufacturer's alleged failure to warn. 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 claim for misrepresentation, then the doctrine would be rendered meaningless. The Pennsylvania district court agreed with *Biomet* to the extent that the claims would be subject to dismissal if they were based upon a failure to warn. However, unlike *Biomet*, the Pennsylvania district court construed the misrepresentation count, which alleged the manufacturer made certain misrepresentations through its advertising, labeling and other communications, as apparently not premised upon a failure to warn. Pleading standards and the specificity of the claims made by the plaintiff are obviously critical in jurisdictions which limit the application of the doctrine strictly to counts couched in failure to warn terms. In those jurisdictions, the defendant manufacturer would need to show that the allegations made by the plaintiff are premised upon a failure to warn despite the labels used by the plaintiff.

V. The Future of the Learned Intermediary Doctrine as a Defense in Florida and Beyond

Florida clearly recognizes the validity of the learned intermediary defense and has applied the doctrine broadly to claims made by plaintiffs against the manufacturers of prescription drugs and medical devices. Although a few jurisdictions have limited or eliminated the application of the doctrine, the defense continues to be accepted in most jurisdictions in the pharmaceutical manufacturing context. It remains to be seen whether the opinions of the *Karl, Perez,* and

Rimbert courts viewing the doctrine as obsolete will be echoed by future courts. To date, Florida has rejected such claims founded on marketing techniques and promotion campaigns of manufacturers. The increase in information available to today's consumers will no doubt present opportunities for future challenges to the doctrine.

1 The Florida Supreme Court first adopted the learned intermediary doctrine in *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989); *see also Upjohn Co. v. Murdo*, 562 So. 2d 680 (Fla. 1990).

2 *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360 (S.D. Fla. 2007).

3 *See* http://druganddevicelaw.blogspot.com/2007/07/headcount-whos-adopted-learned-html (Beck and Hermann blog/website containing chart of treatment of learned intermediary doctrine defense by jurisdiction).

4 *Pinchinat v. Graco Children's Prods., Inc.*, 390 F. Supp. 2d 1141 (M.D. Fla. 2005).

5 *E. R. Squibb and Sons, Inc. v. Farnes*, 697 So. 2d 825 (Fla. 1997).

6 400 So. 2d 820 (Fla. 5th DCA 1981).

7 *Id.* at 822.

8 *Id.*

9 *Id.* at 823 (citing *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974)).

10 *Upjohn Co. v. Murdo*, 562 So. 2d 680, 683 (Fla. 1990).

11 *Id.* at 682-683.

12 *Colville v. Pharmacia & Upjohn Co., LLC*, 565 F. Supp. 2d 1314 (N.D. Fla. 2008).

13 *Id.* at 1322.

14 492 F. Supp. 2d 1360 (S.D. Fla. 2007).

15 400 So. 2d 820 (Fla. 5th DCA 1981).

16 *Biomet*, 492 F. Supp. 2d at 1366-1367.

17 *Id.* at 1367-1368.

18 *Id.* at 1360-70.

19 *Id.* at 1371 (citing *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272 (11th Cir. 2002)).

20 *Id.* at 1371-1372.

21 *In re Norplant Contraceptive Prods. Liability Litigation*, 955 F. Supp. 700 (E.D. Tex. 1997).

22 *Biomet,* 492 F. Supp. 2d at 1375.

23 734 A.2d 1245 (N.J. 1999).

24 *Biomet,* 492 F. Supp. 2d at 1377-1378.

25 *Id.*

26 *Id.*

27 647 S.E.2d 899 (W. Va. 2007).

28 In *Porter v. Eli Lilly and Co.*, 2008 WL 544739, *6 (N.D. Ga. Feb. 25, 2008), the district court noted that the doctrine is well established in state tort law, by some accounting applied in forty-four jurisdictions, including Georgia.

29 34 Fla. L. Weekly D2200, 2009 WL 3430190 (Fla. 1st DCA October 27, 2009).

30 Florida federal district courts have considered the application of the learned intermediary doctrine since *Biomet*. *In re Seroquel Prods. Liability Litigation*, 2009 WL 260989, *8 (M.D. Fla. February 4, 2009)(holding that evidence of warnings and side effects of other drugs taken by plaintiff were not irrelevant under the learned intermediary doctrine as claimed by plaintiff but instead were relevant to the decision to prescribe the antipsychotic drug); *Colville v. Pharmacia & Upjohn Company LLC*, 565 F. Supp. 2d 1314, 1320-1321 (N.D. 2008)(recognizing the learned intermediary defense and finding warning to physician by manufacturer was adequate as a matter of law).

31 641 F. Supp. 2d 1270 (M.D. Fla. 2009).

32 2009 WL 3597194 (E.D.N.Y. October 16, 2009).

33 *Id.* at *10 citing *Hansen v. Baxter Healthcare Corp.*, 764 N.e.2d 35, 42 (Ill. 2002).

34 *Id.* at 10.

35 *Id* at *10 citing *Motus v. Pfizer Inc.*, 358 F. 3d 659, 661 (9th Cir. 2004) (holding that a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician) (citing *Plumer v. Lederle Laboratories, Div. of American Cyanid Company*, 819 F.2d 349 (2d Cir. 1987)); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767 (S.D. Tex. 2008)(granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa's suicide related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd,* No. 08-40170, 2009 WL 837325 (5th Cir. March 30, 2009); *Allgood v.GlaxoKlineSmith PLC*, No. 06-3506, 2008 WL 483574, at *3 (E.D. La. Feb. 20, 2008) (granting summary judgment for defendant because plaintiff has failed to show (1) that defendant did not adequately warn the physician of a risk associated with the drug that was not otherwise known to the physician and (2) that the "failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury"), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, No. 08-30329, 2009 WL 6465285 (5th Cir. March 13, 2009).

36 In another recent Illinois opinion, *Hilderbrandt v. Johnson & Johnson*, 2009 WL 3349913 (S.D. Ill. October 19, 2009), the learned intermediary defense was acknowledged as the law of Illinois in the context of claims of fraudulent joinder.

37 2009 WL 3336032 (N.D. Tex. September 4, 2009).

38 *Id.* at *2 (citing *Hurley v. Lederle Lab. Div. of Am. Cyanamid*, 863 F.2d 1173, 1179 (5th Cir. 1989)).

39 647 S.E.2d 899 (W. Va. 2007).

40 577 F. Supp. 2d 1174 (D. N.M. 2008).

41 *Id.* at 1230.

42 *Id.* at 1214-1215.

43 *Id.*

44 *Id.* at 1217-1222.

45 2009 WL 3271252 (S.D. W. Va. October 14, 2009).

46 2009 WL 2915084 (S.D. W. Va. September 4, 2009).

47 *Id.* at *4-5.

48 2009 WL 3295137 (Tenn. Ct. App. October 14, 2009).

49 *Id* at *13-14. The appellate court, citing numerous cases, noted that the Sixth Circuit, the federal district courts in Tennessee and several other courts in other states had mistakenly cited the Tennessee Supreme Court opinion *Whitehead v. Dycho Co.*, 775 S.W.2d 593 (Tenn. 1989) as accepting the sophisticated buyer doctrine.

50 2009 WL 1708078 (E.D. Pa. June 17, 2009).

51 2009 WL 902351 (E.D. Pa. April 2, 2009).

52 *Id.* at *2-3.

53 *Id.* at *3.

54 *Biomet*, 492 F. Supp. 2d at 1372-1373.