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Texas Supreme Court Rejects Direct-to-Consumer Advertising Exception to the Learned Intermediary Doctrine

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For decades, courts have applied the learned intermediary doctrine, under which a prescription drug or device manufacturer is absolved of any duty to warn the end-user—the patient—if the manufacturer adequately warns the patient's physician. Recently, a minority of courts have rolled back this protection, based on their perception of how the practice of medicine has changed. But on June 8, 2012, the Texas Supreme Court rejected the reasoning of these courts and adopted the learned intermediary rule *in total*. The Court confirmed, for the first time, that the learned intermediary doctrine applies to prescription drugs and held "that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly." *Centocor, Inc. v. Hamilton*, No. 10-0223, 55 Tex. Sup. Ct. J. 774 (Tex. June 8, 2012). The court rejected recent decisions criticizing the doctrine and unanimously held that the court of appeals erred in recognizing a direct-to-consumer ("DTC") advertising exception to the doctrine, reversing and rendering judgment for the prescription drug manufacturer.

I. The Learned Intermediary Doctrine and the DTC Advertising Exception

The learned intermediary doctrine limits a prescription drug manufacturer's duty to warn to an obligation to advise the prescribing physician—who acts as a "learned intermediary"—of any potential dangers that may result from the drug's use. There are several exceptions to the doctrine—one of the most recent (and most talked about) is the DTC advertising exception. The first state to allow such an exception was New Jersey in the 1999 decision in *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999).

In *Perez*, the court held that the learned intermediary doctrine does not apply when a manufacturer markets directly to the

consumer because "[t]he direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product." The court relied heavily on the argument that the learned intermediary doctrine "is based on images of health care that no longer exist." Specifically, the court found that "managed care has reduced the time allotted per patient," and that drug manufacturers have an effective means to communicate directly with patients (i.e., DTC advertising).

Although legal commentators speculated that *Perez* signaled an end to the learned intermediary doctrine, for eight years no other court accepted the DTC advertising exception. But in 2007 the Supreme Court of Appeals of West Virginia adopted the *Perez* decision's logic and rejected the learned intermediary doctrine in its entirety. *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 906-07 (W. Va. 2007). Ultimately, the *Karl* court—like the *Perez* court—found the traditional justifications for the doctrine to be outdated and unpersuasive, relying in large part on the growing prevalence of DTC advertising. But rather than follow *Perez* by adopting a DTC advertising exception, the West Virginia court rejected the application of the learned intermediary doctrine completely, believing there was no benefit in adopting a doctrine along with numerous exceptions so that the doctrine can be justly utilized. *See also Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1214-24 (D.N.M. 2008) (relying on *Karl* and predicting that the New Mexico Supreme Court would decline to adopt the learned intermediary doctrine, despite intermediate appellate court decisions adopting the doctrine).

Although the impact of *Perez* and *Karl* have been limited, the reasoning of these courts is exactly what persuaded a Texas intermediate court of appeals to create a DTC advertising exception to the learned intermediary doctrine in *Centocor*.

II. The Texas Supreme Court Rejects the DTC Advertising Exception

In *Centocor*, Patricia Hamilton and her husband sued drug manufacturer Centocor, Inc., alleging that Ms. Hamilton developed a lupus-like syndrome from her use of the prescription drug Remicade. Remicade's package insert warned that one of its risks was the development of a lupus-like syndrome. Because Remicade is administered intravenously, Hamilton was referred to an infusion clinic to receive the infusions. While receiving the first infusion, Hamilton watched a video produced by Centocor that discussed Remicade's benefits. Hamilton alleged that the video over-emphasized the benefits and intentionally omitted a warning about a lupus-like syndrome. At trial, the jury found Centocor liable, and the trial court entered judgment against Centocor and awarded approximately $4.8 million in actual and punitive damages to Hamilton and her husband.

On appeal, Centocor argued that the learned intermediary doctrine precluded the Hamiltons' claims. Centocor asserted that because it had adequately warned Hamilton's physicians of the risk of developing a lupus-like syndrome, it had no duty to warn Hamilton directly. The Corpus Christi

Court of Appeals (relying heavily on *Perez* and *Karl*) disagreed, recognizing for the first time in Texas a DTC advertising exception to the learned intermediary doctrine. *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 481 (Tex. App.—Corpus Christi 2010).

The Supreme Court of Texas reversed and rendered judgment for Centocor based on the learned intermediary doctrine. Although the Court had never addressed whether the learned intermediary doctrine applies in the prescription drug context, the Court joined the majority of other jurisdictions by confirming that "a prescription drug manufacturer fulfills its duty to warn its product's end users by providing an adequate warning to the prescribing physician." The Court then held that the court of appeals erred in recognizing the DTC advertising exception. Because Centocor had warned Hamilton's doctors regarding the potential side-effect of a lupus-like syndrome, and Hamilton had already consulted with her prescribing physician and decided to take the drug before she saw the video at issue, the Court held that there was no reason to adopt the exception in this case.

While the Court limited its decision to the facts of the case, its reasoning suggests that it would not recognize a DTC advertising exception even under different facts. The Court noted that despite the fact that DTC advertising has increased since the adoption of the learned intermediary doctrine, "the fundamental rationale for the doctrine remains the same: prescription drugs require a doctor's prescription and, therefore, doctors are best suited to communicate the risks and benefits of prescription medications for particular patients through their face-to-face interactions with those patients." Moreover, both federal and Texas law regulate the design, marketing, and distribution of prescription drugs, and the Court observed that this regulation protects the public from harmful products and misleading advertising.

After concluding that there was no exception to the learned intermediary doctrine in this case, the Court then determined that each of the Hamiltons' claims rested on Centocor's alleged failure to provide an adequate warning, that the doctrine applied to all the claims, and that a plaintiff cannot plead around the basic requirements of a failure-to-warn claim. The Court further held that the learned intermediary doctrine is not an affirmative defense, explaining that "[w]hile the learned intermediary doctrine shifts the manufacturer's duty to warn the end user to the intermediary, it does not shift the plaintiff's basic burden of proof."

III. The Future of the Learned Intermediary Doctrine

The Texas Supreme Court's decision in *Centocor* joins other recent decisions refusing to adopt the reasoning of *Perez* and *Karl* and reaffirming that the learned intermediary doctrine continues to be the prevailing rule in the vast majority of jurisdictions. Since the *Karl* decision, courts in Maryland, Florida, Wyoming, Puerto Rico, Georgia, Colorado, Oklahoma, Montana, and Washington D.C. (to name a few) have also reaffirmed their application of the learned intermediary doctrine. *See Gourdine v. Crews*, 935 A.2d

1146, 1150 (Md. Ct. of Special Appeals 2007); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376-77 (S.D. Fla. 2007); *Rohde v. Smiths Med.*, 165 P.3d 433, 436 (Wyo. 2007); *Mendez Montes de Oca v. Aventis Pharma*, 579 F. Supp. 2d 222, 229 (D. P.R. 2008); *Dietz v. SmithKline Beacham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010); *O'Connell v. Biomet, Inc.*, 250 P.3d 1278 (Colo. Ct. App. 2010); *Tortorelli v. Mercy Health Ctr.*, 242 P.3d 549 (Okla. Ct. Civ. App. 2010); *Stevens v. Novartis Pharms. Corp.*, 247 P.3d 244 (Mont. 2010); *Patteson v. AstraZeneca, LP*, No. 10-1760 (JEB), -- F. Supp. 2d ---, 2012 WL 2827640 (D.D.C. July 9, 2012); *see also In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2011 WL 2516333, at *1 (E.D.N.Y. June 23, 2011) (granting summary judgment based on the learned intermediary doctrine under the law of Pennsylvania, California, Missouri, Florida, Michigan, Arkansas, Virginia, Arizona, Illinois, Louisiana, Minnesota, North Carolina, and Mississippi).

With *Centocor*, these decisions confirm that the learned intermediary doctrine is still the majority rule. The fact remains that regardless of DTC advertising, the physician must still prescribe a drug and still plays an integral role in the patient's use of the drug or device. Any concerns regarding the changes in the medical profession are an insufficient reason to reject the learned intermediary doctrine. Accordingly, in a majority of jurisdictions a prescription drug or device manufacturer fulfills its duty to warn by providing adequate warnings to the intermediaries who prescribe the product.

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