LEARNED INTERMEDIARY

Is the "learned intermediary" or "informed intermediary" rule realistic in today's world of television, radio, magazine and internet advertising of prescription drugs? The rule holds that prescription drug manufacturers generally have no duty to warn consumers directly of any risks or side effects associated with use the of their product. Any obligation is fulfilled when the prescribing or treating physician is informed of the risks, side effects and contraindications dictions of a drug so that he or she may decide on its use and advise the patient accordingly.[i] The doctor acts as an informed professional, so the decision to use the drug in a particular instance rests with the doctor and the patient, not the manufacturer. But courts are beginning to reject the "learned intermediary" rule, citing changing conditions in health care and advertising which have rendered obsolete the classical model of the informed doctor prescribing treatment for a trusting patient. A federal appeals court recently certified a "learned intermediary" question to the Connecticut Supreme Court, asking whether the doctrine applies where a man died of severe anaphylactic shock after ingesting a nonsteroidal anti-inflammatory pill from samples given to his wife with no packaging information.[ii] The court's request for certification was based in large part on the New Jersey decision of *Perez v. Wyeth Laboratories, Inc.*[iii]

In *Perez,* a group of women filed suit claiming they were injured by Norplant, a contraceptive device implanted under the skin of a woman's upper arm during an in-office surgical procedure characterized by the manufacturer as minor. A continuous dosage of a synthetic hormone, levonorgestrel, diffuses through the implant's walls and into the bloodstream, preventing pregnancy for up to five years. The manufacturer initiated a massive advertising campaign in women's magazines and on television which, according to the plaintiffs, failed to warn of inherent dangers posed by Norplant, instead touting its simplicity and convenience. The plaintiffs cited several medical publications which found Norplant removal to be painful and difficult, and claimed side effects including dizziness, vomiting, vision problems, mood swings and depression, high blood pressure, and removal complications that resulted in scarring. Accepting the plaintiffs' allegations as true, the court considered whether the "learned intermediary" doctrine should apply to the case. The court noted the rationale for the "learned intermediary" doctrine was best explained by Judge John Minor Wisdom in *Reyes v. Wyeth Labs., Inc.*[iv], in a perspective reflecting the then-prevalent attitude about doctor-patient relationships:

> This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in [the] products. . . . Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of [the] patient. [The physician's] task [is to weigh] the benefits of any medication against its potential dangers. The choice [the physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between

manufacturer and consumer.[v]

But the *Perez* court found these considerations lacking in the now prevalent direct-to-consumer advertising of prescription drugs. The "Norman Rockwell" image of the family doctor no longer exists, and informed consent requires a patient-based decision rather than the paternalistic approach of the past. Also, because of managed care, physicians have considerably less time to inform patients of the risks and benefits of a drug. And, drug manufacturers are aggressively and effectively advertising to consumers and communicating directly to patients. Thus, the court reversed the lower court's granting of summary judgment, and held the "learned intermediary" doctrine was not applicable to direct marketing of prescription drugs to consumers because "when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product."[vi]

A Louisiana appellate court recently applied the "learned intermediary" doctrine to uphold the trial court's granting of a summary judgment motion on behalf of a manufacturer of a prescription drug.[vii] The plaintiff, Donald Calhoun, received sixty milligrams of Toradol after an outpatient surgical procedure and shortly thereafter experienced renal failure. He and his wife filed suit against the drug manufacturer, alleging that Toradol was unreasonably dangerous in construction and composition, unreasonably dangerous in design, unreasonably dangerous because an adequate warning had not been provided to the treating physicians or Mr. Calhoun, and unreasonably dangerous because it did not conform to an express warranty by the manufacturer. The drug manufacturer claimed in its Motion for Summary Judgment that the Calhouns' claims were barred by the "learned intermediary" doctrine. The drug manufacturer relied on the Food and Drug Administration's approved package insert, which included in its warning the following language: ". . .with the use of Toradol, there have been reports of acute renal failure, nephritis, and nephritic syndrome . . ."

In opposition, the Calhouns filed an affidavit of the prescribing physician, who stated that while he was aware that Toradol could cause problems with kidney function, he was not warned by the literature or otherwise that a single sixty milligram dose of Toradol could cause renal failure. The Calhouns contended this sworn statement by the doctor, as the prescribing physician, created an issue of fact as to the adequacy of the warning, thereby precluding the application of the "learned intermediary" doctrine and making summary judgment improper. The appellate court found the package insert for Toradol plainly warned that acute renal failure was a possible reaction from its use. The court wrote:

> [T]he statement in the warning that "there have been reports of acute renal failure" with the use of Toradol was unqualified and certainly not restricted to patients with impaired renal function or underlying renal insufficiency. Therefore, we find, as a matter of law, that the warning as stated was adequate.[viii]

It will be interesting to see whether Louisiana will adopt the *Perez* court's reasoning for a case involving consumer-direct advertising. As drug companies spend more money on direct marketing strategies, the issue is likely to arise.

i *Mikell v. Hoffman-LaRoche, Inc., et al.,* 94 0242 (La.App. 1 Cir. 12/22/94), 649 So.2d 75; *Rhoto v. Ribando,* 504 So.2d 1119, 1123 (La.App. 5th Cir.), *writ denied,* 506 So.2d 1225 (La. 1987); *Kinney v. Hutchinson,* 468 So.2d 714, 717 (La.App. 5th Cir.), *writ denied,* 472 So.2d 35 (La. 1985); *Cobb v. Syntex Laboratories, Inc.,* 444 So.2d 203, 205 (La.App. 1st Cir. 1983).

ii *Vitanza v. The Upjohn Co.,* 99-7539, 2000 WL 545254 (2nd Cir. (Conn.), 5/5/00). The court certified this question:

> On the facts of this case - where (i) a drug manufacturer distributed promotional free samples to physicians and provided appropriate warnings to the physicians, (ii) the drug sample states only that it is to be dispensed by prescription only, (iii) the drug sample is ingested by (and causes injury to) an otherwise unwarned person in the patient's household, and (iv) the drug manufacturer is sued for damages under the Connecticut Product Liability Act, . . . is the drug manufacturer insulated from liability as a matter of law by the learned intermediary doctrine?

iii 734 A.2d 1245 (N.J. 1999).

iv 498 F.2d 1264 (5th Cir.), *cert. denied,* 419 U.S. 1096, 95 S.Ct. 687, 42 L.ED.2d. 688 (1974).

v *Id.* at 1276.

vi *Perez v. Wyeth Laboratories, Inc.,* 734 A.2d 1245 (N.J. 1999).

vii7. *Calhoun v. Hoffman-La Roche, Inc.,* 98-2770 (La.App. 1 Cir. 2/18/00), 2000 WL 202067.

viii *Id.*