Big Pharma: Outsmarting the "learned-intermediary doctrine" defense

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Outsmarting the "learned-intermediary doctrine" defense

Against big pharma, proving that the doctor, properly warned, would indeed have prescribed another drug is crucial to plaintiff's case.

With the expansion of mass-tort litigation, California attorneys may often find themselves representing clients in other jurisdictions or litigating California cases in which the substantive law of a foreign jurisdiction applies.

Pharmaceutical products liability cases are a prime example of this phenomenon. As a result, counsel can no longer rely solely upon California law, but rather must be well versed in the law of other jurisdictions. Depending on the substantive issues involved, the law of the foreign jurisdiction may either mirror California, conflict with California, or be undeveloped. In the context of pharmaceutical litigation one of the key areas that is beginning to produce conflicting rulings is the dreaded "learned-intermediary defense" – the defense that allows even the most reckless of pharmaceutical manufacturers to avoid all liability if plaintiff is not able to establish that the prescribing physician would have altered his or her conduct upon being properly warned by the manufacturer. In this article we briefly explore how California and other jurisdictions have dealt with the learned-intermediary defense and provide some useful tips to overcome this defense.

Modern-day shaman

In ancient indigenous societies a "shaman" acted as an intermediary between the world of humans and gods. The shaman – whose literal translation is "one who knows" – was often depicted as a "healer" or "medicine man," healing illnesses and maladies of his tribe. While modern society and medicine have advanced considerably since the days of shamanism, we continue to rely upon today's "healers" (i.e., physicians) to heal our illnesses. And, while the shaman of ancient times acted as an intermediary between the world of men and the gods, modern day healers act as intermediaries between the human world and a new deity – the pharmaceutical industry.

The law also recognizes the role of learned intermediaries. In that regard, the law of most states, including California, provides that a drug manufacturer need only warn the prescriber regarding the risks associated with its drugs and that the manufacturer need not provide warnings to patients directly. (Carlin v. Superior Court (1996) 13 Cal.4th 1104, 1116 [56 Cal.Rptr.2d 162].) The rationale underlying this rule is that the prescriber, as a "learned-intermediary" standing between the manufacturer and the patient, is generally in the best position to evaluate the potential risks and benefits of a drug and to advise the patient accordingly. (Garside v. Oseo Drug, Inc. (1st Cir. 1992) 976 F.2d 77, 80 (applying Massachusetts law).)

In jurisdictions that adhere to the learned-intermediary doctrine, the law further provides that a plaintiff asserting a failure-to-warn cause of action must prove not only that the manufacturer failed to provide an adequate warning to the prescriber, but also must establish that the inadequate warning was the proximate cause of the injury. (Motus v. Pfizer, Inc. (C.D.Cal. 2001) 196 F.Supp.2d 984 (applying California law).) In other words, plaintiff must show that an adequate warning to the prescriber would have altered the prescriber's conduct so as to prevent the plaintiff's injury. In light of the learned-intermediary doctrine or defense, the fate of the case oftentimes turns on the testimony of the prescriber.

Not all states adhere to the "learned-intermediary doctrine"

Reading drug manufacturer's motions for summary judgment on learned-intermediary grounds as well as leading treatises on the issue (most of which are also drafted by attorneys working for the pharmaceutical industry), one is left with the impression that the learned-intermediary doctrine is universal and has been adopted by every jurisdiction. That proposition was recently challenged, however, by the Supreme Court of West Virginia in State ex rel. Johnson & Johnson Corp. v. Karl (2007) 220 W.Va. 463 [647 S.E.2d 899] ("Karl"). After reviewing the law of each state, the Karl Court concluded that the learned-intermediary doctrine is not universally followed and, in fact, only 22 states have officially recognized the learned-intermediary doctrine (either by decision of the highest state court or by statute). (Id. at p. 904.) The Court further found that the highest courts of six other states have referred to the doctrine favorably in dicta or applied it in other contexts, and the highest courts of the remaining 22 states have not adopted the learned-intermediary doctrine. (Id. at p. 905.) California falls into the category of states that officially recognize the learned-intermediary doctrine. (Stevens v. Perke, Davis & Co. (1973) 9 Cal.3d 51, 65 [107 Cal.Rptr. 45].)
Accordingly, the first step in outsmarting the learned-intermediary doctrine and getting past a motion for summary judgment on this issue is to find out if the doctrine even applies. If the highest court of the state has not adopted the doctrine, then the first attack would be to cite Karl and its progeny and argue that the learned-intermediary doctrine is not applicable. (Rimbert v. Eli Lilly & Co. (D.N.M. 2008) 577 F.Supp.2d 1174; see also Forst v. SmithKline Beecham (E.D.Wis. 2009) 602 F.Supp.2d 960.)

Further, counsel should point to the recent explosion of direct-to-consumer advertising by drug companies to argue that the learned-intermediary doctrine is a relic of the past and would not be adopted by the state's highest court. (Perez v. Wyeth Lab. Inc. (1999) 161 N.J. 1 [794 A.2d 1245].) If you can successfully convince the court not to apply the doctrine, then irrespective of the prescriber’s testimony, you should be able to get past the non-existent learned-intermediary defense. (See e.g., Rimbert v. Eli Lilly & Co., supra at p. 1181.)

The shaman should heed the warnings of the gods

Even if you find yourself in a jurisdiction (or court) that has adopted the learned-intermediary doctrine, not all hope is lost. Many jurisdictions that have adopted the learned-intermediary doctrine apply a rebuttable presumption in favor of the plaintiff – i.e., that a prescriber would have heeded an adequate warning if provided by the manufacturer. (Garside v. Osco Drug, Inc., supra, at p. 80.) In jurisdictions that have adopted this rebuttable presumption (often referred to as the “heeding presumption”), plaintiffs are relieved of their burden of establishing proximate causation, and the defense bears the burden of rebutting the presumption and showing that the doctor would not have heeded the warning.

Accordingly, once you establish that the jurisdiction has adopted the learned-intermediary doctrine, the second step is to determine whether your jurisdiction has adopted the heeding presumption. If your case is in a heeding presumption state, then your goal during the deposition of the prescriber should be to try to prevent the manufacturer from obtaining testimony that rebuts the heeding presumption. This can be accomplished by adequate preparation of the prescriber prior to the deposition as discussed further in this article.

Be aware of the tactics manufacturers may use to rebut the heeding presumption

Defense counsel may seek to rebut the heeding presumption by not only trying to obtain favorable deposition testimony but also by obtaining affidavits or declarations from the prescriber stating that he was independently aware of the risks and that his custom and practice is not to rely such warnings to patients.

By obtaining such a declaration from the prescriber, manufacturers hope to rebut the heeding presumption and show that, even if the company had warned the prescriber, it would not have mattered because the prescriber would not have relayed the manufacturer’s warning to the patient. There are a number of problems with such defense tactics. Some jurisdictions, such as Pennsylvania, prohibit informal and ex parte communication between the manufacturer’s attorney and the prescriber. (See Pennsylvania Rule of Civ. Proc., rule 4005.6; see also Alexander v. Knight (1961) 25 Pa. D. & C.2d 649, 655 (noting that a treating physician owes a duty of total care to his patient and “[t]hat further includes a duty to refuse affirmative assistance to the patient’s antagonist in litigation.").

Thus, if defendants engage in any informal communication with the prescriber, they may be in breach of state laws. Importantly, even when the state does not officially prohibit such informal communications, courts have held that such pre-trial affidavits or declarations (and even deposition testimony) go to the issue of credibility and should be decided by the jury, thus, protecting your case from dismissal at the motion stage. (Garside v. Osco Drug, Inc., supra, at p. 83 and Doe v. Miles Lab., Inc. (4th Cir. 1991) 927 F.2d 187, 195.)

However, not every court sees it this way and may give this evidence weight, like the court in Motus v. Pfizer, Inc., supra, 196 F.Supp.2d 984, where, in applying California law, the court dismissed plaintiff’s case and held the doctor’s pretrial deposition testimony was unequivocal and nothing undermined its veracity.

What to do in jurisdictions that do not adhere to the heeding presumption

In jurisdictions, such as California, which have adopted the learned-intermediary doctrine and refuse to follow the heeding presumption, plaintiffs bear the burden of showing not only that the warning was inadequate but also that an adequate warning to the prescriber would have altered the prescriber’s conduct so as to prevent plaintiff’s injury. These jurisdictions pose the greatest risk to a plaintiff’s case – however, with some planning and preparation, counsel should still be able to overcome the learned-intermediary defense in most cases.

The unlearned-intermediary

Drug companies generally attempt to deflect liability for their failure-to-warn onto the learned-intermediary, a.k.a. the prescriber. However, when inadequate, misleading or nonexistent risk information is provided to the medical professional, the prescriber cannot possibly be operating as a learned-intermediary between the drug company and the patient. In this situation, you will be required to show the prescriber that he did not have all of the risk information necessary to make an informed prescribing decision and thus was not able to conduct a proper risk-benefit assessment.

Protective Orders – secure the opportunity to enlighten the shaman

As the saying goes, “an ounce of prevention is worth a pound of cure.” Likewise, in litigation, a proper plan and foundation at the start of the litigation can help prevent the learned-intermediary defense from succeeding. Thus, the third action to take at the outset of the litigation is to ensure you are permitted to fully apprise the prescriber.

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about the manufacturer’s knowledge of the actual risks associated with use of its product and its failure to warn the prescriber of those risks.

This is accomplished by focusing on the Protective Order, which is entered to protect the manufacturer’s trade secrets and to protect your client’s privacy. When negotiating language to be used in the Protective Order, make sure it includes a clause that provides for the disclosure of the manufacturer’s claimed “confidential documents” to specific qualified persons, including prescribers or case specific medical treaters, as well as to experts and consultants used or retained for purposes of litigation. Documents showing a manufacturer’s knowledge of a risk (or that show the manufacturer’s decision to hide negative data) oftentimes are designated by manufacturers as confidential or trade secret.

Without a proper Protective Order allowing you to show these “confidential” documents to the prescriber, you will be hamstrung from bringing the prescriber to an understanding that he did not have all the information and that the drug company failed to disclose or hid important risk information from the prescriber.

Alternatively, you may want to seek the court’s intervention in unsealing such documents. (See e.g., Fost, 602 F.Supp.2d at 974-75 (unsealing various safety data and internal documents); see also Cunningham v. SmithKline Beecham (N.D.Ind., June 25, 2009) 2008 WL 25792076 (unsealing numerous safety documents and clinical trial data).)

Knowledge is power

Once the protective order has been finalized and granted by the judge and a review of documents has begun, you will be required to locate those documents that show the drug’s risks, the manufacturer’s knowledge of the risks and its failure to disclose those risks to the medical community. (See e.g., Knipe v. SmithKline Beecham Corp. (2008) 583 F.Supp.2d 602, 640 (E.D.Pa.) [quoting verbatim an internal memorandum which showed that the manufacturer knew of a risk yet failed to warn solely to increase the commercial profitability of its drug].)

This brings us to the fourth step in successfully overcoming the learned-intermediary defense. It goes without saying that obtaining the above referenced documents is essential to your entire case, not just the learned-intermediary defense. While obtaining the necessary documents to prove up your case is a subject unto itself, it is mentioned here because you should obtain them and fully understand the “story” underlying the liability of the manufacturer before you embark on the prescriber’s deposition. That way, you will be able to relay the true risks to the prescriber.

This is no small task and will require well-worded discovery, sifting through voluminous documents, and diligent detective work. If you are new to pharmaceutical litigation, you should study up on how to get the documents you need and the tricks drug manufacturers play to prevent you from discovering those smoking-gun documents that show their misdeeds.

In preparing for the prescriber’s deposition, you can expect drug manufacturers to try to manipulate the prescriber into testifying that he or she was provided with adequate information from the manufacturer, that the label was adequate, and that he or she would not have done anything differently. Lawyers for manufacturers often attempt to skew information to make it appear their clients did all they could to disclose the risks and did nothing wrong. Thus, you should anticipate what documents the defense will bring to sway the prescriber in the manufacturer’s favor. However, with the essential documents in hand, well organized and easy to digest, you should be able to steel the prescriber against these defense tactics.

Get to know the shaman

To defeat the learned-intermediary defense, you should get to know the learned-intermediary. Thus, the fifth step, when possible, is to meet with the prescriber (and his/her attorney if one has been appointed to or hired by the prescriber) before the deposition. Most doctors will be skittish at first. It is a fact of life that many doctors recoil at the thought of litigation (and lawyers) even when they are not a party. Regardless, if you tread lightly, you can enlighten the prescriber and bring him/her to understand you are not the enemy. The initial goal is to get the prescriber to recognize that, if the defense is successful, the focus (and the blame) will shift from the company’s failure-to-warn to the prescriber’s failure to relay the risk to the patient.

In your meeting with the prescriber, find out about the prescriber’s general prescribing practices at the time the drug was prescribed to your client and what influenced the doctor to prescribe the drug. In most cases, the prescriber has based the decision to prescribe the product on the prescribing information contained in the package insert or Physicians’ Desk Reference (“PDR”), medical literature (which is oftentimes ghostwritten by manufacturers), medical seminars, the opinions of colleagues and visits by drug company sales representatives. All of this information will be elicited during deposition and the more you know ahead of time, the better you will be able to create a clean record.

Of course, as a third-party witness, everything you discuss with the prescriber is discoverable.

After learning about the prescriber, it is time to educate him. Provide the prescriber with the information the manufacturer failed to provide, i.e., what the manufacturer knew; when the manufacturer knew it; what the manufacturer did not disclose to the prescriber and; when that failure to disclose occurred. Importantly, if you learn in your meeting or at the deposition that the prescriber would have prescribed the drug anyway, when the prescriber admits he was unaware of the risk or the magnitude of the risk (because the company failed to disclose it), the prescriber has no choice but to testify that he could not possibly have relayed that information to the patient and could not properly have weighed the risks and benefits of using the product for the patient, as is required to truly be considered a learned-intermediary.

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Be the first to summon the shaman

Military historians since the age of Tsun Tzu have preached about the importance of being the first to arrive to the battlefield. (See Tsun Tzu, The Art of War, 27 (Lionel Giles Trans., Barnes & Noble Classics 2003) (c.500 BC).) This is wise advice in the context of litigation as well and brings us to our sixth and final step. To successfully overcome the learned-intermediary defense, we strongly recommend that you be the first to notice the prescriber’s deposition to secure the lead of the deposition. By being the first to ask questions of the prescriber, you will be able to set the tone of the deposition, walk the prescriber through the key documents and, most importantly, ask the key questions that elicit answers essential to defeating the learned-intermediary defense.

You will be able to convey to the prescriber – who in most circumstances has received countless sales visits from the manufacturer and attended medical seminars sponsored by the manufacturer touting the efficacy, safety and benefits of its medication – that the company now wants the prescriber to shoulder all the responsibility for the harm caused by its drug.

Being the first to question the prescriber also allows you to set the correct timeline of when certain information was known to the manufacturer and when it was (if ever) revealed to the medical community and the public at large.

In the end, being first to depose the prescriber provides a good outline of testimony to use in opposing any learned-intermediary motion that might be filed and, when you are particularly successful, the manufacturer may even forgo asserting the learned-intermediary defense.

Conclusion

While nothing is foolproof and medical professionals can sometimes be resistant, these steps should assist you in bridging the gap between winning and losing a learned-intermediary motion and ultimately your case.

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