

# A Response to Plaintiffs' Call to Abolish the Learned Intermediary Doctrine

By John A. Camp and Gary M. Pappas

In a recent article on the learned intermediary doctrine in this publication, “Modern Realities Render the Learned Intermediary Doctrine Obsolete” (Winter 2010, Vol. 21, No. 1), Janet Abaray and Erica Kern argue that the advertisement, choice, and delivery of drugs and medical devices in the current health care environment make the doctrine obsolete and actually harmful to consumers. This argument is not based on any new scholarship or jurisprudence. Instead, it is based almost entirely on the rationale and language of the New Jersey Supreme Court’s 1999 decision in *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999), and two subsequent decisions—*State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007) and *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174 (D.N.M. 2008)—rejecting the doctrine. These three opinions have been exhaustively critiqued by scholars and practitioners, and we do not seek to add to those critiques here. Instead, we respond to the authors’ claim that “the learned intermediary doctrine is a myth that harms consumers.”

The authors fail to articulate what the “myth” is—whether it is the doctrine itself, the “Norman Rockwell-style image of the family doctor,” which the authors suggest once justified the learned intermediary doctrine but now no longer exists, or something else altogether. Moreover, they fail to establish just how patients are harmed by a doctrine that requires drug and medical device manufacturers to provide adequate warnings to doctors, the people in the best position to understand and appreciate such warnings and make determinations about them based on the warnings’ contents, the doctors’ independent training, and the patients’ individual needs and medical histories. They also fail

to explain how providing such warnings directly to patients (which is effectively what is being done anyway) would address the alleged harm.

If the alleged harm to consumers is that the doctrine may prevent plaintiffs from recovering from traditionally deep-pocketed defendants, the authors’ argument is both cynical and misguided. First, as discussed below, the learned intermediary doctrine is not a shield against liability. The drug or medical device manufacturer must still provide adequate warnings about all of the risks associated with its prescription product. Under the doctrine, however, such warnings must be provided to the doctor prescribing the product, not the consumer. See, e.g., *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162–63 (4th Cir. 1999). Second, the doctrine actually benefits consumers by mandating that drug and device manufacturers provide warnings to the doctors prescribing their products so those doctors can make educated and fully informed decisions about the best course of treatment for their patients. Doing away with the learned intermediary doctrine, therefore, is more likely to harm consumers because it could remove from the prescription product warning equation the person best suited to assist the consumer-patient in making informed health care choices.

The learned intermediary doctrine derives from the idea that the doctor—the learned intermediary—is in a better position than the patient to understand and weigh the risks and benefits of a particular drug or medical device and make an independent medical decision about whether the drug or device is appropriate for the patient. See, e.g., *Simon v. Wyeth Pharms., Inc.*, 989 A.2d 356, 368 (Pa. 2009); Jerica L. Peters, “*State v. Karl*: An Unreasonable

Rejection of the Learned Intermediary Doctrine,” 48 *Jurimetrics J.* 285, 298–305 (2008). Moreover, the doctor, who is dealing directly with the patient and who knows or has direct access to the patient’s medical history and physical condition, is in the best position to provide the patient with warnings about the risks associated with the drug or device the doctor is prescribing. The authors contend that patients today are “informed and active participants in their health care decisions”; that drug companies advertise directly to consumers; that doctors’ decision making is “constrained by insurance companies and influenced by advertising”; and that, combined, these considerations undermine the doctrine’s underlying rationale. If anything, however, the fact that patients are informed and active participants in their health care decisions and influenced by advertising makes the role of the learned intermediary-physician that much more important. Whatever constraints insurance companies place on doctors or however much doctors are influenced by advertising, doctors still owe a primary and abiding duty to their patients, including warning them of risks and weighing treatment options in light of their independent medical training and each patient’s individual characteristics. If a doctor fails in that duty, the consequence of that failure should not be borne by the manufacturer.

This is not to say that the pharmaceutical manufacturer owes no duty to warn or that its duty to warn is diminished in any way if it is relieved of the obligation to warn consumers directly. To the contrary, under the learned intermediary doctrine, the manufacturer’s warning must still adequately warn of all the risks associated with its product. Instead of owing that duty to warn the patient-consumer

directly, however, the pharmaceutical manufacturer's duty extends only to the physician. As long as the manufacturer has provided adequate information to the physician, it will have discharged its duty to warn. See, e.g., *Baker v. Danek Med. Inc.*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998). Even where there is a factual dispute as to the adequacy of the manufacturer's warranty, if the prescribing physician either understood the warnings or had independent information about the risks, the chain of causation is broken. See, e.g., *Dietz v. SmithKline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010); *Hoffmann-La Roche, Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009). The physician then assumes the duty to advise the patient of the product's risks. Thus, in a failure-to-warn case, if the plaintiff can prove that the warning provided by the pharmaceutical manufacturer to the physician failed to warn adequately of the product's risks, the manufacturer may be held liable.

The learned intermediary doctrine is a commonsense legal doctrine that is almost universally recognized. Prescription drugs and medical devices are unlike other consumer products. See, e.g., *Restatement (Second) of Torts* § 402A cmt. k (1965). As a general notion, when a manufacturer sells a product directly to a consumer, the manufacturer must warn the consumer of the risks associated with its product. This makes sense given a typical product (e.g., a toaster) whose functions and characteristics apply in the same or similar manner to all potential consumers. Prescription medical products, however, are unique, involve highly technical properties, and apply to each patient differently based on his or her physiological makeup and medical history. See, e.g., *Peters, supra*, at 308; Richard B. Goetz & Karen R. Growdon, "A Defense of the Learned Intermediary Doctrine," 63 *Food & Drug L.J.* 421, 437 (2008). Hence, these products can never be sold without a doctor's prescription. Even if such products are widely advertised to potential consumers, the doctor still, by law, fulfills the role of the learned intermediary in determining

whether the product is appropriate for a given patient and, if so, writes the prescription. See *Peters, supra*, at 298–305; Goetz & Growdon, *supra*, at 433–34. In other words, the prescribing physician is integral to the "transaction" between the pharmaceutical company and the consumer. This, of course, is entirely appropriate, in that most patients lack the specialized knowledge, acquired by doctors through years of education and training, necessary to understand the warnings for prescription drugs and devices, because the warnings often contain scientific terms beyond the ken of most consumers, as well as other technical information required by the Food and Drug Administration. Moreover, the doctrine recognizes that communicating warnings to doctors, rather than to consumers, is the most effective means of disseminating such information in a cost-effective and patient-centric manner. Because a prescription is required, there is a guarantee that the patient and doctor must interact in some fashion, thus providing the best opportunity for warnings to be imparted to the consumer. See generally Jennifer Girod, "The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present," 40 *Ind. L. Rev.* 397 (2007).

In their article, Abaray and Kern emphasize that mass media and the Internet have "drastically changed the way patients obtain health information." This is true. Patients today can readily obtain information about the risks associated with pharmaceutical products from print, television, and radio advertisements; manufacturers' websites and other Internet sources like WebMD; and package inserts that accompany every prescription product they purchase. That said, the learned intermediary doctrine recognizes an inherent distinction between prescription medical products and typical consumer products: The average consumer is not in a position fully to understand and appreciate product labels and warnings or to weigh the risks and benefits of a drug or device without the assistance and input of

his or her doctor. See, e.g., *Talley*, 179 F.3d at 162–63.

Echoing *Perez*, the authors argue that direct-to-consumer advertising by drug and device companies proves that manufacturers are capable of warning consumers directly, thus rendering inapplicable one of the primary justifications for the learned intermediary doctrine, that manufacturers lack effective means of communicating with patients. The fact of direct-to-consumer advertising—even wildly effective direct-to-consumer advertising—does not eliminate the fundamental difference between prescription products and ordinary consumer products, however. Nor does it transform patients into "ordinary consumers," as the authors argue. Direct-to-consumer advertising may make patients more educated about their illnesses and conditions and the treatment options available to them than in the past, but it does not follow that using this same platform to impart warnings would ensure that important drug safety and risk information reaches consumers in the context of their health histories and medical conditions. As one commentator has noted:

[I]t is virtually impossible for pharmaceutical manufacturers to provide a warning to specific patients based on their unique medical history and condition and the constellation of other drugs they may be taking. The near impossibility of providing specific warnings remains even though these manufacturers clearly "reach" consumers. The ability to "reach" consumers in the sense of providing them with prescription drug information sufficient to entice them to request a product does not guarantee that the information is tailored to their physiological needs. Direct-to-consumer advertising does not abrogate the need for the learned intermediary doctrine solely because it provides an effective channel for reaching patients.

*Girod, supra*, at 409.

In fact, even a warning articulated by a drug company in the most clear, conspicuous, neutral, and widely disseminated manner would neither guarantee that the warning was heard and understood by every user of the product nor address in any fashion the particular needs, risk-benefit calculus, or consequences concerning any individual patient. Peters, *supra*, at 304–5. One court has contrasted the roles of doctors and manufacturers as follows:

[T]he physician is in the best position to understand the patient’s needs and assess the risks and benefits of a particular course of treatment.

The manufacturer, on the other hand, generally has no ability to assess the suitability of its product for a particular patient in a particular situation. Manufacturers of ethical drugs (i.e., drugs administrable only by a doctor’s prescription) and medical devices make products which, while generally beneficial when used properly in the right circumstances, are often inherently dangerous when used improperly or in improper circumstances. The manufacturer lacks precisely the patient-specific information the physician possesses and uses to determine if, when, and how an ethical drug or device should be used.

....

One of the important functions of the physician is to determine the risks and to explain them to the patient in a way that can be understood.

Accordingly, in circumstances where (1) ethical drugs or medical devices that can be prescribed or installed only by a physician are involved and (2) a physician prescribes the drug or installs the medical device after having evaluated the patient, the manufacturer of the drug or device owes the patient only the duty to warn the physician and to provide the physician with adequate product instructions.

*Talley*, 179 F.3d at 163 (internal citations and quotation marks omitted).

Critics of the learned intermediary doctrine almost always contrast the current health care climate with the “doctor knows best” era nostalgically described by the *Perez* court. It cannot be reasonably disputed, however, that patients are better off today than they were in the past because they have easy access to free content on manufacturers’ webpages, other Internet sites, and printed brochures about their medical conditions and prescription drugs or devices that their treating doctors may prescribe. The modern trend of providing patients direct access to information concerning their health and treatment helps, rather than harms, consumers. While pharmaceutical companies certainly benefit from direct-to-consumer advertising, so do patients, who are now equipped with additional information to discuss with their physicians.

Apart from any consumer advertising, the learned intermediary doctrine is predicated on the distinct notion that it is doctors, not patients, who must make ultimate decisions about medical treatment. Providing consumers additional information may change the doctor-patient dynamic, but patients must still rely on their doctors to prescribe courses of treatment and drugs or devices best suited for them. The doctrine encourages drug and device manufacturers to provide adequate information about their products to physicians, knowing that those physicians are best placed to pass that information on to their patients, or not, in the context of their medical histories, courses of treatment, and other appropriate considerations. See *Talley*, 179 F.3d at 162–63; see also *Dietz*, 598 F.3d at 814 (treating doctor determined that *not* warning patient of risk of suicide was in patient’s best interest). Conversely, with little probative explanation, Abaray and Kern ignore the treating physician’s role in the doctor-patient relationship, which, when acknowledged, fully justifies the doctrine.

The authors instead argue that insurance companies and the government have driven a wedge between patients and

doctors, taking prescription determinations out of doctors’ hands. This may or may not be the case, but it has nothing to do with the application or viability of the learned intermediary doctrine. If an insurance company informs a patient that it will not pay for a certain drug, that is an issue between the patient and his or her insurer and is irrelevant to the issue of whom the pharmaceutical manufacturer must warn. Likewise, the fact that a generic version of a particular drug is available to the patient is apropos of nothing in the duty-to-warn landscape.

The authors’ arguments concerning direct-to-consumer advertising, insurance companies, and the like incorrectly imply that prescribing doctors are simply on-demand dispensers of drugs and devices, leaving treatment decisions entirely up to their patients. They point to no evidence of this, however. A doctor may accede to a patient’s desire for a particular brand-name prescription product among several options, but he or she is still ethically and legally constrained with respect to whether such a prescription is appropriate in the first place.

Abaray and Kern further contend that the learned intermediary doctrine should be abolished because there is evidence that some doctors fail to inform their patients about the risks and side effects of prescribed drugs. The issue in that case, however, centers on the doctor’s act or failure to act, not on anything having to do with a manufacturer. Nevertheless, the authors assert that the effect of the continued application of the learned intermediary doctrine is that patients are receiving no warnings at all. This ignores the warnings included in the packaging of every prescription drug; the warnings accompanying every advertisement; the availability of entire product labels, including all warnings, on manufacturers’ webpages; and the vast amount of information, accurate and inaccurate, available to anyone with access to the Internet. Of course, without the learned intermediary-physician to guide them

through this sea of information, patients are simply overwhelmed with product information and warnings with little, if any, sense of how such information and warnings apply to them in the context of their particular conditions and medical histories. While the doctor-patient dynamic may be far different today than it once was, as the authors argue, this “changed landscape” actually makes the doctor’s role as learned intermediary more critical because the doctor is the one person best suited to synthesize, interpret, and explain all of the information available to his or her patient—especially information about the general benefits of drugs and medical devices.

### Recent Cases

The authors state that “several courts” have refused to adopt the learned intermediary doctrine or have adopted a direct-to-consumer advertising exception following *Perez* in 1999. In fact, however, as of the date the authors wrote their article, they could point to only two decisions—*Karl* and *Rimbert*—to support their claim. The overwhelming majority of opinions from state and federal courts continue to uphold and reinforce the learned intermediary doctrine for all the policy reasons set forth in this article. See, e.g., *Dietz*, 598 F.3d at 812 (reaffirming the doctrine in Georgia); *Guinan v. A.I. DuPont Hosp. for Children*, 597 F. Supp. 2d 485, 498 (E.D. Pa. 2009); *Mason*, 27 So. 3d at 75–77 (reaffirming the doctrine in Florida); *Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 389 (Conn. App. Ct. 2008) (expanding Connecticut’s recognition of the doctrine to prescription medical devices); *Springhill Hosp., Inc. v. Larrimore*, 5 So. 3d 513, 518 (Ala. 2008) (reaffirming the doctrine in Alabama); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806–9 (E.D. Tex. 2002) (explaining that the learned intermediary doctrine is accepted law in 48 states, the District of Columbia, and Puerto Rico); *Goetz & Growdon, supra*, at 423–34 (2008) (explaining that the doctrine “has been adopted and applied by

most jurisdictions, and today is a rule of near-universal applicability in the United States”). As Judge Jack B. Weinstein recently stated in the Zyprexa multidistrict litigation pending in the Eastern District of New York, “There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well established doctrine.” *In re Zyprexa Liab. Litig.*, Nos. 04-MD-1596, 07-CV-3912, 2009 WL 2762170, at \*17 (E.D.N.Y. Aug. 28, 2009). The same trend exists in medical device cases, as evidenced by the recent opinion from the Colorado Court of Appeals in *O’Connell v. Biomet, Inc.*, No. 09CA0224, 2010 WL 963234, at \*2–4 (Colo. App. Mar. 18, 2010) (adopting the learned intermediary doctrine in Colorado; citing, e.g., *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1280 (11th Cir. 2002) (applying Georgia law); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1367–68 (S.D. Fla. 2007) (collecting cases) (applying Florida law)); see also *Breen*, 947 A.2d at 389 (similar 2008 decision from Connecticut).

Despite these strong trends, an intermediate Texas appeals court recently adopted the *Perez* direct-to-consumer advertising exception in an alleged fraudulent warnings case and handed the plaintiffs’ bar only its third victory against the learned intermediary doctrine since 1999. The 75-page opinion in *Centocor, Inc. v. Hamilton* deserves careful attention because it contains ample fodder for defendants and plaintiffs alike to feed their respective arguments for and against the doctrine in future cases. *Centocor, Inc. v. Hamilton*, 2010 WL 744212 (Tex. Ct. App. Mar. 4, 2010); but see *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 781–82 (S.D. Tex. 2008) (predicting that the Supreme Court of Texas will reject a direct-to-consumer advertising exception to the learned intermediary doctrine (citing *Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999))). Fully analyzing the *Hamilton* opinion is an exercise in mental gymnastics, however, and is beyond the scope of this article. We therefore primarily address *Hamilton*’s liability

analysis and policy implications.

The *Hamilton* plaintiff had a complicated medical history including decades of suffering from Crohn’s disease (an autoimmune disorder of the bowel) and rheumatoid arthritis. The plaintiff’s treating gastroenterologist prescribed Remicade to treat her Crohn’s disease and referred her to an infusion clinic for a course of injections. The plaintiff improved substantially after the injections, and her Crohn’s disease actually went into remission. However, the plaintiff also experienced a temporary increase in her rheumatoid arthritis pain while taking Remicade. Eventually, the plaintiff stopped the injections, and her pain returned to its pre-Remicade level.

The plaintiff asserted that her temporary pain flare-up was actually Remicade-induced “lupus-like syndrome,” of which the Remicade label specifically warned. The plaintiff’s doctors testified they were aware of this risk and discussed it with her both before prescribing the first Remicade injections and during her course of treatment. The plaintiff denied receiving these warnings. She testified she never knew that Remicade might be the cause of her temporary pain and would have asked more questions concerning the Remicade infusions had she known. Notably, however, the plaintiff did not testify that, had she been armed with this knowledge, she would have refused the Remicade treatment entirely, especially in light of the success she experienced with her Crohn’s disease during and after the injections.

The plaintiff, nevertheless, sued the Remicade manufacturer for negligent failure to warn and fraud. Under the learned intermediary doctrine, she faced an insurmountable liability hurdle: Her doctors knew of the risk of lupus-like syndrome because the manufacturer’s package insert warning was undeniably adequate. Thus, whether the plaintiff’s doctors actually warned her was irrelevant because the manufacturer had already discharged its duty to warn the learned intermediaries who were in the best position to evaluate the plaintiff’s individual

needs for both treatment options and appropriate warnings.

Accordingly, the plaintiff had to convince the court to bypass her treating doctors in its legal analysis. She urged the court to adopt the *Perez* direct-to-consumer advertising exception, which, as described above, has been almost universally rejected by other courts since *Perez* was decided in 1999. The predicate for this exception in *Hamilton* was a patient testimonial videotape produced by Centocor and presented to the plaintiff at the infusion clinic.

The plaintiff argued that the manufacturer's video intentionally overemphasized the benefits of Remicade while omitting any mention of the "lupus-like syndrome" side effect. She further argued that she relied on the tape to proceed with her injections—but obviously *after* they had already been prescribed by her treating doctors. The videotape itself plainly stated that it was not a substitute for the plaintiff's consultation with her treating doctor about the drug's potential side effects. The tape also referred the plaintiff to the adequate warnings in the package insert accompanying the tape as well as on the manufacturer's website. The plaintiff, however, denied that her copy of the tape included the manufacturer's warnings in the jacket sleeve. She testified that the tape made her "feel good" about Remicade and that, as a result, she believed additional research was unnecessary.

The *Hamilton* court followed *Perez* and held that when a drug manufacturer advertises directly to consumers in a fraudulent manner, an exception to the learned intermediary doctrine exists in Texas. See *Hamilton*, 2010 WL 744212, at \*1, \*43 n.23. In so holding, the court ignored the fact that no direct consumer advertising actually occurred in this case. The plaintiff neither alleged nor proved that she saw any Remicade advertising *before* visiting her treating physician and *before* that physician prescribed the initial course of Remicade injections. She certainly had not gone to her treating gastroenterologist demanding

Remicade based on direct advertising she had seen. In fact, no evidence existed that the plaintiff was even aware of Remicade before her doctor prescribed it for her. Moreover, the videotape itself clearly was not direct-to-consumer advertising. The plaintiff could not turn on the television or visit a website and watch the videotape. The infusion clinic staff played the tape specifically for the plaintiff only *after* her doctor consulted with her, evaluated her individual needs, and prescribed the Remicade injections. Therefore, the rationale of *Perez*, as illogical as it is, clearly did not apply to the facts of this case.

The *Hamilton* opinion appears to have been driven by a desired outcome and is not supported by either the applicable law or the underlying facts. Moreover, as one commentator observed when reviewing this decision, "If you're a defendant, you know you're in trouble when the court decides it's on a first-name basis with the plaintiff." Posting of James M. Beck, Learned Intermediary Causation—Lights Out in Georgia and a Texas Two-Step, Drug and Device Law blog, <http://druganddevice.com/2010/03/learned-intermediary-causation-lights.html> (last visited Apr. 27, 2010). The Supreme Court of Texas will likely have the last word on *Hamilton*. The Supreme Court of Texas, [www.supreme.courts.state.tx.us](http://www.supreme.courts.state.tx.us) (last visited Apr. 27, 2010) (April 5, 2010, docket entry reflecting that the court has granted Centocor's motion to extend the time in which to file a petition for review).

At a minimum, however, *Hamilton* demonstrates the persistence of the plaintiff's bar in attempting to sidestep the learned intermediary doctrine when faced with evidence that plainly justifies a summary judgment for the manufacturer. The case also refutes Abaray and Kern's argument that the doctrine harms patients. In *Hamilton*, the plaintiff's treating doctor—having received fully adequate product warnings—prescribed Remicade *before* the plaintiff ever saw the videotape on which the court relied to recognize the direct-to-consumer advertising exception.

Therefore, removing the *post*-prescription video from the equation—which advised the plaintiff that it was not a substitute for consultation with her physician—the plaintiff would still have received the injections and would have been no better or worse off. In fact, abolishing the doctrine might have caused the plaintiff more harm than good. The plaintiff could have easily overreacted to a direct warning about the risk of temporary lupus-like syndrome (or other remote risks) from Remicade absent a consultation with her doctor, who was uniquely qualified to conduct the necessary risk-benefit analysis considering the plaintiff's individual medical situation and needs. See Goetz & Growdon, *supra*, at 434–35 ("Providing the fullest possible risk information [directly] to consumers could lead to two possible results, both undesirable from a policy standpoint. Presented with a long list of every reported adverse side effect of a drug and unable to determine which are most pertinent to their situations, some consumers might be so concerned about risks that they forgo beneficial medication. Other consumers, again presented with detailed technical warnings that dilute the most important risk and safe usage information, might fail to appreciate pertinent significant risks, an outcome that could encourage inappropriate use."). Had the plaintiff in *Hamilton* overreacted, she would have never had the injections and would have continued to suffer from Crohn's disease long after the temporary pain from the drug-induced syndrome had abated.

## Conclusion

Abaray and Kern conclude that the learned intermediary doctrine should be abolished because "its application allows pharmaceutical manufacturers to escape their traditional duty to warn at the expense of consumer health and well-being." They fail, however, to articulate how abolishing the doctrine would *benefit* consumers' health and well-being. Prescription drugs are altogether different

from other consumer products, and the law has developed in recognition of this fact and the fact that the prescribing doctor is the best conduit for information about the drugs he or she is prescribing. Moreover, the authors apparently fail to recognize that even if a drug or device manufacturer were able to warn consumers directly of the risks associated with its product, explain the side effects and contraindications (if any), and detail the clinical trials with respect to the drug, the consumers would still have to consult their physicians to obtain any prescriptions. This is why the learned intermediary doctrine makes sense:

Where a product is available only on prescription or through the services of a physician, the physician acts as a “learned intermediary” between the manufacturer or seller and the patient. It is [the physician’s] duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on

his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

*Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978).

The doctrine recognizes that this unique dynamic creates a different warning landscape than that of any other

product and ensures that information is provided in the manner most likely to benefit the consumer. Advertising drugs directly to consumers, constraining doctors’ ability to prescribe certain drugs, arming patients with reams of product information, or some or all of these mechanisms in combination do not change this. The truth remains that the learned intermediary doctrine is the most effective and efficient means of ensuring that patients and their physicians make informed, thoughtful treatment decisions. This is why the doctrine is recognized in almost every jurisdiction. Abaray and Kern entirely fail to provide any workable alternative. ■

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*John A. Camp is a member of the Carlton Fields’ Products & Toxic Tort Liability and Business Litigation and Trade Regulation Practice Groups. Gary M. Pappas is a trial attorney at Carlton Fields with more than 20 years of experience in civil litigation.*