Texas Supreme Court Adopts "Learned Intermediary Doctrine"

Court Holds Facts of Case Did Not Justify Creating Exception Based on "Direct-to-Consumer" Advertising

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Under the learned intermediary doctrine, the manufacturer of a pharmaceutical product satisfies its duty to warn the end user (i.e., the patient) of its product's potential risks by providing an adequate warning to a "learned intermediary" (i.e., the doctor) who then assumes the duty to pass on the necessary warnings to the end user. The Texas Supreme Court has just held that the doctrine generally applies within the context of a physician-patient relationship and allows a prescription drug manufacturer to fulfill its duty to warn end users of its product's potential risks by providing an adequate warning to the prescribing physician.

In *Centocor, Inc. v. Hamilton, No. 10–0223* (June 8, 2012), Patricia and her husband sued Centaocor, the manufacturer of the drug Remicade. The plaintiffs filed a pharmaceutical liability lawsuit that claimed the drug manufacturer failed to adequately warn about the risk of developing a lupus-like syndrome as a side effect. In particular, the plaintiffs alleged that the drug manufacturer distributed a video program for consumers/patients about the drug that misrepresented the drug's benefits and risks.

First, the Texas Supreme Court held that the learned intermediary doctrine applies in general to situations such as Patricia's given that she was prescribed and acquired the drug in the context of a physician/patient relationship. Thus, the drug manufacturer owed no duty to provide warnings directly to Patricia and, instead, could satisfy its duty by providing adequate warnings to her doctors. Then, the court found that, even assuming Centocor's warning to those prescribing physicians was inadequate, the plaintiffs still failed to prove that any inadequate warning was the producing cause of Patricia's injuries. It was undisputed that all of Patricia's medical providers were in fact aware that Patricia could potentially develop lupus-like syndrome as a side effect of Remicade. The court determined that the plaintiffs presented no evidence that Patricia's prescribing physicians or even Patricia would have acted differently had Centocor provided a different warning that included additional information about lupus-like syndrome. In short, the evidence suggested the doctors would have prescribed it anyway.

Direct-to-Consumer Advertising

Along the way, the Texas Supreme Court also considered whether any exception to the learned intermediary doctrine applied to the facts. The court of appeals had agreed with the plaintiffs that there should be an exception when the drug manufacturer chooses to market its drug directly to the consumer.

In the course of her prescribed Remicade treatments, Patricia's treating physician showed her an informational video that he had received from Centocor. The plaintiffs alleged that Centocor's video over-emphasized the benefits of Remicade and intentionally omitted warnings about the potential side effect of lupus-like syndrome. The plaintiffs urged the court to adopt an exception to the learned

intermediary doctrine based on direct-to-consumer advertising and thus affirm the court of appeals' judgment because when a drug manufacturer directly markets its product to patients, that manufacturer should have a duty, at minimum, to present non-misleading information about the drug and must be liable for its fraudulent or intentionally misleading marketing. The court refused to apply such an exception: "[w]e acknowledge that some situations may require exceptions to the learned intermediary doctrine, but without deciding whether Texas law should recognize a DTC advertising exception when a prescription drug manufacturer distributes intentionally misleading information directly to patients or prospective patients, we hold that, based on the facts of this case, no exception applies."

The court found that the alleged harm was not caused by Centocor's direct advertising to Patricia. For example, Patricia did not claim that direct advertising prompted her to request Remicade from her doctors. Instead, her claims were based on the video—but she viewed the video only after her doctor had prescribed Remicade and after the infusion process had begun. The court found that "[o]n this record, the rationale for adopting a DTC advertising exception to the learned intermediary doctrine is simply non-existent." As a result, the court found "no reason to adopt an exception where the physician-patient relationship existed, the pharmaceutical company provided a warning to the patient's prescribing doctors that included the side effect of which the patient complains, and the patient had already visited with her prescribing physician and decided to take the drug before she saw the informational video at issue."

The court's opinion does acknowledge that drug manufacturers have dramatically increased their direct-to-consumer advertising and at least leaves open the possibility of applying a direct-to-consumer exception under the right circumstances.

The full opinion can be read here:
http://www.supreme.courts.state.tx.us/historical/2012/jun/100223.pdf