The Future of Drug Warnings: REMS, Medication Guides, and the (Potential) Erosion of the Learned Intermediary Doctrine

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I. Introduction

For most of us, a foundational aspect of drug litigation has been that pharmaceutical manufacturers’ primary risk communication responsibility is to prescribers — physicians and other healthcare providers who are known as “learned intermediaries.” As that term suggests, these intermediaries are considered the filter through which benefit and risk information flows, making decisions and recommendations for their patients.

The FDA, however, may have different ideas about how the relationships among pharmaceutical companies, prescribers, and patients should look. In recent years, triggered in part by broader congressionally allocated authority to require Risk Evaluation and Mitigation Strategies (“REMS”), the FDA has signaled an interest in scrutinizing and broadening how and when drug companies communicate risks and benefits directly to patients. Approximately 80 drugs are under the REMS program and over 200 drugs presently have a patient-directed Medication Guide, and that number is growing. Approved Risk Evaluation and Mitigation Strategies (REMS), U.S. Food and Drug Administration, http://www.accessdata.fda.gov/scripts/cder/rem/s/index.cfm (last visited Mar. 22, 2016).

Recently, the FDA issued a report on standardizing and evaluating REMS programs, discussing planned research by the FDA on improving current counseling of patients on the risks and benefits of prescription drugs and to develop and improve content, format, processes, techniques, tools and delivery of effective patient counseling through REMS programs and Medication Guides. Report: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS), U.S. Food and Drug Administration (September 2014), available at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM415751.pdf [hereinafter Report: Standardizing and Evaluating REMS].

Most notably, the FDA made groundbreaking changes to warnings for a particular drug via a patient brochure, including pictures of significant adverse events associated with the drug, an extraordinary departure from the traditional textual method of providing warnings.

This paper discusses this recent FDA activity and possible long-term effects these changes may have on the continued viability of the Learned Intermediary Doctrine (LID). As the FDA broadens the scope of patient-oriented communications, plaintiffs’ lawyers will no doubt argue that it reflects a new reality, a reality that should include the doctrine’s elimination.

II. REMS Background

The pharmaceutical industry has traditionally been focused on making sure that the product labeling contains all the necessary information required by existing regulations. This includes information about a product’s risks and benefits, its indications, adverse event profiles, warnings, and at times, counseling information for patients.

However, this focus started to change gradually following the establishment of Risk Minimization Action Plans (RiskMAPs) in the mid-2000s, Guidance for Industry: Development and Use of Risk Minimization Action Plans, U.S. Food and Drug Administration (March 2005), available at http://www.fda.gov/downloads/RegulatoryInformation/guidances/ucm126830.pdf and the FDA’s authorization pursuant to the Food and Drug Administration Amendments Act of 2007 (FDAAA) to require REMS for prescription drugs.

A. Statutory Provisions

The 2007 FDAAA amended §505-1 of the Federal Food, Drug, and Cosmetic Act (FDCA) and “established FDAs authority to require REMS for prescription drug and biological products when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh the risks.” Report: Standardizing and Evaluating REMS, at 3.

An additional change came in 2012, with the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA), which reauthorized the Prescription Drug User Fee Act (known as the “PDUFA V,” representing its fifth authorization). Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012). This reauthorization strengthened FDA’s regulatory powers by committing the FDA to several tasks, including “measur[ing] the effectiveness of REMS, continu[ing] to develop techniques to standardize REMS, and with stakeholder input seek[ing] to integrate REMS into the existing and evolving health care system.” Report: Standardizing and Evaluating REMS, at 3.

B. REMS Operation and Requirements

Since their establishment, REMS have become an important mechanism by which the FDA carries out its oversight authority because “[o]nce approved, the REMS document and appended materials serve as the basis for monitoring and enforcement of a sponsor’s compliance with REMS requirements.” Report: Standardizing and Evaluating REMS, at 10. Among the tools now at the disposal of FDA are:

- Requiring the submission of a proposed REMS for new drug applications (NDAs), abbreviated new drug applications (ANDAs), or biologics license applications (BLAs) when FDA deems it necessary;
- Requiring the submission of a proposed REMS if new, post-approval safety information arises for NDAs, ANDAs, and BLAs; and
- Applying a timeframe for assessing the effectiveness of a product’s REMS with minimum assessment frequencies at eighteen months, three years, and seven years after initial approval of the REMS.


Perhaps the most common and visible component of a REMS is the addition of a Medication Guide to prescription information, which is a consumer-directed “plain English” description of the product. However, REMS can include many other components, such as:

- A communication plan for health care providers;
- A requirement that a Medication Guide or patient package insert be developed; and
- Elements to assure safe use (ETASU), which aims to reduce any serious risks of the drug by potentially requiring “health care provider training or certification; certification of pharmacies, providers, or health care settings; restricting dispensing to certain health care settings (as in hospitals or infusion centers) or with evidence or other documentation of safe-use conditions (such
as liver enzyme tests or pregnancy tests); patient monitoring, and/or that patients using the drug be enrolled in a registry.”


Additionally, it is important to note that REMS are not set in stone. Companies may be absolved of specific REMS requirements as certain safety concerns are resolved. The implementation of REMS, however, has clearly given FDA another regulatory tool. Over 200 REMS have been approved since their enactment in 2007. Report: Standardizing and Evaluating REMS, at 10.

### III. Recent FDA Actions and Developments

In September 2014, the FDA reported on standardizing and evaluating the current process for REMS. The FDA proposed to investigate, among other things, the tools through which patient benefit/risk information was provided during prescriber-to-patient counseling under REMS. Part of the issue seems to be that when patients were being recommended drugs with a REMS, the FDA was concerned they were perhaps not receiving sufficient risk information – information that the FDA believed could be valuable in making a decision about whether to initiate or continue the treatment. Given the individualized nature of medical treatment, however, the Agency did caution that it was simply preparing a report on general improvements to REMS patient counseling tools and that it would not dictate precisely what information should or should not be shared with the patient. Report: Standardizing and Evaluating REMS, at 10.

Additional motivation for this action stems from concern that REMS programs may deter some prescribers and patients from pursuing certain treatment merely because that drug has a REMS. Report: Standardizing and Evaluating REMS, at 18–19. Additionally, the FDA recognized that patients “may vary in their ability to receive, understand, recall, and act upon all of the instructions provided by their health care providers during a single counseling session.” Report: Standardizing and Evaluating REMS, at 20. As a result, the actions proposed by the FDA include:

- “Research existing REMS tools, counseling initiatives, programs and the literature for evidence of counseling tools, processes, techniques and attributes that support effective education of patients regarding products with REMS;
- Seek information from internal and external stakeholders and experts on effective counseling processes, practices, techniques, tools, attributes and opportunities for improving upon existing REMS counseling tool content, format, techniques, instructions, processes and implementation;
- Seek input to identify sources of reliable medical information for patients to use, and
- Synthesize findings and publish a report.”


This initiative is designed to explore how to best facilitate the communication of accurate risk information to consumers through their interactions with their health care providers. Report: Standardizing and Evaluating REMS, at 20.

However, the FDA’s interest in the information received directly by the patient is also evident in the agency’s other actions. For example, the FDA notes that it is currently looking at approaches to structured patient benefit/risk assessments and providing additional information directly to patients through Patient...
Medication Information (PMI) inserts that are attached to product labels. Report: Standardizing and Evaluating REMS, at 20. These recent actions by the FDA and its concern regarding the information received and understood by patients is a development worth monitoring.

IV. Case Study: Prolia Patient Brochure Research

In its September 2014 report on REMS, FDA itself suggested a paradigm shift for drug communications, recognizing the ongoing shift towards communicating directly with patients, at least in some cases:

Historically, FDA’s primary vehicle for communicating benefit and risk information regarding a product has been through approved labeling that describes a product’s indication(s), adverse event profile, and warnings, and that also provides counseling information for patients. In some circumstances, when FDA determines a REMS is necessary to ensure a product’s benefits outweigh its risks, FDA may determine that additional patient and/or health care provider communications, training, certification, and/or other restrictions are also required as part of the REMS.

Feedback from stakeholders suggests that when treatment with a drug with a REMS is recommended, patients would value having information to improve their understanding about the product’s serious risks, thereby facilitating more informed decisions (made together with their health care providers) regarding whether to initiate or maintain such a therapy. Since patient-directed information should ideally be conveyed to patients in the form of counseling by their health care provider, effective techniques and tools supporting appropriate provider-to-patient counseling about both risks and benefits would be useful.


Of note, the FDA’s statement does not suggest an abandonment of the primary role of the prescriber, emphasizing that the decision to take a medicine is made in consultation with prescribers, and that the information “should ideally be conveyed to patients in the form of counseling by their health care provider.” Report: Standardizing and Evaluating REMS, at 17. At the same time, though, the thrust is clear that the FDA’s business is no longer limited to communicating with prescribers; the consumer is part of its audience as well.

The following year – in May of 2015 – the FDA approved an update to the REMS with Prolia, a drug indicated for osteoporosis and various other bone-related uses. Letter from Christine P. Nguyen, MD, Deputy Director for Safety, to Julia Zhu, Senior Associate, Regulatory Affairs (May 21, 2015), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125320Orig1s162ltr.pdf. Apparently, as part of the FDA’s initiative to research existing REMS patient counseling tools to measure the effectiveness of patient counseling, it was determined that patients being prescribed Prolia were not understanding the potential side effects of osteonecrosis of the jaw and unusual thigh bone fractures that have been reported with the use of Prolia, even though those adverse events have been reported in both the prescribing information and the patient materials for some time. Accordingly, FDA and Amgen used this information to design an innovative way to portray these side effects through images.

In the 2015 updated REMS, the FDA approved a new patient counseling guide and a patient brochure with images representing the adverse events. For example, the following image appears in both:
With the exception of some small images used to discourage pregnancy in teratogenic drugs, these images appear to be novel in their attempt to capture the attention of consumers and, arguably, to increase their role in making the decision whether or not to take a medicine.

No doubt plaintiffs’ lawyers will present these actions by the FDA as undercutting the learned intermediary doctrine, and seek to have juries evaluate not just the prescriber-oriented labeling, but also the materials directed at patients. But recall that these materials are in what the FDA calls a “Patient Counseling Toolkit,” suggesting that the materials are not intended to be reviewed by patients in a vacuum, but instead to be tools for prescribers, to help them in discussing the risk/benefit decision with their patients.

And patients have always played a role in the decision to take a medicine – and always in consultation with their prescribers. The FDA’s efforts to provide prescribers with more tools to facilitate that decision does not change the intermediary nature of prescribers in the manufacturer-consumer relationship. And the FDA’s efforts should not be interpreted as eliminating, or even as inconsistent with, the learned intermediary doctrine.

V. Learned Intermediary Impact

For many of us, the learned intermediary doctrine (LID) serves an important role as we develop our case strategies. The doctrine itself was recognized as early as the 1940s, Marcus v. Specific Pharmaceuticals, Inc., 77 N.Y.S.2d 508 (N.Y. Special Term 1948), with the term “learned intermediary” starting to appear in the 1960s. Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). Perhaps the most important rationale for the LID is that a patient’s physician is in the best position to determine whether a particular prescription drug is the best course of treatment for a patient. The physician has the medical expertise as well as knowledge regarding the patient’s medical condition in order to make this individualized determination. “Generally speaking, only a physician would understand the propensities and dangers involved [with using a drug].” Gravis v. Parke-Davis & Co., 502 S.W.2d 863, 870 (Tex. Civ. App. 1973). This rationale has been recognized by numerous courts throughout the years.

For example, in Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), a father brought suit against the drug manufacturer after his daughter developed polio after receiving the oral polio vaccine that contained the live polio virus. On the issue of Wyeth’s duty to warn, the court stated:
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. *Reyes*, 498 F.2d at 1276.

Similarly, in *West v. Searle & Co.*, 806 S.W.2d 608 (Ark. 1991), the Arkansas Supreme Court also noted the important role played by the physician and the reliance of patients on a physician’s judgment in the context of prescription drugs. The plaintiff had used a birth control medication that was alleged to have caused a benign liver tumor that subsequently ruptured. Evaluating the plaintiff’s duty to warn claim, the court found the LID persuasive in this instance because in this situation, “a physician must prescribe the drug, the patient relies upon the physician’s judgment in selecting the drug, and the patient relies upon the physician’s advice in using the drug.” *West*, 806 S.W.2d at 613.

In addition to the reason set forth above, courts have also recognized other rationales behind the LID and have summarized the reasons as follows:

1. When compared to the manufacturer, prescribing physicians are in a superior position to warn patients and can provide an independent medical decision as to whether the drug or medical device in question is appropriate for the patient’s treatment.
2. Manufacturers generally lack effective ways to communicate directly with each patient.
3. Imposing a duty to warn upon the manufacturer under these circumstances would unduly interfere with the physician-patient relationship.


In recent decades, however, the LID has come under greater scrutiny by courts. This evolving trend has been due, in part, to the changing medicine and pharmaceutical industries and the methods by which drug manufacturers advertise and promote their prescription drugs to consumers. Indeed, courts were beginning to recognize as early as 1983 that the industry was undergoing changes. *See Logan v. Greenwich Hosp. Ass’n*, 465 A.2d 294, 299 (Conn. 1983) (“Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the 'doctor knows best.’”). At least one state has adopted an exception to the LID in cases where the prescription drug or device manufacturer engaged in direct marketing to the consumer. *See discussion infra* on New Jersey. Given the FDA’s recent focus on consumer understanding of warnings, could it be possible that more courts will re-evaluate their adoption of the LID?

### A. New Jersey

One state that has reconsidered, and altered, the scope of the LID is New Jersey. In *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999), the New Jersey Supreme Court evaluated claims against Norplant, a FDA-approved contraceptive that prevents pregnancy for up to five years. Norplant consisted of six small capsules that would be implanted under the skin of a woman’s upper arm during an in-office surgical procedure. Removal of the capsules occurs in the similar manner. Plaintiffs’ principal contention was that Wyeth had failed to adequately warn about the side effects associated with the contraceptive. The legal issue was whether the LID applied to plaintiffs’ claims against the drug manufacturer. Prior to the plaintiffs’ appeal
to the New Jersey Supreme Court, both the New Jersey trial court and appellate division held that the LID still applied to Wyeth.

In its evaluation of the plaintiffs’ claims and the LID, the New Jersey Supreme Court extensively discussed the changes in the medical field, especially the emerging trends with direct-to-consumer advertising. It noted that “almost all pharmaceutical companies have engaged in this direct marketing practice,” and specifically described advertisements for products ranging from Rogaine to the allergy medication, Claritin. Perez, 734 A.2d at 1251 (internal quotations omitted). Although the court recognized the existing rationales behind the LID, it found that they do not carry the same weight when considered in the context of direct-to-consumer marketing, writing that

the ‘Norman Rockwell’ image of the family doctor no longer exists. Informed consent requires a patient-based decision rather than the paternalistic approach of the 1970s. The decision to take a drug is not exclusively a matter for medical judgment. Second, because managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug. . . . Third, having spent $1.3 billion on advertising in 1998, drug manufacturers can hardly be said to lack effective means to communicate directly with patients when their advertising campaigns can pay off in close to billions in dividends. Id. at 1255–56 (internal quotations and citations omitted).

The New Jersey Supreme Court continued:

First, the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used. Second, it is illogical that requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name. Finally, consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers. Id. at 1256 (citing 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) (footnotes omitted)) (emphasis added).

Accordingly, given the increasing role of patient choice in medicine and the effects of direct-to-consumer marketing, the New Jersey Supreme Court concluded that the LID does not apply to the direct marketing of drugs to consumers.

**B. West Virginia**

In 2007, the Supreme Court of Appeals of West Virginia was faced with the legal question of whether to adopt the LID in State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007). At issue was the drug Propulsid, which was manufactured and distributed by Janssen Pharmaceuticals, a wholly-owned subsidiary of Johnson & Johnson. The court ultimately declined to adopt the LID in West Virginia. In reaching its conclusion, the court also found many of the reasons proffered by the New Jersey Supreme Court’s decision in Perez to be persuasive.

More specifically, the court found the justifications for the LID “to be largely outdated and unpersuasive,” Karl, 647 S.E.2d at 906, because of significant changes in the drug industry, “specifically . . . 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 907. The court found these changes “to be a significant factor in deciding whether to adopt the LID, especially the impact direct-to-consumer advertising has had on the physician/patient relationship.” Id. at 909. In particular, the court noted that direct-to-consumer advertising has resulted in patients taking a larger role in deciding which medications to use. For example, “physicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised. . . . [T]he advertisements [also] encourage lay people to make self-diagnoses by listing symptoms and suggesting the viewer may have the condition that the drug can treat.” Id. (citing Tamar V. Terzian, Note, Direct-to-Consumer Prescription Drug Advertising, 25 Am. J.L. & Med. 149, 157-58 (1999), and Ozlem A. Bordes, The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?, 81 U. Det. Mercy L. Rev. 267, 280-81 (2004)).

Earlier this year, however, the West Virginia legislature enacted new legislation that effectively negates the West Virginia Supreme Court’s decision in Karl. Senate Bill 15, signed into law on February 26, 2016, creates a new provision in the West Virginia Code §55-7-30. 2016 W. Va. Laws S.B. 15. The provision states the Legislature’s intent “to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices.” Id. The bill goes into effect on May 17, 2016, but its impact on pending litigation remains unclear. Id.

C. Arizona

Recently, Arizona courts were also presented with the opportunity to reconsider the states’ application of the LID. In Watts v. Medicis Pharmaceutical Corp., 342 P.3d 847 (Ariz. Ct. App. 2015), the Court of Appeals of Arizona considered whether the LID generally applies to a prescription drug manufacturer. The case involved the drug Solodyn, which is manufactured by Medicis and is used to treat acne. The plaintiff had been prescribed Solodyn on two separate occasions and had taken Solodyn for twenty weeks each time. She was subsequently diagnosed with drug-induced lupus and hepatitis, allegedly as a result of her use of Solodyn.

The plaintiff alleged that she did not receive the full prescribing information, which stated that long-term use of the drug has been associated with drug-induced lupus and hepatitis, from her medical provider. She did, however, receive information about Solodyn from two other sources. One was a “MediSAVE” card given to her from her medical provider that included information noting that “the safety of using Solodyn longer than 12 weeks has not been studied and is not known.” Second, the plaintiff received an informational insert from her pharmacist that warned patients to consult a doctor if the symptoms did not improve within twelve weeks.

The plaintiff sued Medicis alleging consumer fraud and product liability, claiming that the product was defective and unreasonably dangerous because of Medicis’ failure to adequately warn her of the consequences of long-term use. The trial court granted Medicis motion to dismiss. On appeal, the Arizona Court of Appeals vacated the judgment of dismissal, noting that “the realities of modern-day pharmaceutical marketing” make the rationales behind the LID no longer persuasive. Watts, 342 P.3d at 855. In particular,

[D]rug manufacturers are turning with increasing frequency to direct consumer advertising to promote their products. Consumers are regularly presented with advertisements for medications to treat a variety of symptoms, prompting them to ask, encourage, and even pressure their medical providers to prescribe these brand-name medications. Similarly, Internet sites and medical databases give consumers access to a wealth of third-party and manufacturer-provided information about pharmaceutical products. While it is true that a patient must first receive a prescription from a ‘learned intermediary’ in order to obtain prescription drugs, a physician no longer is
necessarily the consumer’s sole source of information about the effects, benefits, and risks of the medications he or she takes. *Id.*

Importantly, the Arizona Supreme Court recently reversed the Court of Appeals decision, rejecting the contention that the underlying rationale for the LID was no longer viable given the changes in modern-day pharmaceutical marketing. *See* Watts v. Medicis Pharmaceutical Corp., *No. CV-15-0065-PR*, 2016 WL 237777 (Ariz. Jan. 21, 2016). Rather, the Arizona Supreme Court found that “[b]ecause patients can obtain prescription drugs only through their prescribing physician or another authorized intermediary and because the ‘learned intermediary’ is best suited to weigh the patient’s individual needs in conjunction with the risks and benefits of the prescription drug,” the LID applies and “generally limits the drug manufacturer’s duty to warn to the prescribing physician.” *Id.* at *4 (quoting Centocor Inc. v. Hamilton, 372 S.W.3d 140, 159 (Tex. 2012)).

While the lower court decision was overturned, Arizona’s cases demonstrate that there are courts which may be persuaded by the changes in modern-day pharmaceutical marketing and the FDA’s possible shifts in how it expects industry to interact with consumers.

These decisions from New Jersey, West Virginia, and Arizona show that some courts are at least willing to consider the modern-day changes in the pharmaceutical industry and the impact the changes have had on sources of information for patients and in turn, the LID. With the proliferation of direct-to-consumer advertising and numerous online sources, patients have more resources today to be informed about the medications they take than ever before. As demonstrated by the decisions referenced above, the presumption that the physician is sole or even primary source of information about a prescription medication no longer holds in certain instances.

**VI. Conclusion**

The drug and medical device industry has long focused, appropriately, on communications to medical providers. These “learned intermediaries” served not only as the sole channel through which patients could obtain prescription products, but also as the primary source of information for patients of the products’ risks and benefits. However, the source of such information has changed significantly in recent years, with the advent of the internet and the proliferation of direct-to-consumer advertising by manufacturers. Patients today have more access to information about a prescription drug or medical device than ever before. This change has prompted a reconsideration of the learned intermediary doctrine in certain jurisdictions.

On the regulatory side, the FDA has enacted several amendments to the FDCA over the past decade that have expanded the FDA’s ability to impact the information a consumer receives upon being prescribed medication. In particular, the establishment of the REMS program has emerged as an important tool for the FDA in its continued oversight of drug safety. More significantly, the FDA’s recent initiative to investigate issues related to prescriber-to-patient counseling shows that there is concern with respect to how information is being presented to patients. That said, in the recent example of graphic information provided in the Prolia patient tool kit, the FDA acknowledged that the information was to be presented via a prescriber, not in a vacuum.

What these developments demonstrate is that both the FDA and the courts are becoming more aware of the changes in how and through what channels patients receive information about prescription products. While the full effect of these changes on the learned intermediary doctrine, a valuable and important doctrine for the defense bar, is still unclear, these developments are certainly worth monitoring.