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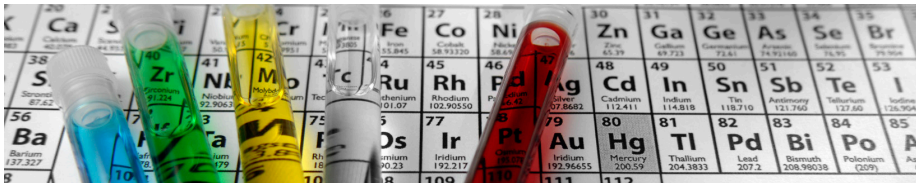
DRUG & DEVICE BULLETIN



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Shook, Hardy & Bacon has successfully defended pharmaceutical and medical device manufacturers in products liability and other high-stakes litigation for over 35 years. Today, SHB represents more than 30 pharmaceutical and medical device parent companies and their subsidiaries in products liability, antitrust, employment, environmental, commercial, and intellectual property litigation. With more than 100 attorneys dedicated to the unique needs and challenges of this industry, SHB has cultivated a reputation for dynamic, cost-effective solutions built on decades of experience.

For additional information on SHB's Pharmaceutical & Medical Device Litigation capabilities, please contact

Gene Williams
Partner
713-227-8008
gmwillians@shb.com

Madeleine McDonough
Division Chair
816-559-2842
202-639-5600
mmcdonough@shb.com

LANDMARK TEXAS SUPREME COURT DECISION: LEARNED INTERMEDIARY DOCTRINE APPLIES IN PRESCRIPTION DRUG CASES, NO DTC EXCEPTION

Addressing the issue squarely for the first time, the Texas Supreme Court has unanimously adopted the learned intermediary doctrine in the prescription drug context thereby confirming that manufacturers are only obligated to warn doctors of the risks of prescription medicines. The Court further ruled that the Court of Appeals erred by adopting an exception to the doctrine for direct-to-consumer advertising. The Texas Supreme Court thus ordered that the plaintiffs, who were awarded damages for injuries allegedly caused by a prescription drug, take nothing because they failed to prove that a different warning to the doctors would have prevented their injuries. ***Centocor, Inc. v. Hamilton*, No. 10-0223, 2012 WL 2052783 (Tex. June 8, 2012)**.

Shook, Hardy & Bacon attorneys **Gene Williams**, **Manuel López**, and **Kathleen Frazier** tried the case in 2006 with John Winter from Patterson Belknap Webb & Tyler LLP. Williams and López worked with Robert M. 'Randy' Roach Jr. and his team from the firm of Roach & Newton, L.L.P. to successfully represent Centocor on appeal.

How the Issues Teed Up

Plaintiff Patricia Hamilton presented with a flare of Crohn's disease, which she had battled her entire adult life. Crohn's disease is an autoimmune condition in which the immune system attacks the digestive system. If left uncontrolled, a "flare" of Crohn's disease often requires surgery to remove part of the affected bowels. From previous bouts with the disease, Hamilton had lost much of her bowels to surgery. To treat the flare, Hamilton's physician prescribed Remicade, which is available with a prescription only. Within weeks, the flare disappeared and never returned.

Hamilton then complained about a temporary side-effect that allegedly first manifested weeks later. This purported side-effect, called "lupus-like syndrome," can cause joint pain and other symptoms that mimic lupus. The treatment is merely for the physician to discontinue the Remicade, which completely cures the problem.

In this case, however, another physician continued to prescribe Remicade for years because it also gave Hamilton tremendous relief from her arthritis symptoms.

Centocor's defense focused on its warnings to Hamilton's physicians. The package insert plainly warned all of the physicians about this lupus-like syndrome. The insert also told the physicians how to cure it. Thus, if the learned intermediary doctrine, which has been part of the state's jurisprudence since 1973, had applied, the Court should have found that Centocor fully discharged its duties under the law. Still, the Court of Appeals circumvented the learned intermediary doctrine because one of Hamilton's physicians had played a videotape about Remicade for her at his office (while she was already receiving the first treatment).

According to the Court of Appeals, the video should have directly warned Hamilton about lupus-like syndrome—even though that side-effect was temporary and fully curable. Because of the video, the Court of Appeals held that Centocor's warnings to the physicians were irrelevant.

How the Supreme Court Handled the Issues

The Supreme Court described the consistent use of the learned intermediary doctrine in Texas by the intermediate courts in the prescription drug context and provided a comprehensive overview of its adoption by other state courts. Given that prescription drugs are "complex medicines, esoteric in formula and varied in effect," the Supreme Court was persuaded that those courts were correct and observed in this regard:

> Because patients can obtain prescription drugs only through their prescribing physician or another authorized intermediary and because the "learned intermediary" is best suited to weigh the patient's individual needs in conjunction with the risks and benefits of the prescription drug, we are in agreement with the overwhelming majority of other courts that have considered the learned intermediary doctrine and hold that, within the physician-patient relationship, the learned intermediary doctrine applies and generally limits the drug manufacturer's duty to warn to the prescribing physician.

The Supreme Court then considered how prescription-drug marketing has changed since the doctrine was first recognized 45 years ago, noting that "some courts and commentators, including the *Restatement*, have recognized limited exceptions to the learned intermediary doctrine." Among those exceptions, adopted by just a few courts, is one applicable when a drug manufacturer directly markets to the consumer.

Highlighting the "sweeping departure from the learned intermediary doctrine" adopted by the New Jersey Supreme Court, which had found that direct-to-consumer ads belie "each of the premises on which the learned intermediary

doctrine rests," the Texas high court noted that few other courts have found its reasoning sound. Cautioning that pharmaceutical manufacturers must be prohibited from "disseminating grossly misleading advertising" and acknowledging that "some situations may require exceptions" to the doctrine, the Court held that no exception applied based on the facts in this case.

Other Issues the Court Addressed

The Texas Supreme Court also held that the learned intermediary doctrine "is more akin to a common-law rule rather than an affirmative defense," thus confirming that plaintiffs retain the burden to prove that the manufacturers' warnings to physicians were inadequate. The Court further determined that the doctrine applied to all of the plaintiffs' claims because each, including fraud by omission, was premised on the company's alleged failure to warn. Finally, the Court found that the plaintiffs failed to meet their burden to prove that "the allegedly inadequate warning was the producing cause of Patricia's purported injuries."