The learned intermediary doctrine in the WebMD era

Product Liability Alert

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Patients today have access to an unprecedented amount of medical information. Expanded access to information about illnesses, conditions, and treatments, offered through websites like WebMD and MayoClinic.org, means that patients are more aware of their options than ever before.

At the same time, FDA is requiring more patient-oriented disclosure from manufacturers of medicines, biologics, and medical devices in the form of Patient Information Guides and Patient Checklists to ensure that patients are fully aware of the benefits and risks of treatments. Increased access to consumer health information means increased awareness of treatment options and the risks incident to those treatment option.

In courts, meanwhile, juries are both consumers and fact-finders. They are aware of the greater availability of health information and they find patient empowerment themes persuasive.

Does this patient-consumer awareness and engagement in medical decision-making warrant re-thinking the learned intermediary doctrine?

The learned intermediary doctrine

The learned intermediary doctrine is the legal principle which reflects the reality of the doctor-patient relationship.

The manufacturer describes, in evidence-based medical and scientific terms, the known risks of the medication or device. Patients rely on doctors to interpret these risks, to provide them with the information necessary to make informed medical decisions, and to assist them in choosing the best course of action given the patient's unique medical history. Only the physician, with years of training and experience and awareness of each patient's unique medical history, can have an appropriately contextualized discussion of the risks and benefits of the treatment options available for that patient. The learned intermediary doctrine provides that a manufacturer's duty to warn runs to the physician who prescribed the medication, not to the individual patient or the general public. The physician is in the best position to make an individualized assessment as to whether the benefits of a medication or treatment for a particular patient outweigh its risks.

Modern-day threats to the learned intermediary doctrine

Recent arguments advocating against the learned intermediary doctrine emphasize the role of direct-to-consumer advertising as interrupting the relationship between patient and physician; the role of insurance companies (payers) in guiding prescribing decisions for physicians; and patients' broad access to medical information on the Internet. Opponents of the learned intermediary doctrine argue that the doctrine is obsolete in light of patients' increasing ability to influence their physicians' prescribing behavior. Using these rationales, a minority of courts have rejected or narrowed the doctrine.

In *Perez v. Wyeth Labs. Inc.*,[1] the New Jersey Supreme Court heralded the end of the era of "doctor knows best" in holding that the learned intermediary doctrine promoted a paternalistic approach to medicine and should not apply in cases involving a medication promoted with direct-to-consumer advertising.*Id.* at 1255. "Consumer-directed advertising of pharmaceuticals…belies each of the premises on which the learned intermediary doctrine rests."

Similarly, in *Rimbert v. Eli Lilly & Co.*,[2] the district court held that, "this two-pronged phenomena – a dramatically increased marketing directed to consumers and the use of the internet by consumers to conduct their own medical research – would persuade the Supreme Court of New Mexico that the justification for the learned-intermediary doctrine is quickly becoming, if not already the case, outdated."

The reinforcement of the learned intermediary doctrine

Notwithstanding the changing relationship between doctors and patients, courts continue to reinforce the applicability of the learned intermediary doctrine. This tendency is most evident in a recent set of cases involving generic amiodarone, a medication used to treat potentially fatal arrhythmias.

In the amiodarone cases, the plaintiffs alleged not that the generic manufacturer failed to warn the prescriber – a preempted claim – but that the manufacturer violated a duty it owed to provide a medication guide to plaintiffs under FDA regulations. Understanding that traditional failure-to warn claims are preempted under *Mensing* and *Bartlett*,[3] the plaintiffs took a different tack: they claimed that the manufacturer failed to provide a medication guide to the individual plaintiffs – in essence, arguing that the FDA regulation imposed a duty to warn the plaintiff.

In two recent decisions, the Fourth and Eleventh Circuits held that the learned intermediary doctrine still governs and barred the amiodarone plaintiffs' medication guide claims. In *Tutwiler v. Sandoz, Inc.*,[4] the Eleventh Circuit held that the medication guide claim was barred by the learned intermediary doctrine and that the plaintiff could not escape application of the doctrine by alleging that she would have avoided the medication if she had known of its dangers. "Regardless of what Ms. Tutwiler would or would not have done with the information, Alabama law requires a showing of what [her physician] would have done with it."[5] The Eleventh Circuit's ruling recognizes that, even if the federal regulation requires manufacturers to distribute medication guides, *state law* does not recognize a duty to warn the individual patient.

Using a different rationale, the Fourth Circuit followed suit in *Bean v. Upsher-Smith Pharms*.[6] There the Court held that the medication guide claim was barred by South Carolina's learned intermediary doctrine. The court noted that FDA's medication guide requirement did not circumvent the learned intermediary doctrine because it was "the FDA's intent that the Medication Guide rule not alter the duty, or set the standard of care for manufacturers.'"[7] In other words, notwithstanding the federal regulation requiring manufacturers to supply a medication guide to users, federal law did not impose a duty to warn the individual patient

Both the Fourth and Eleventh Circuits have acknowledged that medication guide claims are nothing more than an

attempt to circumvent the learned intermediary doctrine and that the doctrine remains relevant, notwithstanding FDA's increasing willingness to require patient-directed disclosures. Courts across the country continue to affirm the learned intermediary doctrine in most jurisdictions. For example, see *Centocor, Inc. v. Hamilton*,[8] declining to acknowledge a direct-to-consumer exception to the learned intermediary doctrine and *Watts v. Medicis Pharma. Corp.*[9] (same).

The ongoing relevance of the learned intermediary doctrine

These two recent circuit decisions underscore the continued relevance of the learned intermediary doctrine. Consumers do *and should* continue to rely on their physicians for medical advice relating to the best treatment options for their individual care.

Medical information is readily available to consumers. But its wide availability does not mean it is an appropriate, or even an accurate, basis for decision-making about patient health. One need only to watch late-night television or surf social media to experience the myriad of unreliable medical information that bombards patients every day – medical information that may lead to poor decisions and tragic outcomes. For instance, a cardiac patient-consumer may decide to discontinue his anti-coagulant medication after watching attorney advertising on late night TV, only to suffer a debilitating stroke. Or parents may be persuaded by celebrity-driven social media messages to shun vaccination, causing their children and communities to become infected with preventable, dangerous diseases that had almost been eradicated.

Our US medical system continues to put the physician between the medication or treatment and the patient for a reason: only the physician has the proper education and training to fully assess the complex algorithm of treatment needs, medical history, concomitant medications and ultimate risk and benefit to the patient. We may live in a time when more information is available about medications and treatments, but patient-consumers still need someone with the knowledge to help them evaluate and weigh this mass of information. The trained physician is still the best person to do this. It is the physician alone who knows the patient's history and individual risk factors and can convey the risks and benefits of treatment to the patient, based on each person's specific, individualized situation.

Acknowledging this reality, courts continue to uphold the doctrine as properly placing the physician between the manufacturer and patient for the purpose of conveying warnings of a treatment or medication.

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1 *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. Sup. Ct. Aug. 9, 1999).
2 *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1218 (D.N.M. 2008).
3 PLIVA, Inc. v. *Mensing*, 564 U.S. 604 (2011) and Mutual Pharm. v. *Bartlett*, 570 U.S. __ (2013).
4 *Tutwiler v. Sandoz, Inc.*, No. 17-13985, 2018 WL 1719024 (11th Cir. Apr. 9, 2018).
5 *Id.* at *3. In *Mitchell v. Wyeth Pharms., Inc*., 356 F. Supp. 3d 634 (W.D. Tex. Dec. 17, 2018), the Western District of Texas held that the federal regulations required only that the manufacturer provide sufficient medication guides to the pharmacy (or give the pharmacy the ability to print additional copies). That the plaintiff did not receive a copy of the medication guide did not create an issue of fact as to whether the manufacturer satisfied its duty under state and federal law to supply the guide.
6 *Bean v. Upsher-Smith Pharms*., No. 17-2263, 2019 WL 1513597 (4th Cir. Apr. 8, 2019).|
7 *Id.* (citing 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998)).
8 *Centocor, Inc. Hamilton*, 372 S.W.3d 140 (Tex.2012).
9 *Watts v. Medicis Pharma. Corp.*, 239 Ariz. 19 (2016).

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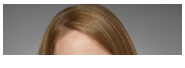

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