Keeping Focus

By Joshua D. Greenberg

If advocates concentrate on the critical fact that physicians determine whether patients are allowed to purchase prescription drugs, it is likely that more courts will join the consensus that there is no exception to the LID for DTC advertising.

The Learned Intermediary Doctrine and Direct-to-Consumer Advertising

This article examines courts’ decisions on the extent to which direct-to-consumer (DTC) advertising affects application of the learned intermediary doctrine (LID) to pharmaceutical manufacturers for failure-to-warn claims. First, the article provides background on the LID, focusing on the reasons for its nearly universal adoption. The article then summarizes a New Jersey Supreme Court decision that created an exception to the LID for situations where a pharmaceutical manufacturer engaged in DTC advertising. The next section shows that the New Jersey Supreme Court’s decision is an outlier. The article then examines two other outliers—decisions by the highest court in West Virginia and by a federal district judge in New Mexico that widespread DTC advertising of pharmaceutical products eliminates the rationale for the LID entirely, not only in cases involving a product that was advertised directly to consumers. The article continues by considering recent decisions, including two within the past year, that decline to rule that DTC advertising affects application of the LID. Next the article demonstrates that the three prior cases that issued such rulings are bad decisions that should not be followed, as DTC advertising does not undermine the reasons for the LID. The article then explains that certain materials designed for consumers do not constitute DTC advertising, and therefore should not affect application of the LID even in jurisdictions that recognize an exception for DTC advertising. The article concludes that although the effect of DTC advertising on the LID remains an open issue in a surprisingly large number of jurisdictions, the consensus that no such effect exists is likely to grow if advocates keep the focus on prescribing physicians’ critical roles.

Background on the Learned Intermediary Doctrine

The LID provides that a pharmaceutical manufacturer that adequately warns physicians who prescribe its product cannot be held liable for failing to warn patients directly. The LID recognizes that prescription pharmaceutical products are funda-
mentally different from ordinary products in two ways. These differences are so compelling that virtually every jurisdiction in the United States has adopted the LID.

First, a consumer can select, buy, and use an ordinary product without anyone else’s approval. In contrast, the law requires a licensed physician to approve a patient’s use of a prescription pharmaceutical product to be provided on a patient-specific basis. A physician’s medical expertise is required to determine which parts of the complicated information in the labeling for a prescription pharmaceutical product are relevant to a particular patient. As the U.S. Court of Appeals for the Fourth Circuit has observed, “the information regarding risks is often too technical for a patient to make a reasonable choice.” *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999) (internal quotation marks omitted). Moreover, without individualized medical judgments on which warnings are appropriate for patients, the flood of warnings that appear in the labeling for prescription pharmaceutical products would scare many patients into not using the products. As the Kentucky Supreme Court has explained, “since the typical manufacturer’s warning provides a list with scores of potential side effects, no matter how minute the possibility of occurrence, the lay consumer might overreact to such warnings and forego beneficial, or even vital, medical treatment.” *Larkin v. Pfizer*, 153 S.W.3d 758, 764 (Ky. 2004).

Courts do not distinguish between prescription drugs and medical devices for purposes of the LID. For simplicity, this article refers to these products collectively as “pharmaceutical products” or “prescription drugs.”

**The New Jersey Supreme Court Creates an Exception for DTC Advertising**

In *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. 1999), by a vote of five to two, the New Jersey Supreme Court held that the LID does not apply when a pharmaceutical manufacturer markets its products directly to consumers. *Id.* at 1254–57. Relying on law review articles and comments to support its conclusion, the New Jersey Supreme Court determined that DTC advertising of pharmaceutical products “belies each of the premises on which the learned intermediary doctrine rests.” *Id.* at 1256. Among other things, the court reasoned that DTC advertising leads patients to play more active roles in their healthcare decisions, thereby “invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used.” *Id.* (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 Wm. Mitchell L. Rev. 931, 956 (1993)). The court also asserted that DTC advertising interferes with the physician-patient relationship by encouraging patients to request advertised products by name. *Id.* In addition, the court maintained that DTC advertising rebuts the notion that the characteristics of such products are too complex to be communicated effectively to lay consumers. *Id.*

**The New Jersey Supreme Court’s Decision Is an Outlier**

Before *Perez*, it seems that only two courts in the nation had decided whether the LID has an exception for DTC advertising. Both answered the question in the negative. First, a federal district court in Oregon ruled that “despite any promotion aimed directly at consumers, the physicians of [the plaintiffs] exercised ‘individualized medical judgment’ justifying application of the learned intermediary doctrine.” *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989). Second, the U.S. Court of Appeals for the Fifth Circuit held that DTC advertising does not justify an exception to the LID because “as long as a physician-patient relationship exists, the learned intermediary doctrine applies.” *In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999).

For eight years after *Perez*, other courts consistently declined to recognize an exception to the LID for DTC advertising. For example, an appellate court in Pennsylvania explained that DTC advertising of pharmaceutical products “does not enhance the public’s ability to acquire them, as the skill and knowledge of the physician still must be brought to bear in a determination of whether the pharmaceutical is appropriate to the condition of the patient.” *Lennon v. Wyeth-Ayerst Labs, Inc.*, No. 1793 EDA 2000, 2001 WL 755944, at *2 (Pa. Super. Ct. June 14, 2001). A trial court in that Commonwealth similarly reasoned that “although [the manufacturer] engaged in direct-to-consumer advertising, the consumer still required a prescription from a physician, a learned intermediary, to acquire [the medication].” *Albertson v. Wyeth Inc.*, Nos. 02–2944 (Aug. Term), 02–0007 (Aug. Term) & 02–0935
assertions in Perez and in a number of law review articles. See id. Despite its focus on DTC advertising, the court announced that its ruling governs all prescription drugs, regardless of whether or not they were advertised. See id. at 914.

In Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174 (D.N.M. 2008), a federal judge in New Mexico predicted that the New Mexico Supreme Court would not adopt the LID. Id. at 1214–24. Although the State’s intermediate appellate court had issued three opinions recognizing the LID and the overwhelming majority of courts nationwide had likewise adopted the LID, the judge insisted that the New Mexico Supreme Court “would be more persuaded by the analysis in [Karl].” Id. at 1217. This is so, the judge asserted, because of the dramatic increase in DTC advertising in recent years. Id. at 1217–18, 1222 n.5.

Recent Decisions Decline to Rule that DTC Advertising Affects the LID

During the nearly five years since Rimbert was decided, no court has recognized a DTC exception to the LID or rejected the LID in a decision that was upheld on appeal. In contrast, several courts have declined to rule that DTC advertising affects application of the LID.

Most recently, in In re Avandia Marketing, Sales Practices and Products Liability Litigation, MDL No. 1871, Civ. A. No. 10–2401, 2013 WL 3486907 (E.D. Pa. July 10, 2013), a federal district court in Pennsylvania followed the state-court decisions in Lennon and Albertson and held that there is no exception to the LID for DTC advertising. Id. at *2. The court explained that the plaintiff “could not obtain [the drug] without a physician’s prescription.” Id.

In DiBartolo v. Abbott Laboratories, ___ F. Supp. 2d ___, No. 12 Civ. 900(NRB), 2012 WL 6681704 (S.D.N.Y. Dec. 21, 2012), a federal district court in New York rejected the plaintiff’s argument that the defendant manufacturer’s “extensive marketing in the public domain” of the drug at issue warranted an exception to the LID. Id. at *8–9. The court explained: “Even in a world with widespread DTC advertising… physicians continue to fulfill the core functions that underlie [the LID]: they ‘evaluate a patient’s needs, assess the risks and benefits of available drugs and then prescribe a drug, advising the patient of its risks and possible side effects.’” Id. at *9 (quoting Wolfgruber v. Upjohn Co., 423 N.Y.S.2d 95, 96 (N.Y. App. Div. 1979)).

In another case decided last year, the Texas Supreme Court held that an intermediate appellate court in that State “erred by creating an exception to the learned intermediary doctrine for direct-to-consumer

Two More Outliers Reject the LID Entirely Based on DTC Advertising

In State ex rel. Johnson & Johnson Corp. v. Karl, by a vote of three to two, the highest court in West Virginia declined to adopt the LID. 647 S.E.2d 899, 901, 914 (W. Va. 2007). No other state supreme court in the nation has taken this position. The West Virginia Supreme Court of Appeals based its decision primarily on the “proliferation of drug advertising” since 1997, “especially the impact direct-to-consumer advertising has had on the physician/patient relationship.” Id. at 908–09. According to the court, DTC advertising of prescription drugs “obviates each of the premises upon which the [LID] rests” and warrants rejecting the doctrine in its entirety. Id. at 910. The court did not offer any concrete evidence to justify this conclusion. See id. at 907–14. Instead, the court relied on the

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Although the Texas Supreme Court did not foreclose recognizing a DTC advertising exception in a future case, see id. at 162, it indicated that it was skeptical of doing so. It stated that “patients who seek prescription drugs based solely on DTC advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient.” Id. at 163. The court further stated that despite the increased use of DTC advertising by pharmaceutical manufacturers, “the fundamental rationale for the [LID] remains the same: prescription drugs require a doctor’s prescription and, therefore, doctors are best suited to communicate the risks and benefits of prescription medications for particular patients through their face-to-face interactions with those patients.” Id. at 164.


The Cases Holding that DTC Advertising Affects the LID Are Unpersuasive and Should Not Be Followed

Perez, Karl, and Rimbert are bad decisions that courts should not follow. DTC advertising does not warrant an exception to the LID, much less rejecting the LID entirely. DTC advertising does not change the primary rationale for the LID: the fundamental fact that a patient cannot legally obtain a prescription drug without a physician’s approval. That a patient asks her physician to prescribe a drug that she saw advertised on TV does not vitiate the physician’s independent medical judgment—and duty—in deciding whether that drug is appropriate for that patient. As the DiBartolo court recognized, “although it may be true that DTC advertising encourages patients to ask specifically for the advertised drug, a physician who prescribed a drug to a patient simply based on the patient’s request, without an individualized medical assessment, would likely be liable for malpractice. In such a situation, a failure-to-warn claim against the manufacturer would raise a serious issue of causation.” DiBartolo, ___ F. Supp. 2d ___, 2012 WL 6681704, at *9 (citation omitted). Similarly, the Texas Supreme Court observed in Centocor that “[t]he court of appeals’ reasoning that the new era of DTC advertising relegates physicians to a mere dispensary role of prescriptions fails to consider the important professional and ethical standards the law requires of physicians.” Centocor, 372 S.W.3d at 162 n.24. The law regarding the LID should not be premised on an assumption that physicians are routinely committing malpractice by acquiescing in patients’ requests for prescriptions without making independent medical judgments as to the propriety of those prescriptions.

Moreover, the Perez, Karl, and Rimbert courts did not cite any study on the effects of DTC advertising—let alone one that supports their rulings. The available evidence contradicts those courts’ assumptions that DTC advertising negatively affects physician-patient relationships so that physicians no longer make individualized medical judgments before prescribing drugs for their patients. The FDA’s most recent study on the subject found that DTC advertising does not lead patients to heavily pressure their physicians to prescribe advertised drugs. Of the 500 physicians surveyed for the study, only “[e]ight percent… said they felt very pressured to prescribe the specific brand-name drug when asked.” FDA, The Impact of Direct-to-Consumer Advertising, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm (last updated Apr. 12, 2013). Further, “the vast majority (91 percent) of physicians reported that the patient did not try to influence the interaction in a way that would have been harmful to the patient.” FDA, Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results 91 (Nov. 19, 2004), available at http://www.fda.gov/downloads/Drugs/ScienceResearch/ ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf. Whereas DTC advertising does not interfere with physician-patient relationships, it does yield tangible health benefits. The FDA study found that “when a patient asked about a specific drug, 88 percent of the time they had the condition that the drug treated.” FDA, The Impact of Direct-to-Consumer Advertising, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm (last updated Apr. 12, 2013) (discussing study released in November 2004). The overwhelming majority of patients who respond to DTC advertisements by asking their physicians about a specific drug thus have the condition that the drug treats. Such inquiries facilitate, rather than interfere with, physicians’ prescribing decisions. The assumptions underlying Perez, Karl, and Rimbert are incorrect.

Patient Brochures, Informed Consent Forms, and Medication Guides Are Not Direct-To-Consumer Advertising

If you are litigating a case in a jurisdiction that recognizes an exception to the LID for DTC advertising (New Jersey is currently the only such jurisdiction), keep in mind that certain communications from pharmaceutical manufacturers that are designed to reach patients do not count as DTC advertising. For example, the FDA permits patient brochures, informed consent forms, and medication guides. These are not DTC advertising and are not subject to the LID. If you are litigating a case in a jurisdiction that recognizes an exception to the LID for DTC advertising (New Jersey is currently the only such jurisdiction), keep in mind that certain communications from pharmaceutical manufacturers that are designed to reach patients do not count as DTC advertising and are not subject to the LID.
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not fall within that exception. Specifically, patient brochures distributed by physicians, informed consent forms, and medication guides are not DTC advertisements.

In *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229 (N.J. App. Div. 2006), the plaintiffs argued that the defendant pharmaceutical manufacturer engaged in DTC advertising by giving physicians brochures for them to make available to their patients and by having patients sign an informed consent form. *Id.* at 1236–37. A New Jersey appellate court ruled that the plaintiffs “read *Perez* too broadly.” *Id.* at 1236. The court concluded that “the placement of informational brochures in a physician’s office cannot fairly be equated with a course of mass advertising or be deemed direct-to-consumer advertising so as to remove the predicates of the learned intermediary doctrine.” *Id.* The court supported its conclusion by citing an FDA regulation that designates such materials as labeling rather than advertising. *Id.* (citing a regulation that is now codified at 21 C.F.R. §202.1(d)(2)). The informed consent form likewise was not DTC advertising, as it was merely “intended to memorialize the information supplied to the patient by the prescribing physician.” *Id.* at 1237.

With respect to medication guides, the FDA has stated that providing them should not affect application of the LID, as “courts have not recognized an exception to the ‘learned intermediary’ defense in [other] situations where FDA has required patient labeling.” FDA, *Prescription Drug Product Labeling; Medication Guide Requirements*, 63 FR 66378–01, 66384 (Dec. 1, 1998). There appears to be no case addressing whether the LID applies when a pharmaceutical manufacturer has provided a medication guide. The LID should apply with full force in this context. Medication guides are designed to provide risk information to patients who have already been prescribed a medication, not to promote the use of a medication. See FDA, *Medication Guides*, http://www.fda.gov/drugs/drugsafety/ucm085729.htm (last updated May 16, 2013) (“Medication Guides are paper handouts that come with many prescription medicines.”). Medication guides thus are not a form of DTC advertising.

Conclusion

Given the frequency with which prescription drugs are advertised directly to consumers, it is surprising that courts in the overwhelming majority of jurisdictions have not specifically addressed whether the LID has an exception for such advertising or whether such advertising warrants jettisoning the LID entirely. Of the relatively small number of courts that have decided these issues, a clear majority have held that DTC advertising does not affect application of the LID. Predictions that outlier rulings like *Perez*, *Karl*, and *Rimbert* would spark a trend in the opposite direction have proven mistaken. Recent opinions provide further support for the consensus that there is no exception to the LID for DTC advertising. If advocates keep the focus on the critical fact that physicians determine whether patients are allowed to purchase prescription drugs, it is likely that more courts will join that consensus in the future.