Defending claims related to prescribing drugs or using medical devices

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Review of health care liability claims since the early 1990s shows that without interruption there has been some form of mass tort litigation involving medical devices or products. The 1990s began with the breast implant litigation that is finally now in its last death throes. The breast implant litigation was succeeded by the pedicle screw litigation, which was followed quickly by a short course of claims that focused on the Norplant birth control device. This was followed by claims that involved the diet drugs fenfluramine (Pondimin), dexfenfluramine (Redux), and phentermine (so-called "fen-phen" cases). After more than 3 years, these claims seem to be finally winding down. Now we are dealing with recent multimillion dollar judgments rendered in connection with troglitazone (Rezulin) and cisapride (Propulsid). Earlier this year, cerivastatin sodium (Baycol) was pulled from the market. Given this history, it is not unreasonable to expect future claims over that medication. This history also tells us that there will be litigation related to medical devices and medications in the future.

Two common threads have run through all of these cases of mass medical product litigation. First, the health care providers involved in the utilization or prescription of these products were defendants and key players in these claims. Second, the manufacturers of these devices and products all made concerted efforts, at least early on, to place some, if not all, of the responsibility for any damages suffered by the patients at the feet of the involved health care providers. While the continued, determined efforts of the health care providers' defense counsel have been successful so far in protecting these providers from liability, this battle will be ongoing and a key part of any future litigation that involves medical products or devices, particularly pharmaceuticals. To better educate prescribers on these claims, their exposure in these situations, and the manufacturers' blame-shifting efforts, this article discusses a significant concern in this type of litigation, the "learned intermediary" doctrine.

The learned intermediary doctrine is the primary defense used by medical product and device manufacturers in medical device and product litigation. This doctrine is utilized not only to defend the claims asserted against the manufacturer by patients but also to shift blame for patients' injuries from the manufacturer to the health care provider who utilized or prescribed the product. In fact, it often appears that manufacturers expend more effort and resources to establish this defense than to defend their products. Thus, health care providers should be aware of and understand this doctrine. Otherwise, they may find themselves alone in defending this type of claim.

A manufacturer that makes, markets, and sells a prescription medication can be sued for what is known as a "failure to warn." Essentially, this claim alleges that the patient was not warned of the risks, hazards, and potential side effects of the medication. In this type of case, the patient must show either that no warning was provided or that the warning provided was inadequate or defective, and that the failure to warn was a "producing cause" of an injury to the patient (1). In situations that involve prescription medications, if the manufacturer, marketer, or seller provided warnings about the medication to the prescribing health care provider, the learned intermediary doctrine may apply. In this situation, the manufacturer has a duty to warn the prescribing physician of the medication's dangers. The warning at issue is generally in the form of the product insert or "label" information. Generally, a health care provider has access to this information through the *Physicians' Desk Reference*. With this disclosure of risks by the manufacturer, the prescriber assumes the duty to warn the patient about the dangers of the medication (2). The prescriber, relying on his or her training, experience, and knowledge of the patient, chooses whether to prescribe the medication, and if prescribed, the manner, dose, and duration of the medication's use (3). By so warning the prescriber, the manufacturer not only discharges its responsibility but transfers the responsibility to warn the patient to the prescriber.

One purpose behind this doctrine is to encourage the manufacture of medications. This is achieved, in part, by shielding the manufacturer from liability when it provides proper warning to a properly trained prescriber (4). Absent this doctrine, a medication manufacturer would in essence be an insurer to every patient to whom the drug was prescribed, regardless of the prescriber's conduct (5).

Initially, this doctrine did not apply to situations in which a physician did not really exercise an individualized judgment on a medication's propriety or usage. Primarily this involved circumstances surrounding immunizations (6). Subsequently, this individualized judgment issue was felt to be unimportant. The focus became whether there was a physician-patient relationship, not

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whether the prescriber performed a patient-specific analysis (7). If a physician-patient relationship existed, the doctrine could be utilized. The prescriber, however, does not have to be a physician. For example, an advanced practice nurse who is given the right to prescribe medication and treat patients without the supervision of a physician can be an appropriate conduit through which the manufacturer can discharge its duty to warn (8). Again, the key issues are that a provider-patient relationship exists, warning information was provided to this intermediary, and the intermediary was capable of offering the patient individualized medical treatment and could convey [and in fact has a duty to convey] the warning information (9).

For the doctrine to apply, meaning that the manufacturer has properly discharged its duty, the warning provided to the prescriber must be adequate. If "the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user [i.e., the patient]" (10). Whether the warning provided was adequate or misleading is the real crux of this issue. Oftentimes, medication risks that were downplayed or trivialized while the medication was being marketed suddenly become, in the manufacturer's eyes, more clear, concrete, and significant. Thus, the representations and information given to health care providers by sales representatives are of the utmost importance. These representatives are frequently a primary source of manufacturer information for prescribers. Representations made in literature referenced or utilized by these individuals or utilized to respond to inquires by the manufacturer's own medical affairs department are also important. Moreover, it is important to note that published studies not only are often sponsored by a medication's manufacturer but may also be ghostwritten by an outside agency at the manufacturer's request. This information is of the utmost importance to the prescriber's defense in this circumstance because it shows exactly how the manufacturer characterized warnings about its medications.

The existence of a Food and Drug Administration (FDA)–approved package insert does not establish that the manufacturer provided an adequate warning (11). A warning is adequate if the insert specifically mentions the circumstance or side effect complained of by the patient (12). An important point to consider, however, is whether the actual risk that this circumstance or eventuality could occur was adequately conveyed. Our position in representing prescribers in these claims has been that a warning is not adequate, and is in fact misleading, if the likelihood with which an adverse event can occur is not accurately disclosed. For example, in the diet drug litigation, our contention was that the risk of primary pulmonary hypertension was not adequately disclosed. Up until shortly before the medication was withdrawn from the market, the package insert referenced only 4 reports of primary pulmonary hypertension, despite the fact that the manufacturer had received many reports of this occurrence. In this situation of absent accurate information on the likelihood of the risk, it would be impossible for the prescriber to make an individualized judgment on the propriety of the medication or to adequately warn the patient. Simply put, the warning is inadequate because a meaningful risk-benefit analysis cannot be done if the real likelihood of a risk is not conveyed.

Remember also that the process does not simply end in situations in which the warning is determined to be inadequate. To defeat application of this doctrine, causation must also be established. There must be evidence that the inadequate or misleading warning caused the injury at issue. This requires the prescriber to show that an adequate or different warning would have affected his or her decision to prescribe the medication on the occasion in question (13). An example is a situation in which if the true likelihood of an adverse event was disclosed, the medication probably would not have been prescribed because of that risk. Considering the risk, other, less risky alternatives would have been used.

One final point merits discussion. In attempts to shift blame, manufacturers often claim they warned against a medication's use because such use was unapproved or "off-label." This is particularly troublesome for 2 reasons. First, manufacturers are well aware of the fact that nothing is substandard, inappropriate, or wrong about this practice. Off-label use is recognized by the FDA. Specifically, the FDA does not govern medical practice or the legality of a prescriber's off-label use of prescription drugs (14). Both the courts and the FDA recognize the benefit and necessity of off-label use of drugs (15). Further, off-label use and its role in proper medical care are recognized and addressed in the *Physicians' Desk Reference* (16). Further, medication manufacturers essentially promote off-label use of their medications by sponsoring studies that support such uses of their products, by sponsoring experts in certain fields of medicine to speak in support of a medication's off-label use, and by having studies or articles ghostwritten on off-label uses. Moreover, Medical Economics, the publisher of the *Physicians' Desk Reference*, publishes a companion guide that contains an "off-label treatment guide." Because of these efforts, any attempt of manufacturers to claim that they warned against off-label or unapproved uses is clearly misleading and intellectually dishonest.

The unfortunate lesson here is that prescribers have to practice defensive medicine in dealing with those who sell and promote medical products. Before litigation, manufacturers are ever present, supporting and encouraging prescribers to utilize their stream of products. When the water rises, beware; manufacturers will head for high ground behind the learned intermediary doctrine and leave prescribers to face the flood alone. Be knowledgeable and prepared.

1. *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied).
2. Ibid. See also *Alm v. Aluminum Co.*, 717 S.W.2d 558, 591–592 (Tex. 1986); *Reyes v. Wyeth Lab*, 498 F.2d 1264, 1276 (5th Circuit 1974).
3. *Reyes*, 498 F.2d 1276.
4. *In Re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374, 379 (5th Circuit 1999).
5. *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. App.—Corpus Christi 1973, writ ref nre).
6. *Reyes*, 498 F.2d 1277.
7. See *Hurley v. Lederle Lab*, 863 F.2d 1173, 1178–1179 (5th Circuit 1988).
8. *Wyeth-Ayerst Lab. Co. v. Medrano*, 28 S.W.3d 87, 93 (Tex. App.—Texarkana 2000, no writ).
9. See *Hurley*, 863 F.2d 1178–1179; *Medrano*, 28 S.W.3d 93.
10. *Alm*, 717 S.W.2d 592, citing *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801 (Tex. 1978); *Crocker v. Winthrop Lab.*, 514 S.W.2d 492 (Tex. 1974).
11. *Gonzales*, 561 S.W.2d 804.
12. *Rolen*, 856 S.W.2d 609.
13. See *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex.

App.—El Paso 1989, writ denied); *In Re Norplant,* 955 et supp 710–711.

14. See *Fenrite v. Abbott Northwestern Hospital,* 568 N.W.2d 535, 542 (Minn. App.), *rev denied,* November 18, 1997; *Klein v. Biscup,* 673 N.E.2d 225, 231 (Ohio App.), *appeal denied,* 667 N.E.2d 987 (Ohio 1996); 21 U.S.C. Section 906; 59 Fed. Reg. 59820, 59821 (FDA November 18, 1994).
15. See, e.g., *Ortho Pharmaceutical Corp. v. Cosprophar, Inc.,* 32 F.3d 690, 692; *Washington Legal Foundation v. Kessler,* 880 F. Supp. 26 (D.DC. 1995).
16. Foreword to *Physicians' Desk Reference,* 55th ed. Montvale, NJ: Medical Economics, 2001.