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Will The Learned Intermediary Doctrine Survive A New Paradigm?

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Law360, New York (January 11, 2017, 11:54 AM EST) --In the historic, paternalist doctor-patient relationship, the balance of information, power and decision-making resided with physicians. Patients were allowed to see their doctor only at a time convenient for the physician, often weeks out, and patients had very little or no access to their own medical charts, data and test results. Indeed, Hippocrates, despite the well-known "first do no harm" teaching, believed in shielding patients from some truths about their conditions. However, that traditional, "doctor knows best" era of medicine is at an end. As physician and researcher Dr. Eric Topol explains in his recent book, The Patient Will See You Now (a book these authors commend to any attorney representing life-sciences or healthcare clients); advancements in technology are democratizing medical information, data and healthcare services in a way that is increasingly shifting the balance of power to patients.

For example, today, patients can speak with a doctor over their computers or smartphones, at a time and place that is convenient for them. This includes 24-hour hotlines staffed by doctors in remote locations capable of immediately calling in prescriptions for simple ailments. Likewise, patients now have access to extensive amounts of research and medical data online, and increasingly greater access to their own medical information, including access to patient charts, test results and medical histories via online patient portals. More interestingly, patients are now creating their own medical data on smart, connected devices, like performing their own physical exams and checking their heart rate, blood pressure and blood-glucose level. Patients can even obtain diagnoses of certain conditions, like skin rashes, without ever even speaking with a doctor, by snapping a picture of it, an uploading it to smartphone apps, which use algorithms to return accurate diagnoses. Technology has also made it easier for patients to connect with each other, to share details about their experiences, provide support and pool resources and knowledge to find cures to rare diseases that researchers might otherwise ignore.

In short, advances in technology are eroding the traditional barriers to the flow of medical data and information. As Topol explains, "All of these movements of self-generated data by smart, hyperconnected patients represent a serious challenge to medical paternalism."

So what then, does this movement toward greater patient access to medical information portend for legal doctrines, like the learned intermediary doctrine (LID), that are based, at least in part, on the traditional notion of the doctor-patient relationship?

Although a small, minority of courts have in recent years concluded that this changing dynamic should herald the demise of the LID, closer scrutiny reveals that the core, traditional justifications for the LID still hold true, notwithstanding the changing physician-patient paradigm. That is, despite increasing access to patient data, a well-informed physician remains in the best position to assess the risks and benefits of a drug or device for a particular patient, given the physician's knowledge of the patient's needs, preferences and medical history. As Topol himself notes, "Data and information are not knowledge, of course, and for the latter, the doctor will continue to be its purveyor."

Historical Justifications For The Learned Intermediary Doctrine

The LID is a defense to a plaintiff's failure-to-warn claims in a product liability action. Under the LID, a drug or medical device manufacturer discharges its duty to warn by adequately warning the patient's physician, rather than warning the patient directly. There are four core justifications for the LID that courts and commentators most often cite:

First, a drug or medical device company's warnings should be directed to physicians, because physicians are in the best position to assess the risks and benefits of a drug or device for a particular patient, in light of the patient's goals, needs and medical history. In short, doctors know their patients. Second, warnings directed to the physician are the appropriate focus because prescription drugs and medical devices are available only through a licensed physician, who serves as an important stopgap between patients and drug and medical device companies. As the hub for information from both manufacturers and from patients, the doctor can preserve the patient's privacy within the doctor-patient relationship. Third, routing prescription drug and medical device risk and benefit information through physicians, who must obtain informed consent from patients, ensures that patients receive adequate information in making decisions about their medical care by bootstrapping the doctor's professional responsibility obligations. Fourth, without a knowledgeable expert's assistance, patients cannot be expected to understand complicated scientific risk and benefit information.

As explained below, each of these core justifications for the LID still support the viability of the defense, notwithstanding increased patient access to medical information.

The Core Justifications For The Learned Intermediary Doctrine Support Its Continued Relevance, Notwithstanding The Evolving Doctor-Patient Relationship

Physicians remain best suited to weigh individual patients' needs in conjunction with the risks and benefits of a prescription drug or device. Although greater and more easily accessible patient data will make medical care more accurate, patient-focused and efficient, it does not necessarily make patients any more adept at applying technical medical knowledge to reach an informed decision on a safe and appropriate course of treatment on their own. Technical medical knowledge is, and will remain, the doctor's primary domain. Indeed, to embrace the complete erosion of the LID as a result of the changing dynamic between physicians and patients, one would have to conclude that patients are experts in medicine, or at least competent enough to make informed decisions about the appropriateness of potentially dangerous drugs and medical devices. That is hardly truer today than it was historically, notwithstanding the amount of medical information now available to patients. Physicians spend years in school and in residency before they are competent to render medical treatment, and even then, are not experts in every medical field.

Furthermore, increased patient access to medical data and information does not make manufacturers any

more knowledgeable about individual patient's needs, goals and medical histories, sufficient to permit them to fill the shoes of doctors. Rather, physicians remain the only ones that can connect the dots between a patient's goals, needs and medical history, and the most appropriate course of treatment.

Prescription drugs and medical devices may still only be obtained through a licensed physician, and for good reason. Although scholars, patient groups and physicians continue to debate the benefits and drawbacks of direct to consumer advertising of prescription drugs and devices, today, as historically, prescription drugs and devices remain available only through a licensed physician. This means that, notwithstanding whatever information a patient reads or hears in the mass-media, he or she must still have a conversation with their physician about the risks and benefits of a desired course of medical treatment before proceeding. It also means that a physician, in their expert opinion, must believe that the benefits of a desired course of treatment outweigh its risks, before a patient can receive a drug or device. Medical ethics dictate that a physician exercise independent professional judgment in attempting to reach the best possible result for a patient, and a physician's signature on a script signifies the expert's belief that the particular drug or device will benefit the patient, regardless of any outside influence. Physicians are motivated to heed warnings and make good decisions not merely because it is in the patient's best interested, but also in their own.

In this way, a well-informed physician is intended to be an intervening party between the patient and any outside influence in the full sense of the word. Indeed, the demise of the traditional barriers between patients and manufacturers only heightens the importance of the physician's role as a stop-gap between patients and outside influences.

There is still no reliable means for drug and device manufacturers to ensure that risk and benefit information is transmitted to all potential patients. Although advances in technology have made communicating directly with patients easier for drug and device manufacturers, there is still no ready means for manufacturers to ensure that all potential users of a drug or device receive complete and adequate knowledge, except when that information is transmitted through a physician, whom a patient must see before receiving a drug or device. Therefore, routing drugs and device warnings through physicians, and requiring physicians to obtain informed consent, provides the best possible scenario for patients in making an informed choice.

Furthermore, eroding the LID would create a perverse incentive for manufacturers to flood mass-media with risk information. There are over 11,000 pharmaceutical drugs alone approved for marketing in the United States, and only a microscopic fraction of those are actually promoted directly to consumers. Inundating consumers with risk information on thousands of additional drugs and devices would be overwhelming, and counterproductive. Also, the additional cost in warning consumers directly may very well force some drugs off the market, or prevent others from being developed in the first place.

Patients cannot be expected to understand complex risk and benefit information. Drug and device labels do not just contain simple, easy to understand warnings or risk/benefit information like other consumer goods, but instead, commonly include dozens of pages of information on topics like chemical structure and biochemical pathways, pharmacodynamics, pharmacokinetics, absorption, metabolism, indications and dosage, efficacy, drug interactions, contraindications and clinical trial and animal study information, among other information. Patients cannot be expected to synthesize this information, much less meaningfully apply it to their own circumstances in making healthcare decisions, without the assistance of an expert physician.

Moreover, requiring manufacturers to warn patients directly would give rise to multiple dilemmas. For

example, would drug companies be responsible for filling the shoes that physicians currently fill in distilling medical information about a drug or device into a form that is understandable to a lay person, and if so, would that open the door to additional liability for drug and device companies for not "adequately" warning patients about the risks of a drug or device in an understandable form? Also, drug companies are routinely (and unfairly) criticized by engineering plaintiffs lawyers for not including obscure scientific articles, details about preclinical studies or clinical trials, and anecdotal case reports or adverse events in their labeling. It is impossible to square this common "everything and the kitchen sink" argument, with producing direct-to-patient labeling that adequately informs patients in terms they understand, without overwhelming and confusing them.

In the end, the simplest solution is to leave obtaining informed consent to the experts: physicians.

Conclusion: The Learned Intermediary Doctrine Should Survive The Changing Doctor-Patient Paradigm, But The Law Must Evolve

For all these reasons, the core justifications for the LID support its continued validity, notwithstanding the evolving doctor-patient relationship. But, the physician-patient relationship continues to evolve at an ever-increasing pace, and lawyers practicing in this area should be mindful of these developments' potential impact on the LID, and other legal principles that incorporate our traditional understanding of doctor-patient interactions. For example, in taking a pharmaceutical drug or medical device plaintiff's deposition, one should consider asking a series of questions directed toward the plaintiff's personal access to and use of medical records and healthcare technology. A patient's failure to avail himself of the tools designed to enhance his care could help support arguments about assumption of risk, proximate cause, contributory negligence, mitigation of damages and more. As technology continues to forcefully evolve the doctor-patient relationship, the rate at which patients embrace these changes will largely determine the rate at which product-liability principles evolve.

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