DIRECT-TO-CONSUMER
ADVERTISING AND THE LEARNED
INTERMEDIARY DOCTRINE:
TRENDS AND SAFE HARBORS
FOR PHARMACEUTICAL
MANUFACTURERS

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Prescription pharmaceutical manufacturers continue to increase spending on direct-to-consumer ("DTC") advertising. This trend prompted outspoken consumer advocates, legal commentators, and personal injury attorneys to pursue aggressive strategies in an effort to undermine the well-established learned intermediary doctrine and potentially increase manufacturer liability in failure-to-warn product liability cases. Most courts have declined to follow a 1999 New Jersey Supreme Court decision holding that DTC advertising creates an exception to the learned intermediary doctrine. But a recent West Virginia Supreme Court decision once again calls the viability of the doctrine into question.

In addition, DTC-advertising opponents lately have pressed state and federal legislators and regulators to tighten oversight of DTC advertising. While this development ultimately may increase the administrative burden for drug makers, it also may serve to further shield these manufacturers from liability in personal injury litigation. This article examines historical trends in pharmaceutical DTC advertising and outlines best practices for manufacturers to maximize the strength of defenses in failure-to-warn product liability litigation.

THE LEARNED INTERMEDIARY DOCTRINE INTERSECTS WITH DTC ADVERTISING

The learned intermediary doctrine arms pharmaceutical manufacturers with a powerful defense in product liability lawsuits. Unlike most product liability cases, where the law imposes a duty on manufacturers to warn consumers directly about the risks of their products, the learned intermediary doctrine excuses a prescription drug manufacturer from warning each patient directly. Rather, a drug manufacturer prevails on a failure-to-warn claim so long as it provided an adequate warning to the physician, usually accomplished through the product's labeling or product insert. Physicians possess sophisticated educational backgrounds and expertise in their field and thus are better able to comprehend scientific warnings. First developed more than 50 years ago, the learned intermediary doctrine is followed in more than 40 states, the District of Columbia, and Puerto Rico. (Vermont courts have apparently never had the opportunity to consider the doctrine.)

The learned intermediary doctrine is premised on real-world dynamics in the health-care field. A physician has a relationship with the patient and can perform the appropriate balancing test, weighing the benefits of prescribing the drug against the risks of doing so. A physician is well positioned to take into account all relevant information regarding the patient, such as medical history and symptoms. On the other hand, a manufacturer possesses far less, if any, information necessary to provide the patient-specific analysis required before a drug is prescribed.
Within the past 20 years, pharmaceutical manufacturers have changed how they advertise their products. Before 1980, manufacturers tended to market their products solely to health-care professionals through sales personnel and written materials. Starting in the mid-1980s, however, DTC television advertisements dramatically increased. Boots Pharmaceuticals is often identified as the first manufacturer to advertise a prescription drug to consumers; in 1983, it used a television spot to promote its prescription-strength ibuprofen product, Rufen. In 1984, Upjohn implemented an advertising campaign for its prescription hair-regrowth product, Rogaine. Several other manufacturers followed suit.

The U.S. Food and Drug Administration ("FDA") initially encouraged the increased dissemination of information regarding prescription drugs. But some outspoken critics suggested that DTC advertisements served to mislead individual consumers and interfere with the physician/patient relationship. Others asserted that DTC advertisements would result in patients' pressuring their physicians to prescribe certain drugs, thus disrupting the carefully balanced risk/benefit analysis performed by physicians. After some deliberation, the FDA requested a voluntary moratorium on DTC advertising to further study its impact on consumers and the doctor-patient relationship.

In 1985, the FDA issued a rule requiring DTC advertisements to meet the regulatory requirements governing advertisements to medical providers. Under the rule, pharmaceutical companies were required to provide a so-called "brief summary" to consumers. The "brief summary" typically included the entire, lengthy reprinting of FDA-approved labeling for the drug, including detailed warnings, potential complications, and contraindications. This requirement chilled advertising to consumers on radio or television because manufacturers were unable to feasibly provide the "brief summary" in such a limited time and space. To avoid the rule, pharmaceutical companies subsequently invested in advertisements that either: (1) mentioned a drug's name but not what condition it treated, or (2) discussed the symptoms of a condition and urged patients to seek medical advice.

The FDA's DTC-advertising rule did not last long. Schering-Plough's 1996 television ad for Claritin allergy medication featured the distinctive voice of Cole Porter singing, "Blue skies shining on me, nothing but blue skies do I see." In the advertisement, Schering-Plough did not mention the name of the drug or the condition it treated, presumably to avoid the FDA rule. The vague advertisement left many consumers confused, a result that prompted the FDA to reevaluate its DTC-advertising rule.

On August 8, 1997, the FDA published Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements. The FDA relaxed its prior rule on how pharmaceutical manufacturers could advertise to consumers, especially with respect to broadcast-media advertisements. Instead of requiring manufacturers to provide all information required by the "brief summary," manufacturers need only make an "adequate provision" for interested members of the public to obtain the FDA-approved labeling and warnings. A manufacturer meets FDA requirements by providing in the advertisement a toll-free number for consumers to request information, a web-site address where the warnings are posted, a cross-reference to a print advertisement that contains the "brief summary," and a referral to a physician for consultation before making a decision about medical treatment. The new rule resulted in increased spending on DTC advertisements. From 1997 to 2005, total DTC spending increased from $1.1 billion to $4.2 billion, averaging an increase of about 20 percent per year.

This rise in DTC-advertising expenditures caused courts and commentators to raise new questions about the viability of the learned intermediary doctrine. For example, the American Law Institute Reporters initially took no position on the doctrine in early drafts of the Restatement (Third) of Torts: Products Liability § 6(d), leaving open the question of whether manufacturers should have a duty to warn patients directly. Later, the section was modified to include a proposed exception to the learned intermediary doctrine that required manufacturers to always warn patients directly when "the manufacturer advertised or otherwise promoted the drug or medical device directly to users and consumers." By the time the Restatement (Third) was published in 1998, the drafters deleted that proposal in favor of a comment that left the issue to be decided by "developing case law." See § 6(d), comment b.

The New Jersey Supreme Court's subsequent decision in Perez v. Wyeth Laboratories Inc., 734 A.2d 1245 (N.J. 1999), altered the litigation risk calculus for pharmaceutical manufacturers engaging in DTC advertising. There, the plaintiffs
had prescription-only Norplant contraceptive capsules implanted in their upper arms. The plaintiffs claimed that the manufacturer had engaged in a “massive advertising campaign” directed at women on television and in magazines. According to the plaintiffs, while the ads lauded the benefits of Norplant capsules, they lacked warnings about possible side effects. The trial court dismissed the claims because, under the learned intermediary doctrine, the manufacturer had properly warned physicians about the risks of the product. That the manufacturer also had advertised its product directly to consumers was immaterial because “a physician nevertheless retains the duty to weigh the benefits and risks associated with a drug before deciding whether the drug is appropriate for the patient.” Id. The appellate court affirmed summary judgment for the manufacturer.

The New Jersey Supreme Court reversed. In so doing, the court considered the dramatic increase in spending on DTC advertising by pharmaceutical companies and found that “[p]ressure on consumers is an integral part of drug manufacturers’ marketing strategy.” Id. at 1251. Citing the Restatement (Third)’s invitation to “develop case law” related to DTC advertising, the court found that DTC advertising had eroded the predicates upon which the learned intermediary doctrine was founded. Specifically, the court reasoned that modern patients increasingly drive treatment decisions versus previous eras, when doctors had a “paternalistic” approach. Moreover, the court pointed to managed care as reducing the time a physician could spend with a patient informing her of the risks associated with a particular drug. In addition, because manufacturers spent $1.3 billion on advertising, the court took comfort in the fact that manufacturers had the resources to communicate effectively with each patient. Based on these developments, the court found that DTC advertising “belies each of the premises on which the learned intermediary doctrine rests” (id. at 1256) and thus created an exception to the learned intermediary doctrine.

After Perez, some commentators proclaimed the end of the learned intermediary doctrine as we once knew it. But eight years after Perez was decided, “no state [had] joined New Jersey” in adopting the DTC-advertising exception to the learned intermediary doctrine. E.g., Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006) (citing cases). See also In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 811–813 (E.D. Tex. 2002) (“New Jersey law is in direct conflict with the law of every other jurisdiction in the United States”). Most considered Perez to be the exception, not the rule.

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Perez now has company. The West Virginia Supreme Court’s recent opinion in State ex rel. Johnson and Johnson v. Karl, et al., No. 33211, 2007 W. Va. LEXIS 57 (W. Va. June 27, 2007), promises to rekindle debate about whether the learned intermediary doctrine can survive in a world with DTC advertising. That case involved a wrongful death lawsuit filed by the estate of a woman who had been prescribed Propulsid and died three days after she began taking the drug. The defendant manufacturer, through a petition for writ of prohibition before trial, sought to overturn the trial court’s failure to adopt the learned intermediary doctrine. The West Virginia Supreme Court denied the writ. In so doing, the court held that “manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers” and declined “to adopt the learned intermediary exception to this general rule.” Id. at *55. The court borrowed heavily from the New Jersey Supreme Court’s analysis in Perez, noting that “significant changes” have postdated the adoption of the learned intermediary doctrine in many states, including “the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information.” Id. at *30–31.

Detractors of DTC advertising persist. Critics continue to argue that DTC advertisements typically do not support major public-health issues, in that the majority of these ads focus on expensive drugs for bothersome, incurable conditions such as toenail fungus or acid reflux. Others assert that DTC advertising needlessly increases health-care spending by encouraging patients to insist on expensive name-brand medications they have seen on television rather than equally effective generic brands. Still others point to the large numbers of FDA warning letters issued to pharmaceutical companies regarding DTC advertising and conclude that these advertisements mislead many consumers.

The focus on DTC advertising has spilled over to legislative and regulatory bodies. Congress is considering legislation that would give the FDA additional authority to impose tighter safety requirements on drugs once they go to market, including heavy restrictions on consumer advertising. For example, the Senate recently passed Senate Bill 1082, the Prescription Drug User Fee Amendments of 2007, by a 93-1 vote. Among other things, the bill grants the FDA increased power to oversee DTC advertisements and authorizes the imposition of civil fines of up to $300,000 for manufacturers that disseminate false or misleading advertising. While it is unclear at this point what the final legislation will entail with regard to DTC advertising, most agree that the eventual new law will strengthen FDA oversight of DTC advertising in many ways.

States, too, are focused on legislation to restrict DTC advertising. California, for instance, has proposed various bills that would, among other things, require manufacturers of drugs for life-threatening chronic conditions to pay the California Department of Health services a rebate equal to the costs of marketing the drug. Another bill would have prohibited the Department from entering into a contract to purchase a drug or placing the drug on the Medi-Cal contract drug list if the product had been advertised in California via DTC advertising. While these measures failed, California did pass a resolution requesting that the FDA aggressively monitor and regulate DTC advertising of prescription drugs by pharmaceutical companies and urging the President and Congress to ban DTC advertising. See California Assembly Joint Resolution 49 (Rep. Nation) (2006). Numerous states also have attempted to require pharmaceutical companies to disclose their DTC-advertising spending. Such measures have been successful in Vermont, Maine, Minnesota, West Virginia, and the District of Columbia as well as California.

**IMPACT OF DTC-ADVERTISING TRENDS ON PRODUCT LIABILITY LITIGATION**

Increased federal and state regulatory oversight and additional reporting requirements no doubt will increase financial and administrative burdens for pharmaceutical companies that promote products through DTC advertising. But this trend may benefit manufacturers as well. Detailed FDA regulations on DTC advertising, including such things as preapproval of advertisements, strengthen a manufacturer’s federal preemption defense in failure-to-warn product liability lawsuits, even in jurisdictions that may have declined to adopt the learned intermediary doctrine. *E.g.*, Perez, 734 A.2d at 1259 (*For all
practical purposes, absent deliberate concealment or non-disclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.

In addition to federal preemption, compliance with governing federal regulations, in some jurisdictions, provides for manufacturer immunity or a rebuttable presumption of nondefectiveness in product liability lawsuits. E.g., Tex. Civ. Prac. & Rem. Code § 82.007 (providing for rebuttable presumption that a manufacturer is not liable for failure to warn if labeling and warnings are compliant with FDA regulations); Mich. Comp. Laws § 600.2946(5) (providing that a prescription drug is presumptively not defective if compliant with FDA regulations, subject to limited exceptions).

Pharmaceutical manufacturers should consider, at a minimum, implementing two “best practices” to maximize the effectiveness of FDA compliance in future lawsuits premised on DTC advertisements. First, manufacturers should thoroughly document the FDA review and approval process for DTC advertisements. Among other things, this ensures that compliance evidence is readily available for affirmative use in failure-to-warn lawsuits that implicate the advertisement. Second, manufacturers should continue to emphasize both in warnings to physicians and in DTC advertisements that DTC advertisements do not in any way intend to replace the necessary physician/patient consultation or risk/benefit analysis required before any drug is prescribed for a patient.

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