The learned intermediary doctrine and its effects on prescribing physicians

RUSSELL G. THORNTON, JD

Over the past 13 years, one constant in the field of health care liability claims has been litigation over medical devices and products. The 1990s began with the silicone gel breast implant litigation. The balance of the 1990s was devoted to litigation on Norplant and the diet drug combination fenfluramine-phentermine (fen-phen); these cases are still ongoing. The new millennium has opened with litigation regarding the medications Propulsid, Rezulin, Vioxx, Celebrex, OxyContin, and Baycol. The Baycol litigation represents a trend where the pharmaceutical company seeks to deflect the criticism toward the prescribing physicians. The manufacturer that touted the efficacy, safety, and benefit of its medication now wants to have the public and legal community view the prescriber as the culprit. While there have been efforts at "tort reform" both federally and in numerous state legislatures—reform that includes some protections for pharmaceutical claims (e.g., HR 5 passed by the US House of Representatives in March 2003)—this legislation has not been passed by the US Senate. From a medicolegal standpoint, this litigation will likely be part of the health care liability claim landscape for some time.

One of the key facets to this litigation for prescribing physicians is the learned intermediary doctrine. This defense has been utilized by manufacturers in all of the pharmaceutical claims mentioned. The effect of this defense, if successful, is to shift the focus, and ultimate responsibility, for any failure to warn about the medication's risks from the manufacturer to the prescribing physician. This may move the prescribing physician from being a low-profile, minor defendant in these claims to being a primary target and possibly the sole target.

In product liability cases, Texas, like most other states, has adopted Section 402A of the Restatement (Second) of Torts (1). Under the Restatement, a manufacturer is liable for the products it sells if they are in "a defective condition unreasonably dangerous to the user or consumer" (2). A product is unreasonably dangerous if there is a defect in its design or marketing (3). A medication is defectively designed if the risks of harm associated with the medication's use outweigh its benefit (4). A medication is improperly marketed, a so-called "marketing defect claim," if the manufacturer did not provide proper instructions about how to use the medication or did not adequately warn about the medication's risks (4).

The learned intermediary doctrine is utilized by pharmaceutical manufacturers in response to marketing defect claims. In a marketing defect claim, the manufacturer is liable if 2 facts are established. First, the manufacturer failed to warn the prescribing physician adequately about the use and risks of the medication. Second, the inadequate warning produced or caused the claimant's injury, i.e., a "producing cause" (5). A producing cause is defined as "an efficient, exciting, or contributing cause that, in a natural sequence, produces the injury" (6). Because product liability claims are "strict" liability claims, the claimant does not have to show any negligent conduct by the manufacturer (1, 2).

While a manufacturer generally owes a duty to warn the user of the risks of its products, the manufacturer of prescription medications is not required to warn each patient who receives its medication. If the manufacturer warns the prescribing physician of the proper use and risks of its medication, its duty is discharged and it is excused from providing this information directly to each user (7). Further, if the prescribing physician is aware of the risks associated with the use of the medication, any failure to warn by the manufacturer cannot be a producing cause of the claimant's injury (4). These 2 principles form the basis of the learned intermediary doctrine.

Courts have determined that requiring the manufacturer to warn only the prescribing physician is a reasonable manner in which to handle prescription medications given that prescription medications are "complex medicines, esoteric in formula and varied in effect" and that the prescribing physician takes into account the unique situation of each patient, as well as the characteristics of potential medical treatments, and then exercises "an individualized medical judgment bottomed on a knowledge of both patient and palliative" to determine the proper treatment (8). It is reasonable to limit the manufacturer's responsibility to warn just the prescribing physician, as opposed to each individual patient, since the prescribing physician has an independent duty to warn the patient of the risks associated with treatment (9), and it is that individual who has knowledge of the risks and benefits of medication and can more readily and effectively convey these risks to the patient (10). Further, it is the prescribing physician who determines the suitability, type, and quantity of medication to be prescribed (11).

The mere fact that a prescribing physician was warned of the proper use and the risks and hazards of a prescription medication

From Stinnett, Thiebaud & Remington, LLP, Dallas, Texas.

Corresponding author: Russell G. Thornton, JD, Stinnett, Thiebaud & Remington, LLP, 4800 Fountain Place, 1445 Ross Avenue, Dallas, Texas 75202 (e-mail: rthornton@strlaw.net).

is not sufficient to shift potential liability from the manufacturer to the prescribing physician. For a warning from the manufacturer to the prescribing physician to discharge the manufacturer's duty to warn, the warning given must be adequate and not misleading (12). This is one of the primary areas of dispute between claimants, manufacturers, and prescribing physicians in pharmaceutical litigation.

The fact that the warning provided was inadequate or misleading, however, is not enough to shift the focus away from the prescribing physician and establish liability against a manufacturer. As already discussed, the failure to warn must be a producing cause of the claimant's injury. To determine whether the failure to warn was a producing cause of the claimant's injury, we look at whether the prescribing physician was aware of the risks associated with the use of the medication (4). The inquiry becomes, Would an adequate warning have altered the prescribing physician's decision to prescribe the medication? Obviously, if the prescribing physician was aware of the risks at issue and still prescribed the medication, an inadequate warning or a failure to warn the prescribing physician had no role in causing the claimant's injury from use of the medication.

For example, a patient claimed that the medication Sufenta was unreasonably dangerous because the manufacturer did not disclose in its advertising that the medication had a tendency to cause secondary respiratory depression or respiratory arrest. Since the physician who administered the medication was aware that patients receiving this medication needed to be closely observed for respiratory depression, and he utilized this medication being fully aware of this risk, any failure to warn about this risk by the manufacturer of Sufenta was not the cause of the patient's permanent damage (4). Similarly, the manufacturer of succinylcholine was sued for the death of a child from cardiac arrest secondary to hyperkalemia after the medication was administered in the course of intubating the patient. The claim was that the manufacturer failed to warn of the risk of hyperkalemia associated with use of succinylcholine. In his deposition, the physician who administered the succinylcholine testified that he knew that succinylcholine could cause hyperkalemia in certain patients. He did not know, however, that this patient had a medical history that placed him at risk for this occurrence. The court ruled that since the physician was aware of the risks associated with the use of succinylcholine, any failure to warn by the manufacturer did not cause the child's death (13).

As you can see, the nature or adequacy of the warning (liability issue) is very closely related to whether the absence of a proper warning caused the claimant's injury. For prescribing physicians to distance themselves from a dispute over a prescription medication, they must be able to show that a proper warning would have caused them to not prescribe the medical treatment at issue, to prescribe a different medication to treat the claimant's problem, or to monitor the patient differently if the same medication was prescribed and that this monitoring would have prevented the claimant's injury.

In recent prescription medication litigation, the focus has not been on whether a warning was given but on whether the warning given was inadequate or misleading. In the diet drug litigation, the focus was on the medication fenfluramine (Pondimin). There was no question that the manufacturer never warned physicians of the risk of potential heart valve damage associated with use of the medication. Thus, the manufacturer could not utilize the learned intermediary doctrine for claims that involved alleged heart valve damage from the medication. Pondimin, however, also had the potential to cause primary pulmonary hypertension (PPH). While the manufacturer did warn of the potential risk of PPH in the package insert, the issue was whether the warning was misleading. For most of the time that Pondimin was on the market, the package insert mentioned only that 4 cases of PPH had been reported in association with the use of Pondimin. This risk was about the same as the background rate for PPH in the general population. Because the manufacturer was aware that more than 4 cases of PPH were associated with the use of Pondimin, the contention was that the warning provided was inadequate and misleading. Prescribing physicians testified that if they had been aware of this information, combined with the risk of heart valve damage associated with Pondimin, they would not have prescribed the medication for their patients.

In the current Baycol litigation, the focus is primarily on the coprescription of Baycol and gemfibrozil for patients with severe cholesterol abnormalities and on the use of a higher strength of Baycol (0.8 mg, as opposed to 0.4 mg) as a starting dose. The issues here are the manufacturer's general safety disclosures about Baycol (it represented Baycol to be at least as safe as the other marketed statins) (14), whether the warning about the combination of Baycol with gemfibrozil was adequately or effectively communicated to prescribing physicians, and whether any warning was provided to prescribing physicians to not start patients on the higher dose.

With respect to the combination use issue, the facts indicate that Baycol was represented as having a more favorable drug-to-drug interaction profile than the other statins (14) and was indicated for patients who might need treatment with a combination of medications (15). There is evidence, however, that the contraindication with gemfibrozil, once it was discovered, was not effectively communicated to prescribing physicians, if at all (16).

With respect to the use of higher-dose Baycol, the evidence indicates that Baycol was represented as having no dose-related side effects (14) and as being suitable for higher-risk patients who needed additional cholesterol reduction (14). Further, evidence shows that Baycol was the most myotoxic of the marketed statins (17). Thus, evidence exists to show that the warnings provided were not adequate and that if the true facts were known about the medication's safety profile, prescribing physicians would have utilized one of the other 5 statins available when Baycol was marketed.

Prescription medications are an integral and necessary part of medical treatment and practice. We have learned from the pharmaceutical litigation that has been a part of the medical-legal landscape for the past 13 years that prescribing physicians will be included in these claims. We also know that a lot of money is at stake in the prescription medication market and that this market is very competitive. Sales representatives are very positive about their products and are going to place their products in the best light possible, especially in relation to the products of their competitors. On this backdrop, understand that manufacturers are becoming more aggressive in defending these

claims by trying to place the focus and blame for any problems on the prescribing physicians through use of the learned intermediary doctrine.

Accordingly, do not believe everything that you are told about a medication. We have learned from the diet drug and Baycol litigation that everything is not always what it appears to be. Before expressing opinions about the safety of a medication or what you would do retrospectively in one of these claims, be sure that you know all of the facts. While you may have a great deal of information in your hands, understand that there is always more to these situations than you know or could reasonably know. Exercise caution. In these claims, the attitude of the manufacturers appears to be, in the words of a client, "When the water rises, some head for high ground." You get left behind to stem the tide. Do not be left standing alone to defend a patient complaint about a prescription medication because you did not know all of the facts first, did not consider each patient's unique circumstances, and did not adequately discuss the risks and benefits of the medication with the patient. Lastly, documentation, as in most medicolegal cases, can mean the difference between success or loss. Document your discussions with the patient about the risks and benefits.

1. *McKisson v. Sales Affiliates, Inc.,* 416 S.W.2d 787, 792 (Tex. 1967).
2. Restatement (Second) of Torts, Section 402A (1965).
3. *Caterpillar, Inc. v. Shears,* 911 S.W.2d 379, 382 (Tex. 1995); *Joseph E. Seagram & Sons, Inc. v. McGuire,* 814 S.W.2d 385, 387 (Tex. 1991).
4. *Stewart v. Janssen Pharmaceutica, Inc.,* 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied).
5. *Merrill Dow Pharmaceuticals, Inc. v. Havner,* 907 S.W.2d 535, 539 (Tex. App.—Corpus Christi, writ granted), *rev'd o.g.,* 953 S.W.2d 706 (Tex. 1997).
6. Texas Pattern Jury Charges, Malpractice, Premises and Products (2000).
7. See *Alm v. Aluminum Co. of America,* 717 S.W.2d 588, 591 (Tex. 1986).
8. *Reyes v. Wyeth Lab.,* 498 F.2d 1264, 1276 (5th Cir. 1974).
9. See Section 6.01, article 4590i, et seq., *Texas Revised Civil Statutes Annotated* (Vernon's Supp. 2003).
10. See *Gravis v. Parke-Davis & Co.,* 502 S.W.2d 863, 870 (Tex. Civ. App.—Corpus Christi 1973, writ ref'd n.r.e.).
11. See *Rolen v. Burroughs Wellcome Co.,* 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied).
12. *Alm,* 717 S.W.2d at 591; *Bristol-Myers Co. v. Gonzales,* 561 S.W.2d 801, 804 (Tex. 1978); *Crocker v. Winthrop Lab.,* 514 S.W.2d 429, 433 (Tex. 1974).
13. *Boswell v. Burroughs Wellcome, Inc.,* 1997 WL 198746 (Tex. App.—Dallas 1997) (not designated for publication).
14. See Bayer Lipobay/Baycol core messages development (0.4 & 0.8 mg) strategy, May 5, 2000; Bayer Lipobay/Baycol product strategic plan, June 7, 1999.
15. See Bayer International Meeting Report, 3rd Opinion Leader Seminar, Treatment of Lipid Disorders, June 24–25, 1998, Aschau, Bavaria.
16. See Bayer e-mail from Patricia Stenger to Richard Goodstein, "What the reps from Bayer or SB are saying/doing," March 9, 2000; Tig Conger, Baycol senior management brand review, September 5, 2000.
17. Davidson MH. Controversy surrounding the safety of cerivastatin. *Expert Opinion on Drug Safety* 2002;1:207–212.