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The Learned Intermediary Doctrine: A Retrospective Review to the Present

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Background and General Application of the Learned Intermediary Doctrine

History of Learned Intermediary Doctrine

- The learned intermediary rule was first articulated in the New York case of *Marcus, v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508 (App. Div. 1948).
- The phrase "learned intermediary" was first used in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966):
  - "We are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a **learned intermediary** between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided."

Rationale for the Learned Intermediary Doctrine:

- Warnings go to physicians because they are the only people who know both a particular patient's medical history as well as the risk/benefit profile of the drug/device being prescribed.
- Limiting warning duties to physicians makes the common law consistent with warning duties imposed by the FDA.
- Routing prescription drug/device information through the doctor preserves the physician/patient relationship from outside interference.
- The complicated medical terminology necessary to explain the risk/benefit profile of prescription drugs/devices is difficult for ordinary patients to understand.
- Practical difficulties often preclude drug/device companies from direct communication with patients.

New Jersey Product Liability Act: N.J.S.A. 2A:58C-4

- Codifies the Learned Intermediary Doctrine.
- A prescription drug manufacturer's duty to provide adequate warnings is owed to prescribing physicians and not to patients.
- "[A] pharmaceutical manufacturer generally discharges its duty to warn by supplying physicians with information about the drug's dangerous propensities") *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989).

Causation Issues Related to the Doctrine

- In order to survive summary judgment, “plaintiff must show that adequate warnings would have altered her doctors’ decision to prescribe [her medication]” *Strumph v. Schering Corp*., 133 N.J. 33 (1993)
- In order to demonstrate that an inadequate warning proximately caused plaintiff’s injury she “must show that [an] adequate warnings would have altered her doctors’ decision to prescribe [the drug].” *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989)

Causation Issues Related to the Learned Intermediary Doctrine

- "If the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury." *Ebel v. Eli Lilly & Co.*, 321 Fed. Appx. 350, 356 (5th Cir. 2009)
- Similarly, if a physician has not read the product warnings, there can be no liability because nothing about the adequacy of the warnings caused the injury. *In re: Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78059 at *19 (S.D.W.V. June 4, 2013).

Causation Issues Related to the Learned Intermediary Doctrine

- The learned intermediary doctrine shields the manufacturer from liability even if the doctor learns of the risks from a source other than the manufacturer. *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004):
  - "the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially the same knowledge as an adequate warning from the manufacturer should have communicated to him"

NJ Heeding Presumption

- The first appellate application of a heeding presumption in a products case in New Jersey occurred in an asbestos case, *Coffman v. Keene Corp.*, 133 N.J. 581, 591 (1993).
- The Court held that the plaintiff was entitled to a presumption that if properly warned, he would have "heeded" the warning.
- In order to rebut the presumption, the defendant needed to produce only inferential evidence that plaintiff would not have heeded an adequate warning.
- Mostly applied in workplace injury cases.

NJ Heeding Presumption

- New Jersey appellate courts have never sanctioned the application of a heeding presumption in a case involving prescription pharmaceuticals.

  - *Perez v. Wyeth Labs, 161 N.J. 1, 24 (1999)*, 161 N.J. at 28-29 (mentioning the heeding presumption's adoption and rejection by other courts, but not suggesting that New Jersey plaintiffs should benefit from such a presumption to meet their proximate cause burden);

  - *London v. Lederle*, 290 N.J. Super. 318, 327 (App. Div. 1996) *aff'd and modified*, 152 N.J. 14 (1997) (holding that a drug manufacturer cannot be liable where the additional warning would not have affected the prescribing doctor's decision to prescribe, without mention of a heeding presumption);

  - *Appleby v. Glaxo Wellcome, Inc.*, 2005 U.S. Dist LEXIS 32875 at *18 (D.N.J. December 13, 2005) (relying on *Strumph* in granting summary judgment to prescription drug manufacturer on plaintiff's failure-to-warn claim);

  - *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639 (Law Div. March 3, 2006) (stating that New Jersey has adopted the "learned intermediary" rule in determining prescription drug inadequate warning claims and making no mention of a heeding presumption).

NJ Heeding Presumption

- Heeding presumption articulated by Judge Garruto in the HRT case of *Deutsch v. Wyeth*.
- Presumes that a doctor would refuse to prescribe a drug approved by the FDA as safe and effective simply because some additional risk information is added to the labeling.
- *See* June 20, 2007 Memorandum of Decision.
- Not adopted by any other New Jersey court.

Heeding Presumption: Guidance from Other Jurisdictions

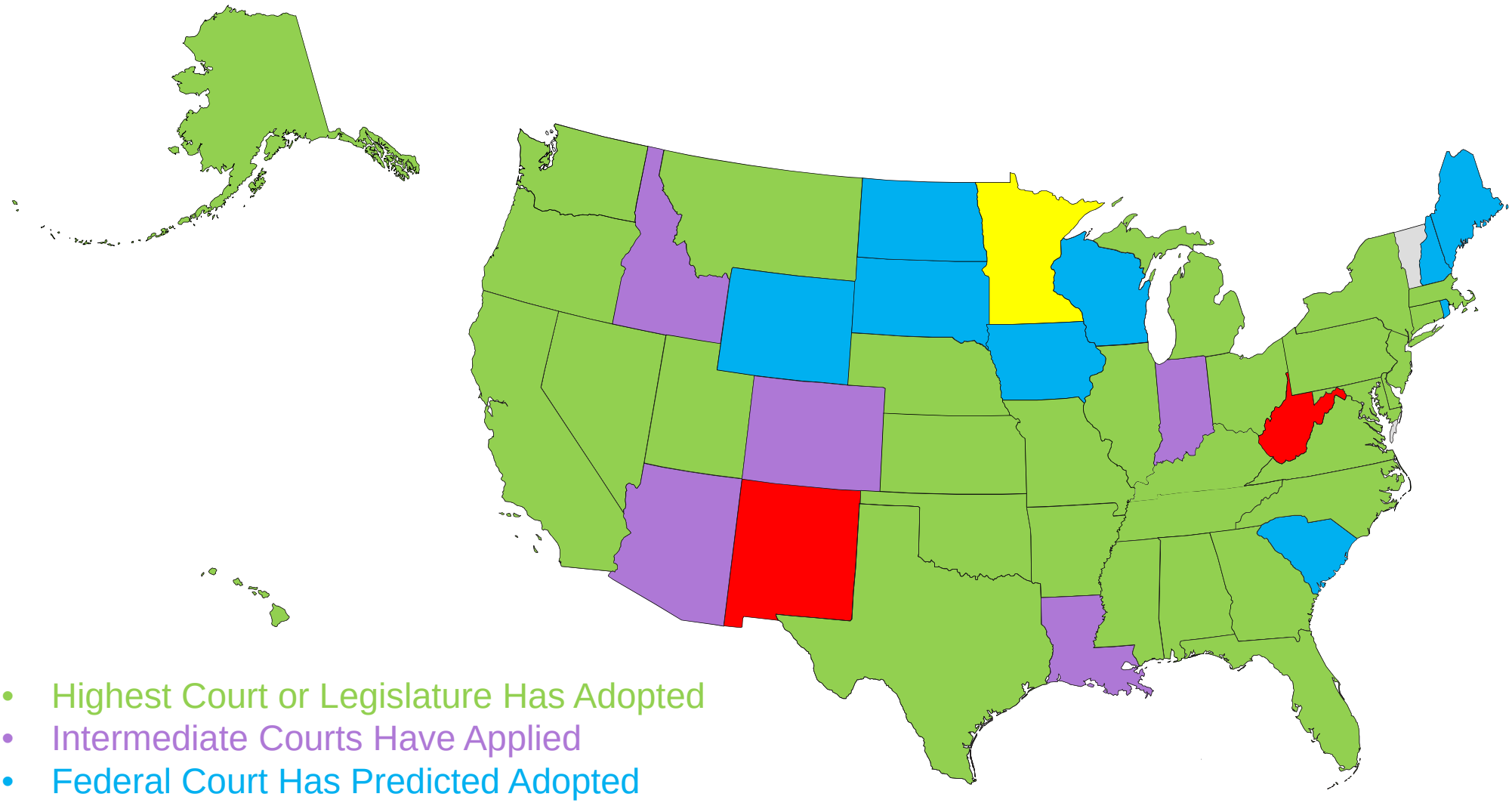
- The Fifth Circuit has described the situation:
  - "heeding" in the prescription drug context "means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus," not that the prescription would not have been written. *Thomas v. Hoffman La-Roche*, 949 F.2d 806, 814 (5th Cir. 1992);
- *Ackermann v. Wyeth Pharmaceuticals*, 2008 WL 1821379 *8 (5th Cir. 2008) (refusing to apply a "read and heed" presumption to cases involving learned intermediaries).

Heeding Presumption: Guidance for Practice

- For a physician making a prescribing decision, “heeding” a warning about a medicine is not the equivalent of refraining from prescribing it.
- If it were, then doctors would not prescribe any prescription medicines because all FDA-approved drugs carry warnings.
- Heeding new or different risk information about a medication means taking it into account in weighing the benefits and risks for specific patients, not deciding not to prescribe it.

Failure to Warn Claims in States with No Learned Intermediary Doctrine

Adoption of the Learned Intermediary Doctrine



- Highest Court or Legislature Has Adopted
- Intermediate Courts Have Applied
- Federal Court Has Predicted Adopted
- Rejected
- Issue Never Addressed

Learned Intermediary Doctrine: West Virginia

- The Supreme Court of Appeals of West Virginia wholesale rejected the learned intermediary doctrine. *State ex rel. Johnson & Johnson v. Karl*, 647 S.E.2d 899 (2007).
- The *Karl* court found that DTC advertising had impacted the physician patient relationship. *Karl*, 647 S.E.2d at 907, 909.
- However, the court did not limit its rejection of the learned intermediary doctrine to only cases involving DTC advertising it outright rejected the learned doctrine. *Id.* at 901, 913.

Learned Intermediary Doctrine: New Mexico

- The United States District Court for the District of New Mexico became the second court to wholly reject the doctrine. *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1214 (D. N.M. 2008).
- The court did so in spite of the fact that the Court of Appeals of New Mexico repeatedly applied the learned intermediary doctrine in the 1970s and 1980s.
- The court reasoned that massive DTC advertising, coupled with the fact that patients now routinely "self-diagnose" themselves via Internet research and then request specific prescriptions from their physicians based on such self-diagnoses, would convince the Supreme Court of New Mexico that the learned intermediary doctrine is outdated. *Id*. at 1218; *id*. at 1222 .

Learned Intermediary Doctrine: New Mexico

- "The Court believes that the Supreme Court of New Mexico, given the opportunity in 2008, would not adopt the learned-intermediary doctrine, because of the erosion of the justifications for adoption of the doctrine, given the changing dynamics between doctors and patients, patients' self-diagnosis, and DTC advertising by drug manufacturers.“
- However, both the federal courts and the New Mexico Court of Appeals continue to apply the learned intermediary doctrine. *See In re Trasylol Products Liability Litigation*, 2011 WL 2586218 (S.D. Fla. June 23, 2011) (applying New Mexico law); *Silva v. SmithKlineBecham Corp.*, No 31,276, (N.M. App. Feb. 7, 2013).

Learned Intermediary: Wisconsin

- In *Maynard v. Abbott Laboratories*, No. 12-C-0939, 2013 WL 695817 * 4 (E.D. Wisc. Feb. 26, 2013), the Eastern District of Wisconsin opined without precedential support that the learned intermediary doctrine did not apply in Wisconsin.
- It is suspected that this statement was derived from a single opinion from the United States District Court for the Eastern District of Wisconsin in which the Court declined to apply the learned intermediary doctrine because "[t]he Wisconsin Supreme Court has never determined whether the doctrine applies to drug manufacturers in Wisconsin and no lower Wisconsin Court has adopted it." *See Forst v. SmithKline Beecham Corp*., 602 F. Supp. 2d 960, 968 (E.D. Wisc. 2009).

Learned Intermediary Doctrine: Wisconsin

- The *Maynard* decision, however, ignored the fact that multiple Wisconsin state trial court, appellate decisions and other federal district court decisions had previously applied the doctrine to cases governed by Wisconsin law.
- *See, e.g., Straub v. Berg*, 2003 WL 26468454, *7 (Wis. Cir. Jan. 6, 2003) (Granting summary judgment on the basis of the "learned intermediary doctrine defense.") *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, *20 (E.D. Wis., May 12, 1999); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 829-30 (N.D. Ind. 1999) (applying Wisconsin law).

Learned Intermediary Doctrine: Texas

- The Court of Appeals of Texas in Corpus Christi ruled that the learned intermediary doctrine did not apply where the drug manufacturer produced an informational video for patients to be distributed via physicians, and the video did not mention the side effect at issue. *Centocor, Inc. v. Hamilton*, 2010 WL 744212.
- However, the Texas Supreme Court overturned this decision and endorsed the learned intermediary doctrine in the context of prescription drugs, holding that:

  > "The learned intermediary is best suited to weigh the patient's individual needs in conjunction with the risks and benefits of the prescription drug."

  Centocor Inc. v. Hamilton, 372 S.W.3d 140 (2012).

What Happens When Learned Intermediary Doctrine Does Not Apply?

- Default to state law on duty to warn.
- Manufacturer has a duty to provide an adequate warning to the patient, not to her doctors.
- Still have to prove causation.
- Need to explore patient's general understanding and tolerance of risk, as well as her understanding and tolerance of risks of the specific product.

Exceptions to the Learned Intermediary Doctrine

Direct to Consumer Advertising: Effect on the Learned Intermediary Doctrine

- In *Perez v. Wyeth Labs*, 161 N.J. 1, 24 (1999), the New Jersey Supreme Court created an exception to the learned intermediary doctrine where a manufacturer engages in DTC (direct to consumer) advertising,
- Exception was created only for advertising ***that influenced the plaintiff's decision*** to take the medicine.
    - "The issue on remand will be whether, on summary judgment motion there is sufficient evidence for a reasonable jury to determine…that the absence of information or presence of misleading information in Norplant advertising was in violation of FDA requirements." (*Id*. at 26.)

Direct to Consumer (“DTC”) Advertising

- The physician's role in deciding which prescription drug is selected has been altered.
- With the arrival of direct-to-consumer advertising, patients now enter physicians' offices with preconceived expectations about treatment because of information obtained from DTC advertisements.
- That physicians "are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised" and that "physicians may relent to patient pressure, even if it is not in the best interest of the patient." *Perez*.

Direct to Consumer ("DTC") Advertising

- The Supreme Court was clear that in proving proximate causation, a plaintiff must establish that an advertisement violated FDA requirements, **and** that such advertisement was a substantial factor in bringing about the harm suffered. *Id*. at 26.
  - *Appleby v. Glaxo Wellcome, Inc*., No. Civ. 04-0062 (RBK), 2005 WL 3440440, *4-5, fn. 5 (D.N.J. December 13, 2005) ("it is clear that a plaintiff who has never seen any advertising cannot be harmed by flaws in the advertising");
  - *In Re Meridia Products Liability Litig*., 328 F.Supp.2d 791, 812, fn. 19 (N.D. Ohio 2004) "Plaintiffs have provided no reason to believe that defendants violated the FDA's rules and regulations. Therefore even applying *Perez* get the Plaintiffs nowhere.");
  - *New Jersey Citizen Action v. Schering-Plough Corp*., 367 N.J. Super. 8, 15-16 (App. Div. 2003) (rejecting a "fraud on the market" theory of reliance under the New Jersey Consumer Fraud Act in a case alleging fraudulent DTC advertising of prescription drugs).

Direct to Consumer "DTC" Advertising

- The nature of the alleged advertising can be dispositive of the application of the Perez exception. *Banner v. Hoffmann-La Roche Inc.*, 383 N.J. Super 364, 376 (App. Div. 2006).
- *Banner* involved acne medication called Accutane and Roche had supplied doctors' offices with brochures and had placed "non-branded ads" in magazines. *Id*. at 376.
- The court held: "the placement of informational brochures in a physician's office cannot be fairly 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.
- Our conclusion in this regard is bolstered by 21 C.F.R. §01.1(k)2(2), which does not treat such materials as advertising, but as labeling." *Id*. at 376.

DTC Exception: Other States

- Approximately eight years after *Perez*, a federal court in Florida noted that "[s]ince *Perez* was decided, no court – including any Florida court – has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception." *Beale v. Biomet, Inc*., 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007).
- New Jersey remains the only state where the DTC exception has been recognized and applied.

DTC Exceptions: Practice Tips

- Counsel should determine whether the plaintiff ever saw DTC advertising for the drug in question. *De Oca v. Adventis Pharma*, 579 F. Supp. 2d 222, 228-30 (D.P.R. 2008) (refusing to adopt *Perez* because there was no evidence that plaintiff saw DTC advertisements).
- If the plaintiff saw DTC advertising for the drug in question, counsel should determine whether such DTC advertising prompted the plaintiff to ask his doctor for a prescription for that medication, or whether it was his doctor who initiated the conversation about the medication.

DTC Exception: Practice Tips

- Counsel should ask the physician whether she weighs the risks and benefits of a drug before prescribing that drug to a patient.
- Counsel should then ask her whether she routinely discusses the side effects of drugs with her patients. Establish that she would not simply prescribe a medication to a patient because the patient asks for the medication.

Effect of Direct to Patient Warnings

- Even where a manufacturer owes a duty to warn a consumer directly of the risks of a product, a manufacturer cannot be held liable for breaching that duty if a warning would not have dissuaded the consumer from using the product.
- *In re Zyprexa Products Liability Litigation*, 2009 WL 1514628, *12 (E.D.N.Y. June 1, 2009) (granting summary judgment to prescription drug manufacturer in case governed by West Virginia law because plaintiff testified that he never read any of defendant's warnings);
- *Bushong v. Garman Co.*, 843 S.W.2d 807, 811 (Ark. 1992) (defendant was entitled to summary judgment where plaintiff admitted that he never read warning labels).

DTC: Texas

- Last year, the Texas Supreme Court overturned an intermediary appellate court ruling that applied a direct-to-consumer advertising exception to the learned intermediary doctrine. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 142-43 (Tex. 2012)
- "Patients who seek prescription drugs based solely on DTC advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient." *Id.*
- Thus, the fundamental rational for the learned intermediary doctrine remains the same.

DTC: Other States

However, there were signs that some courts outside of New Jersey agreed that DTC advertising warranted a rejection of the learned intermediary doctrine.

- *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770-72 (Ky. 2004) (Wintersheimer, J., dissenting) (three of the seven members of the Supreme Court of Kentucky (including the Chief Justice) citing Perez and urging rejection of learned intermediary doctrine);
- *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (stating in dicta that prescription drugs are no longer marketed primarily to "sophisticated and discerning intermediaries" and that the "new drug-marketing environment calls out for enhanced consumer protection").

Direct to Patient Warnings

- Plaintiffs may argue that 21 C.F.R. §310.515 (which requires estrogen-containing medications to contain a "patient package insert") also creates an independent duty under New Jersey law to warn patients directly.
- No New Jersey court has held that 21 C.F.R. §310.515, or any other federal regulation requiring a patient package insert, creates such a duty or abrogates the learned intermediary doctrine.
- The only state to adopt this position is Massachusetts. *See MacDonald v. Ortho*, 475 N.E.2d 65 (1985).

Direct to Patient Warnings

- *Banner v. Hoffmann La-Roche Inc.*, 891 N.J. Ad. 1229 (N.J. App. Div. 2006)
- Informational patient brochures given to physicians to make available to patients are not DTC advertising.
- 21 C.F.R. sec. 202.1(1)(2)) designates such materials as labeling, not advertising.
- The FDA has classified medication guides and informed consent materials similarly and these materials are not advertising.

Physician Compensation

- In *Murthy v. Abbott Laboratories*, 847 F. Supp. 2d 958 (S.D. Tex. 2012), involving the manufacturer's (not a physician's) duty to warn, the court held that compensation of a prescribing physician for his participation in the clinical trial created an exception to the learned intermediary rule.

  > [W]hen a physician is compensated by a drug company, some of the assumptions underlying the learned intermediary doctrine no longer hold. The doctrine is premised on the notion that the physician is an objective intermediary who will draw an independent judgment about the best course of treatment for his or her patient. . . . [W]hen a physician receives compensation or gifts from drug companies, his or her role as the neutral decision-maker is diminished. As such, dismissal of [plaintiff's] failure to warn claim on learned intermediary grounds would not be appropriate at this time.

Physician Compensation

This holding is contrary to prior precedent, which had yet to find any financial involvement that so compromised physician independence as to vitiate the learned intermediary rule.

- *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 569 N.E.2d 875, 879 (Ohio 1991) (per patient payments to study participants did not oust the rule);
- *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 163-64 (4th Cir. 1999) (prescriber being a paid consultant for defendant did not oust rule) (applying Virginia law);
- *In re Trasylol Products Liability Litigation*, 2011 WL 2117257, at *4 (S.D. Fla. May 23, 2011) (same) (applying Alabama law);
- *In re Zyprexa Products Liability Litigation*, 2010 WL 348276, at *11 (E.D.N.Y. Jan. 22, 2010) (prescriber making hundreds of thousands of dollars while "conduct[ing] paid research for at least ten pharmaceutical companies, including defendant," and "serv[ing] as a paid speaker for at least six pharmaceutical companies, including [defendant]" did not oust rule) (applying Illinois law) ;
- *Little v. Depuy Motech, Inc.*, 2000 WL 1519962, at *9 (S.D. Cal. June 13, 2000) (participation in clinical trial did not oust rule);
- *In re Vioxx Cases*, 2006 WL 6305292 (Cal. Super. Dec. 19, 2006) ("[p]ayment to a physician, standing alone, does not deprive the physician of learned intermediary status");
- *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334, at *20, 24 (Tex. Dist. June 7, 19990 (prescriber being a paid speaker for defendant did not oust rule).

Recent Learned Intermediary Decisions

Siefried v. The Hygenic Corporation

- Texas Court of Appeals decision – August 2013
- Extends learned intermediary doctrine to a physical therapist using a medical device.
- Court found that:
  - Physical therapists are experienced in treating and caring for patients, are trained in and familiar with the use of resistance bands used for physical therapy, and supervise and monitor the patients as they use the bands.
  - Therefore, a physical therapist designing and supervising the physical therapy regimen can pass on applicable product warnings to the patient, based on the patient's physical condition and particular needs.

Falsberg v. GlaxoSmithKline, PLC

- Washington Appellate Court – September 2013
- Rejected plaintiffs' attempt to expand the duty to warn under the learned intermediary doctrine to "warn every health care provider" rather than the prescribing physician only.
- Concluded that "strong policy considerations support Washington's focus upon the prescribing physician in applying the learned intermediary doctrine."
- "Our Supreme Court has emphasized that in examining the nature of the relationship between a drug manufacturer, a prescribing physician and a patient, the prescribing physician plays a unique and important role."

Morgan v. Smithkline Beecham Corp.

- *In re AvandiaLitig.*, MDL 1871 applying Pennslyvania law
- Plaintiff brought a purported class action seeking a refund of what he spent on Avandia alleging that defendant violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL").
- Court dismissed the claim because plaintiff failed to allege any facts that would get him around the learned intermediary doctrine. The court also refused to recognize a direct-to-consumer exception to the learned intermediary doctrine.
- "The existence of the learned intermediary doctrine in Pennsylvania makes it difficult, if not impossible, for plaintiffs to successfully bring a UTPCPL claim based on a prescription drug."

Patteson v. AstraZeneca LP

- District Court of D.C. – July 2012
- Rejected plaintiffs' theory that the learned intermediary doctrine does not apply where the drug was "overpromoted" by the manufacturer
- Court did not adopt the overpromotion theory but instead concluded that, even if such an exception existed, it would not apply here.
- The overpromotion exception requires "individualized proof that such overpromotion caused the physician to initiate or maintain the prescription at issue."
- "Repeated visits by sales representatives to a physician regarding the pharmaceutical drug alone do not constitute overpromotion."

DiBartolo v. Abbott Labs

- Southern District of New York - December 2012
- Under New York law, learned intermediary doctrine is not an affirmative defense but rather defines the scope of the duty to warn.
- There is no DTC exception under New York law:
  - "The physician therefore remains an "informed intermediary" to whom manufacturers should direct prescription drug warnings. Indeed, although it may be true that DTC advertising encourages patients to ask specifically for the advertised drug, a physician who prescribed a drug to a patient simply based on the patient's request, without an individualized medical assessment, would likely be liable for malpractice. In such a situation, a failure-to-warn claim against the manufacturer would raise a serious issue of causation." 2012 WL 6681704, at *9.

DiBartolo v. Abbott Labs *(con't)*

- Also rejected the physician compensation exception under New York law.
- This exception is not part of a trend supporting an exception to the rule when drug manufacturers compensate physicians.
- According to the Court (1) "Such [compensated] physicians would not be absolved of their duty to prescribe drugs to patients only when medically appropriate." *Id.* at *10 n.6. (2) "It is not clear . . . that manufacturer-compensated physicians would in fact neglect their professional duties to an extent that would undermine " the learned intermediary rule. *Id.*

Baymiller v. Ranbaxy Pharma., Inc.

- District of Nevada – July 2012
- Court rejected claims against pharmacists on the basis of the learned intermediary doctrine.
- Relied on *Klasch v. Walgreen Co., 264 P.3d 1155 (Nev. 2011)*, where the Nevada Supreme Court adopted the learned-intermediary doctrine in the context of pharmacist/customer tort litigation and held that pharmacists have no duty to warn of a prescribed medication's generalized risks inherent in the prescriptions they fill.
- This doctrine "prevents pharmacists from constantly second-guessing a prescribing doctor's judgment simply in order to avoid his or her own liability to the customer." However, when a pharmacist has knowledge of a customer-specific risk, the pharmacist has a duty to exercise reasonable care in warning the customer or notifying the prescribing doctor of the customer-specific risk.
- This is the position taken by most states that have considered the issue.

Miller v. Ortho-McNeil Pharmaceutical, Inc.

- November 2013
- Northern District of Ohio – applying Mississippi law
- Granted summary judgment on 2 grounds:
  - Risk of blood clots associated with product were set forth in product warnings and prescriber testified that she was aware of the risk
  - Lack of causation – plaintiff did not show that a different warning would have changed the prescribing decision.
- Court found warnings adequate as a matter of law because they warned the prescriber specifically of the risk of blood clots.

Hanhan v. Johnson & Johnson

- November 2013
- Northern District of Ohio – applying California law
- Plaintiff argued that learned intermediary doctrine did not apply in hormonal contraceptive case because “physicians passively allow patients to make most birth control decisions.”
- Court held that California law does not recognize such an exception.
- Also rejected argument that learned intermediary doctrine did not apply because federal regulations require a specific patient package insert for the drug.

Carnes v. Eli Lilly & Co.

- December 2013
- District of South Carolina
- Court ruled that under the learned intermediary doctrine, it is the plaintiff's burden to demonstrate that the additional, non-disclosed risk was sufficiently high that it **would have changed the treating physician's decision to prescribe the product for the plaintiff.**
- Rejected plaintiff's argument that certain study results should have been disclosed in the label where the prescriber testified that even if provided with this information, he still would have prescribed the drug.

Luttrell v. Novartis Pharmaceutical Corp.

- Ninth Circuit – Feb. 2014, applying Washington law
- Affirmed summary judgment on basis of the learned intermediary doctrine.
- "the learned intermediary doctrine requires a showing that the prescribing physician, not the patient, would have taken a different course of action if better warnings had been issued"
- Plaintiff's contention that his doctor would have taken a different course of action was belied by the record showing that "the doctor understood the connection between bisphosphonates and the risk of [ONJ], and that in his medical opinion the benefits of the treatment for the patient outweighed those risks."

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