

The Impact of Direct-to-Consumer Advertising in Pharmaceutical Product Liability Cases

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In the world of pharmaceutical product liability litigation, the learned intermediary doctrine has been an effective tool in defending failure to warn claims. Embraced by at least 45 jurisdictions,⁵ the doctrine provides that a pharmaceutical manufacturer fulfills its duty to warn if the manufacturer provides adequate warnings to the physician.⁶ Beginning in as early as 1948, in the context of products liability, courts have recognized a difference between goods sold directly to the public and those which require a doctor's prescription.⁷ The phrase "learned intermediary" originated in the 1966 case *Sterling Drug, Inc. v. Cornish* where a liability suit was brought against the producer of chloroquine phosphate for failing to warn physicians of its potential to cause irreversible retinopathy.⁸ In *Sterling*, the court noted, "we are dealing with a prescription drug rather than a normal consumer item. In such a case, the 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 if advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the plaintiff can be avoided."⁹

The fundamental rationale for the learned intermediary doctrine is the

fact that consumers cannot obtain prescription drugs without a doctor's prescription. Courts have identified four factors that support the application of the learned intermediary doctrine. They include: (1) the fiduciary nature of the doctor-patient relationship; (2) drug manufacturers lack effective means to communicate directly with consumers; (3) doctors are able to decipher complex warnings and relay them to their patients; and (4) doctors are able to filter relevant information to the patient to apprise them of the risks without discouraging necessary treatment.¹⁰

Much has been made recently of Direct-to-Consumer (DTC) advertising of pharmaceuticals and its impact on the learned intermediary doctrine in light of the decision handed down in *Perez v. Wyeth*. A discussion of case law both before and after *Perez* demonstrates that the learned intermediary doctrine remains to be a viable defense for pharmaceutical companies in a majority of states. Furthermore, in New Jersey, the lone state that has found an exception to the learned intermediary doctrine on the basis of DTC advertising, compliance with FDA regulations for labeling and advertising provides a strong, albeit rebuttable, presumption that a manufacturer has satisfied its duty to warn consumers about potentially harmful side effects associated with its product.

Nonetheless, recent case law appears to demonstrate that courts find the

opinion in *Perez* well reasoned and a change with respect to the learned intermediary doctrine may be on the horizon given stepped up advertising to consumers directly.

What is Direct to Consumer Advertising?

In the context of this article, DTC advertising is the unsolicited promotional endeavor by a pharmaceutical company or other provider of medical services to present information about medicine or medical services to the public in the popular media.¹¹ Although considered recent phenomena, DTC advertising dates back to the early 1700s, when medications were first advertised in U.S. newspapers.¹² One of earliest modern uses of DTC advertising occurred in 1981, when the pneumonia vaccine Pneumovax[®] was advertised in Readers Digest Magazine.¹³

In 2005, pharmaceutical marketers spent approximately \$4.86 billion on DTC advertising to market more than 150 prescription medications to the general public.¹⁴ The product most advertised to consumers during 2005 was Lunesta. Sepracor Inc. spent \$227.3 million promoting the prescription sleep aid during the drug's first year on the market.¹⁵

DTC advertisements have become a stable yet controversial feature of the media landscape.¹⁶ Critics charge that

DTC advertisements lead to the over-prescribing of unnecessary, expensive, and potentially harmful medications.¹⁷ Proponents counter that DTC advertising can serve a useful educational function and help avert underuse of effective treatments for conditions that may be poorly recognized, highly stigmatized, or both.¹⁸

Despite the controversy, the amount of DTC advertisements continues to increase because, among other reasons, they educate consumers about certain conditions and treatments and concomitantly result in an increase of sales of the products. For instance, one study of 64 drugs found a median increase in sales of \$2.20 for every \$1 spent on DTC advertising.¹⁹

***Perez v. Wyeth*—“The Beginning of the End?”**

Although a strong defense in most product liability actions against pharmaceutical companies, the learned intermediary doctrine is not an absolute rule. Courts have found circumstances where a warning directly to the patient is required. These circumstances include: vaccine inoculations²⁰; oral contraceptives²¹; contraceptive devices²²; over-promoted drugs²³; and (6) drugs withdrawn from the market.²⁴ *Perez v. Wyeth* was the first decision to find an exception to the learned intermediary doctrine based on DTC advertising.

Perez involved a products liability cause of action against the makers of the Norplant contraceptive device. Plaintiffs’ principal claim alleged that Wyeth, the distributors of Norplant in the United States, failed to adequately warn about side effects associated with the contraceptive.²⁵ According to plaintiffs,

Wyeth began a massive advertising campaign for Norplant in 1991, directed at women rather than at their doctors.²⁶ The *Perez* court held that when manufacturers of prescription drugs or medical devices engage in direct-to-consumer marketing for their products, they may not be shielded from liability by the learned intermediary doctrine.²⁷

In support of its position, the Supreme Court of New Jersey cited to Restatement (Third) of Torts for the proposition that situations may exist to impose a duty on the manufacturer to warn the patient directly when the health-care provider assumes a “much-diminished role as an evaluator or decision maker.”²⁸ According to the *Perez* court, DTC advertising creates such a demand for a prescription drug, that physicians are likely to acquiesce to the wishes of their patients and not engage in a risk-benefit analysis to determine whether the drug is appropriate. Furthermore, the court noted, “[o]ur medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received ... from a physician.... [Today,] medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and often paid for by third-party providers.”²⁹

Although *Perez* carved an exception to the learned intermediary doctrine when pharmaceutical companies engage in DTC advertising, it did provide a rebuttable presumption that a manufacturer satisfies its duty to warn if it complies with FDA regulations concerning labeling and advertising.³⁰ As one court recently noted, “[t]hough technically rebuttable, ‘for all practical purposes, absent deliberate concealment or nondis-

closure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.”³¹

***Perez* Goes It Alone**

In 2002, three years after the *Perez* decision, one United States District Court noted that “[s]ince *Perez*, no other court in any jurisdiction has directly addressed an advertising exception to the learned intermediary doctrine, making New Jersey the only jurisdiction to recognize this exception.”³² In 2004, the multi-district litigation judge overseeing the Meridia litigation rejected plaintiffs’ arguments to adopt a DTC advertising exception based on a federalism issue because no other state had followed New Jersey’s lead. *In dicta*, the court, a U. S. District Court in Ohio, noted, however, that “the *Perez* opinion was certainly well-reasoned.”³³ The Sixth Circuit Court of Appeal affirmed this decision but did not discuss whether or not a DTC advertising exception applies. Rather, it affirmed the district court’s order as to the non-New Jersey cases and stated that, for New Jersey cases, there was no evidence that the defendants violated FDA’s regulations.³⁴ As such, the plaintiffs did not overcome the rebuttable presumption articulated in *Perez*.

Not only is *Perez* the only court to find an exception to the learned intermediary doctrine as a result of DTC advertising, but courts in other jurisdictions have rejected *Perez*-like arguments both before and after the *Perez* decision. For instance, applying Texas law, the Fifth Circuit Court of Appeal stated that “as long as the physician-patient relationship exists, the learned intermediary doctrine applies, despite alleged ‘aggres-

sive' marketing."³⁵

While no reported appellate decisions exist in Pennsylvania, trial courts in that jurisdiction have rejected a 'DTC exception' to the learned intermediary doctrine.³⁶ One court noted that media dissemination of information concerning the existence of drugs does not enhance the public's ability to acquire them because the skill and knowledge of the physician still must be brought to bear in determining whether the pharmaceutical is appropriate for the patient.³⁷

Finally, although not following the *Perez* decision, the Supreme Court of Connecticut, noted, *in dicta*, that courts have the ability to deal with changing circumstances in the health care industry especially regarding the marketing of prescription drugs. The court specifically identified the *Perez* Court's DTC advertising exception to the learned intermediary doctrine. The court stated that this exception, along with the others noted above, involve situations where there is a lack of communication between patients and their physicians or where patients essentially control the selection of the product. *Vitanza v. Upjohn Co.*, 778 A.2d 829, 847 (Conn. 2001).

The Possible Proliferation of *Perez*

As noted above, no court outside of New Jersey has adopted a DTC advertis-

ing exception to the learned intermediary doctrine. However, courts may be able to find precedent for applying a DTC exception by examining language and holdings in cases involving aggressive marketing campaigns. For example, in *Stephens v. G.D. Searle & Co.*, the plaintiff alleged that the defendant's birth control pill had caused her stroke. A U. S. District Court in Michigan did not explicitly create a Direct-to-Consumer advertising exception, but took into account the manufacturer's "zealous marketing practices" as a factor in applying the oral contraception exception to the learned intermediary rule.³⁸ Similarly, in *Hill v. Searle Laboratories*, the Eighth Circuit Court of Appeal, applying Arkansas law, held that a woman who was given an IUD was entitled to a direct warning from the manufacturer of the device. The court reasoned that the manufacturer's mass advertising of its product was "important" to its analysis but not determinative.³⁹ In *Garside v. Osco Drug Inc.*, a U. S. District Court in Massachusetts suggested, *in dicta*, that an exception to the learned intermediary doctrine may exist when a "manufacturer bypasses the traditional patient-physician relationship" by advertising directly to the consuming public.⁴⁰

Importance of Discovery

Given the trend to continue, if not in-

crease, DTC advertising, it is essential to safeguard the learned intermediary doctrine as plaintiffs attempt to spread *Perez's* DTC exception to other jurisdictions. To that end, written and deposition discovery establishing that a plaintiff had little or no control over the selection and prescription of the product and minimizing plaintiff's reliance on any DTC advertisements will be significant evidence in defending against application of a DTC exception in other jurisdictions.

Additionally, the deposition of the prescriber will be instrumental to refute the misperception that prescribers acquiesce to their patients' demands for medications. Testimony that the prescriber used her skill, knowledge, experience, and training and that she controlled the selection and prescription of the product will frustrate efforts for the adoption of a DTC exception in other jurisdictions.

Conclusion

The learned intermediary doctrine is a valuable tool in defending pharmaceutical product liability failure to warn lawsuits. It is incumbent to protect this well-reason doctrine and to demonstrate that patients, no matter how persistent, cannot obtain a pharmaceutical product without a prescription written by an educated and experienced health care provider.