

Direct- to-Consumer Advertising and the Learned Intermediary Doctrine

by

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Television and the mass media continues to change our evolving culture. Drug commercials are now ubiquitous, and sexual enhancement drugs are openly advertised without blushing. The law is lagging behind, but it is now recognizing that direct-to-consumer advertising [DTC] of drugs is altering the balance of information that the drug consumer now has to rely upon, as compared to the prior era of limited consumer information when the learned intermediary doctrine was adopted because the prescribing doctor had all of the information and made the decision on what drugs a patient would take.

In the past, the learned intermediary (ie. the prescribing doctor), was the gatekeeper of drug therapy. Prescribers still write the prescriptions, but DTC advertising is “pushing” the market. Big Pharma is spending millions of dollars on “informational” ads that influence consumers by educating them in the way that Big Pharma wants them educated. With DTC, Big Pharma can frame the issues that generate acceptance of its products and encourage patients to ask their doctors for a particular drug. Increasing, doctors are also allowing their patients to decide what drugs they want to take after a full disclosure is made. Big Pharma is producing and buying the commercials because the DTC is effective; the advertising pays for itself with increased sales.

The Courts are slowly coming to grips with this new paradigm that undercuts the rationale of the learned intermediary doctrine. In the past, the prescribers were the only ones with the knowledge of the risks and benefits of drug therapy. Now, with pressure from both sales representatives and the “informed” public, prescribers are subjected to marketing forces that usurp objective deliberations on appropriate drug therapy.

This paper will address how the present state of the learned intermediary doctrine and the effects that the DTC is having on the viability of this defense. Additionally, this paper will discuss the evidence from the drug company, the Plaintiff, the doctor and the sales representative that may be helpful in avoiding the defense, or at least in creating a jury issue.

I. Learned Intermediary Defense

Traditionally, one who markets goods must warn the foreseeable ultimate users of the dangers inherent in the products. McCombs v. Synthes (U.S.A.) et al., 250 Ga. App. 543 (2001).

However, in 1966, the Eighth Circuit, whether consciously or unconsciously, set in motion the road to the “learned intermediary defense” as it is successfully used today by manufacturers of pharmaceuticals and medical devices to avoid liability to the end consumer. Specifically, in Sterling Drug v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966), the Eighth Circuit used the term “learned intermediary” for the first time holding that, “the [drug] purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.” Id. Thus began the winding path to the current state of the learned intermediary defense.

In its simplest form, the “learned intermediary defense” provides manufacturers of prescription drugs and medical devices with a liability defense “where a drug [or medical device] is available only upon the prescription of a duly licensed physician.” Demmler v. SmithKline Beecham Corp., 448 Pa. Super. 425, 430 (1995). The learned intermediary doctrine, as it is sometimes called (rather than “defense”), requires only that the drug manufacturer warn the prescribing physician of the risks associated with the drug, not the general public. Id.

The rationale behind the doctrine or defense was articulated by the Fifth Circuit Court of Appeals in Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974), as follows:

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 his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he 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.

Id. Recently, even with the development of direct to consumer advertising, the courts are still holding to the traditional rationale behind the defense. In 1995, in Demmler v. SmithKline Beecham Corp., cited above, Mrs. Demmler suffered a hypertensive crisis causing partial paralysis and brain damage as a result of taking a physician-prescribed dosage of the drug Parnate. Demmler, 448 Pa. Super. 425, 426 (1995). Mrs. Demmler and her husband instituted an action against SmithKline, the manufacturer of the drug, alleging inadequate warnings, inadequate product descriptions and overpromotion of Parnate. Id. The trial court granted summary judgment in favor of SmithKline on all counts, except the plaintiffs’ claim regarding inadequate warnings as it related to an alleged antidote to hypertensive crisis associated with Parnate. Id. However, subsequently, the trial court found that there was no evidence to support such a claim and dismissed the remaining portion of the

plaintiffs' action. Id. The plaintiffs appealed to the Fifth Circuit. Id. at 430.

On appeal, the Fifth Circuit affirmed the trial court's holding finding that the plaintiffs failed to present sufficient evidence from which a reasonable jury could infer that SmithKline manufactured and sold a defective product. Id. at 433. Relying on the "learned intermediary doctrine," despite the plaintiffs' allegation of overpromotion of the drug by SmithKline, the Fifth Circuit held that "[l]iability will not be imposed upon a drug manufacturer 'for unfortunate consequences attending the use of a prescription drug merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.'" Id. at 435; *citing* Incollingo v. Ewing, 282 A.2d 206, 220 (1971); *quoting* Restatement (Second) of Torts, § 402A.

Likewise, the Georgia courts have adhered to the traditional explanation permitting such a defense. In Hawkins v. Richardson-Merrell, Inc., 147 Ga. App. 481 (1978), Mrs. Hawkins suffered a severe allergic reaction after being prescribed and taking a sulfa drug. Id. The Georgia Court of Appeals explained that in order for Mrs. Hawkins' claim against the manufacturer of the drug to survive, the manufacturer must have a legal duty "to warn the person for whom the physician has prescribed a drug of known adverse reactions." Id. at 482 *citing* Reyes v. Wyeth Laboratories, *supra*, the court in Hawkins held,

that where prescription drugs are concerned, the manufacturer's duty to warn is limited to any obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. 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 his products. Hawkins, 147 Ga. App. at 483.

Even though the Restatement (Third) of Torts has provided a mechanism through which the courts may implement an exception to the strict learned intermediary defense, most courts have declined to do so. However, with the right evidence on the effects of direct-to-consumer advertising, the learned intermediary doctrine may be converted into a jury issue, just as any other defense, rather than a basis for summary judgement.

II. Direct-to-Consumer

Major changes to tort law often begin in the northeastern appellate courts. The Palsgraf opinion of 1928 is a major example we became familiar with in law school. Palsgraf v Long Island Railroad Co., 162 N.E. 99 (NY 1928). In 1999, the New Jersey Supreme Court created an exception to the learned intermediary defense that is still being developed in trial courts around the country. Perez v Wyeth Laboratories, Inc., 161 N.J. 1, 734 A2d 1245 (1999). This exception is known as the "direct-to-consumer" exception [DTC]. This exception has not been expressly accepted outside of New Jersey. Mendez Montes De Oca v Aventis Pharma, 579 F. Supp.2d 222, 229 (D. Puerto Rico

2008). However, the West Virginia Supreme Court adopted the Perez rationale when it declined to adopt the “learned intermediary” doctrine because of DTC. State ex. rel. Johnson & Johnson Corp. v Karl, 220 W. Va. 463, 647 S.E.2d 899 (2007). In West Virginia, there is no need for an exception since the learned intermediary doctrine does not exist. If the doctrine had existed, then it is apparent that the exception would have been adopted.

The Perez opinion recognized the obvious— that drug companies market their drugs directly to consumers through television commercials and mass media. The court noted, “Our medical-legal jurisprudence is based on images of health care that no longer exist.” Perez, 161 N.J. at 4. In the past, patients relied on doctors to warn them of the risks of medications. The drug companies directed their marketing efforts to doctors. The Court noted that “for good or ill,” this marketing arrangement has now changed.

With drug companies directly marketing their drugs to consumers, the drug companies should not be relieved of their obligation to provide adequate warnings to consumers. Id. at 5, 11-15. The law must change with the marketplace and reflect its realities, and the Restatement, along with a New Jersey statute based on the Restatement, provided an avenue for the exception. See Restatement(Third) of Torts: Products Liability § 6(d) (1997); Perez, 161 N.J. at 9, 14-17. The Restatement requires a prescription drug manufacturer or medical device manufacturer to warn patients of foreseeable risks if it is foreseeable that the health-care provider will not be in a position to warn the patient. Id.

DTC places pressure on consumers and is an integral part of the marketing strategy. L. Noah, “Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues,” 32 Ga. L. Rev. 141 (1997); M. Allen, “Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine,” 20 Campbell L. Rev. 113 (1997). DTC “alters the calculus of the learned intermediary doctrine.” Perez, 161 N.J. at 17-19; Edwards v Basel Pharms, 116 F.3d 1341, 1343 (10th Cir. 1997); *see also* T. Schwartz, “Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule,” 46 Food Drug Cosm. L.J. 829 (1991).

DTC must also be considered with New Jersey’s informed consent rule that a patient must be informed of all risks that a reasonable patient would want to know of before deciding on medical treatment, such as drug therapy. Perez 161 N.J. at 20. This objectively-prudent-patient rule has also been adopted in Georgia. Ketchup v Howard, 247 Ga. App. 54, 543 S.E.2d 371 (2000) This same informed consent standard should apply to drug manufacturers. A federal district court in Florida, where doctor’s are not required to fully inform a patient of risks, has rejected the DTC exception. Beale v Biomet, Inc., 492, F. Supp. 1360, 1370, 1376 (S.D. Fla. 2007).

In Beale, the district cited Eleventh Circuit precedent that a doctor’s actual knowledge of the risks establishes the doctor as a learned intermediary and, therefore, he is an intervening cause as a matter of law. Beale 492 F. Supp.2d at 1371 *citing* Ellis v C.R. Bard, Inc., 311 F.3d 1272, 1283 n.8 (11th Cir. 2002). In Beale, the court also discussed the “overpromotion” exception, in which sales

representatives misrepresent a drug's risks, and the prescribers rely on the misrepresentations. Beale 492 F. Supp.2d at 1377. In that instance, the defendant drug company may be liable for negligently overpromoting a drug.

Causation of injury is the most difficult issue. The causation issue is whether the doctor's failure to warn the patient is the proximate cause of the injury when the doctor was fully informed of the risks and prescribed anyway. Although the doctor writes the prescriptions, DTC creates patients who enter the doctor's office with preconceived ideas of drug therapy. Perez, 161 N.J. at 26 citing T. Terzian, "Direct-to-Consumer Prescription Drug Advertising," 25 Am.L.J.& Med. 149, 157 (1999). Since a proximate cause must only be a substantial contributing factor of the alleged harm, issues of fact exist concerning the influence that the DTC had on the consumer's decision to take the injurious drug, and the effect of the doctor's actions as a superceding or intervening cause of injury, is a jury issue. Perez, 161 N.J. 29-30.

Causation was the hinge issue when the DTC exception was addressed by a Georgia federal district court. Porter v Eli Lilly & Co., 2008 WL 544739 (N.D. Ga. Feb. 25, 2008). In Porter, the prescriber testified that he would have prescribed Prozac regardless of a warning on the increased risk of suicide. Judge Forrester determined that the Georgia Supreme Court was unlikely to adopt the DTC exception to the learned intermediary doctrine, and he also noted that no Georgia court had adopted Restatement (Third) of Torts §6(d)(2). Porter, 2008 WL 544739, 7-9. Judge Forrester granted summary judgment because the prescriber testified that he would have prescribed the Prozac regardless of the alleged necessary enhanced warning, and, therefore, as a matter of law, Plaintiff could not establish liability with any evidence. Id. at 9. The prescriber's unambiguous testimony rebutted any presumption that Plaintiff might have enjoyed from an inadequate warning. Id. at 11-12.

The Eight Circuit has also held that the causal link between an inadequate warning and a patient's injury is broken when the prescriber already knew of the risks that should have been in an adequate warning. Ehls v Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004). Other courts have held that a prescriber's testimony that he was fully aware of a drug's risks still presents a jury issue precluding summary judgment. Williams v Lederle Laboratories, 591 F.Supp. 381, 384 (S.D. Ohio 1984)[a fact question exists on prescriber's credibility]; Bennett v Madakasira, 821 So. 2d 794, 806 (Miss. 2002)[prescriber's testimony is subject to credibility determination]; Strump v Schering Corp., 606 A.2d 1140, 1146-48 (N.J. Super. 1992) [prescriber's testimony of how he would have prescribed with proper warning is subject to cross examination at trial]; Doe v Miles Laboratories, Inc. 927 F.2d 187, 195 n. 32 (4th Cir. 1991)[prescriber's testimony is unreliable hindsight]; Hoffman-Rattet v Ortho Pharmaceutical Corp., 516 N.Y.S.2d 856, 860 (1987)[prescriber's testimony is unreliable because he will be trying to protect his reputation and avoid malpractice]; Seley v G.D. Searle & Co., 423 N.E.2d 831, 839 (Ohio 1981)[prescriber's testimony does not preclude factual issues]. Also, the Plaintiff may submit testimony on what a reasonable prescriber would have likely done with an adequate warning. Thomas v Hoffman-LaRoche, Inc., 949 F.2d 806, 812 (5th Cir. 1992); Garside v Osco Drug, Inc., 976 F.2d 77, 81-82 (1st Cir. 1992).

III. Evidence to Avoid Learned Intermediary Defense

The issue of learned intermediary only arises in inadequate warning cases. Defective manufacture or design cases are decided by other issues in which the doctor's knowledge is irrelevant. In an inadequate warning case, the first issue is whether the prescriber was adequately warned. If he says that he was not adequately warned, then the learned intermediary defense is weakened because the doctor was not 'learned.' Therefore, the prescriber is one of the first witnesses that you want to meet with.

The prescriber is also the most important liability witness. His unambiguous testimony that he would have prescribed regardless of the warnings sets up a winning summary judgment motion. Some lawyers prefer to sue the prescriber because the pressure of a potential judgment against him for failing to fully inform the patient of the risks often makes the prescriber more open to good prescribing practices. Evidence of a prescriber's prescribing habits may show that he changed his prescribing habits after additional risks were publicized. The drug companies buy prescribing information on the doctors through IMS and other data collection companies that buy the information from pharmacies. You should obtain this information and chart his volumn of prescriptions both before and after the new risks were made public.

If you have not sued the prescriber, and you have set up a meeting with him, take the drug label, usually referred to as the package insert, and show it to the prescriber. Then discuss the other risks which the drug company knew of, and be specific about dosage and length of time of the prescription. While the drug's risks may have been low if prescribed for 3 months, did the prescriber know of the increased risks if the drug was prescribed for a period of years? Did the doctor think that long-term clinical trials had been completed on the drug. Did the doctor know that monitoring tests were appropriate at certain intervals or after a certain period of drug therapy.

The primary issue is whether the doctor had adequate information to make an informed decision on the risk and benefit of the drug. If the undisclosed risk would have made a difference to the prescriber, particularly if the prescriber would have reconsidered the prescription, then Plaintiff can avoid summary judgment.

There are several ways in which the risks may not have been fully disclosed. For instance, a lower dosage or a shorter duration of prescription may have significantly reduced the drug's risk. All drugs have a dose-response relationship which support an argument that the drug will have greater effects if given in larger doses or for a longer period of time. If the prescriber admits to being influenced by the sales representatives with misleading information, then the court may also not consider him a learned intermediary or may consider the overpromotion exception applicable.

The DTC exception, as opposed to the application of the learned intermediary defense, relies on the testimony of your client. You must show that your client relied on some DTC. Also, that your client was the one that made the decision of whether to take the drug in the end. If the doctor did not know of the risks, then he could not warn the patient. And so, if the patient would have considered

this information, then a jury question exists on whether the information of the undisclosed risks was a proximate cause of the injury.

Questions that you should address with your client include the following:

- Did your client see the TV commercials, or the printed media, or the patient educational brochures in the doctor's office that were left by the sales representatives? Show your client copies of the ads, and your client will need to identify the materials he relied upon.
- Did your client ask the doctor for the drug because he had seen it advertised? Yes.
- What did the doctor tell the client about the drug? Very little.
- Did the doctor let the patient make the final choice of what drug to take? Prescribers usually say yes.

- Did the client know of the risks? All drugs have risks, but client did not know the degree of risk.
- Did the client read the package insert? Yes.
- How did your client interpret the package insert? From what he could understand, there was very little risk

All of these questions and responses are being considered by the Courts in determining whether to apply the DTC exception. All responses may not be needed, but at a minimum, you must show the client's reliance and the client's decision to take the drug based on his understanding that the risk of taking the drug was less than the actual risk. If the right facts are presented, then the court may apply the DTC exception.