



The prescription drug case

That a drug is unreasonably dangerous is the standard to be argued in pharma actions



BY KRISTINE MEREDITH

Your phone rings. The caller says he believes he was injured by a prescription drug, and he's heard that others have been too. He thinks the drug is bad. His injuries sound severe, and you're interested in possibly taking his case. But you've never handled a drug case before, and you know next to nothing about them. Is his case any good? Should you take it? What does drug litigation involve? Are you suited for it?

Here are some basics.

All drugs have risks

No doubt about it, all drugs carry the risk of side effects. Any given drug will, eventually, injure *someone*. So regardless of how serious the client's injury is, that doesn't mean the prospective client has a case. The question is usually *not* whether the drug is dangerous, but whether it was *unreasonably* so.

Ultimately, the dangers associated with any given drug may be deemed unavoidable. Then the question will be whether the manufacturer accurately disclosed all that it knew about those risks or whether, instead, it downplayed the risks to enhance sales.

Legal issues unique to drug cases

Statute of limitation: Generally the discovery rule applies in drug cases. Nonetheless, the prospective client who relies on the discovery rule must show that a reasonable investigation during the

limitations period would not have disclosed a link between his injury and the drug.¹ That means that FDA investigations, ongoing medical research and media coverage can all be relevant to the statute of limitations defense.

Learned intermediary defense: In most products liability cases, we examine the warnings that the manufacturer provided to the product's end user. In drug cases, however, the inquiry centers around the warnings the manufacturer provided to the prescribing doctor. Because a patient cannot get a drug without a doctor's prescription, it is the doctor's understanding of the risks that is paramount. The warning given to the prescribing physician must include the potential risks, side effects, or allergic reactions that may follow the foreseeable use of the product. Furthermore the manufacturer has a continuing duty to warn physicians as long as the product continues in use.²

To prevail, the plaintiff must usually prove that, had there been an adequate warning, the doctor would not have prescribed the drug. The prescribing doctor may be reluctant to second-guess his own treatment decisions. He will often testify that he was cognizant of the risks and dangers of the drug and that even if proper warnings had been provided, it would not have changed his course of treatment. This is the nub of the "learned intermediary defense."

Overpromotion: Even where the manufacturer's written warnings to the doctor were by all standards adequate, the manufacturer can nonetheless be liable if it "overpromotes" the drug.

Overpromotion may nullify the doctor's testimony that he would have prescribed the drug regardless of whether it carried a better warning. For example, the manufacturer may be liable if its sales representatives, when they visit doctors, downplay the drug's risks, suggest prescribing the drug for ailments that don't justify the known risks, or withhold information about complications or contraindications. The information the representatives provide doctors verbally can negate the written warnings that come with the drug. The jury may infer that the advertising and promotion induced the physician to prescribe the drug when it was not sound practice to do so.³

Suing the doctor: Because the prescribing doctor provided a service and did not sell the drug, the theory against the doctor is usually medical negligence.⁴ Typically he is not named as a defendant in the product liability drug cases. The primary reason to not name the prescribing doctor is to avoid driving him to the other team. Or at least, to not foreclose any chance of case-related contact during litigation by putting the doctor on the other side of the "v".

Causation: In every drug case, the plaintiff must first prove "general causation." That is, the plaintiff must prove that the drug is capable of causing the injury or disease complained of. For example, a plaintiff who alleges she developed breast cancer because of a drug must prove that the drug can, indeed, cause breast cancer. Once that is proven, the plaintiff must show "specific causation." To do that, she



must show that her disease or injury was, in fact, caused by the drug and not by some other factor such as a genetic predisposition or her exposure to other carcinogens.

Preemption: All drugs come with written warnings. Manufacturers argue that, if their warnings have been approved by the FDA, then that should shield them from liability for allegedly inadequate warnings. In *Wyeth v. Levine* (2009) 129 S.Ct. 1187, the Supreme Court held that compliance with FDA regulations may *not* be enough for the manufacturer to avoid liability. A jury can still find a manufacturer liable for not adequately warning of a drug's risks. Compliance with FDA regulations will shield the manufacturer from liability *only* if the requirements imposed by a state law duty to warn would conflict with the duties imposed by the FDA. That will seldom be the case.

The science and other matters: The attorney representing someone injured by a drug will, of course, need to learn about her client's disease or illness. She'll learn about pharmacodynamics (what a drug does to the body) and pharmacokinetics (how the body reacts to and breaks down the drug). She'll become familiar with epidemiological studies (research showing the frequency at which a disease or illness appears in various populations and why) and statistical concepts such as bias, confounding and confidence intervals. She'll spend time reviewing the research and other material the drug manufacturer submitted to the FDA to obtain approval of a new drug. Depending on the particular case, she may need to become familiar with the FDA guidelines concerning promoting drugs for on label and off label uses.

Venue, aggregation of claims and case management: The prospective client may ask about joining the "class action" he's been hearing about. But defective drug cases are hardly ever handled as class actions. There are just too many differences among the individual injuries for the cases to obtain class certification. The cases are, however, almost always "aggregated." That is, they are either consolidated in a state court Judicial Council Coordination

Proceeding, or coordinated by the Judicial Panel of Multi-District Litigation and assigned to a federal district judge. Frequently, the litigation involving a particular drug is scattered around the country in a few state court proceedings and one federal MDL.

Regardless of where the plaintiff resides, or where the plaintiff was injured, the attorney will usually have a choice of venues. For example, in the current Yaz and Yasmin birth control cases, an attorney can file in one of the pending state court proceedings. Regardless of his plaintiff's state of residence, he can avoid removal by joining one of the local defendants in the chain of the drug's distribution. *Forum non conveniens* is not usually a concern in the state court coordinated actions because *forum non conveniens* rules are relaxed in the case of mass torts. Alternatively, the attorney may file a complaint directly in the federal MDL.

The purpose of aggregating the individual lawsuits for pre-trial purposes is, of course, to coordinate discovery and resolve legal issues that may be common to all the cases. With so many cases pending, the courts will impose structure on the various cases to avoid chaos. A plaintiffs' executive and steering committee will be appointed to lead the plaintiffs' discovery and briefing efforts. Those appointed to the committees will be expected to perform the lion's share of the work for the plaintiffs' common benefit.

Often they will also be expected to finance the massive costs involved in prosecuting the actions. In turn, the committee members will be entitled to a percentage of any fee earned in each of the cases filed – even those cases filed by other attorneys. If an intrepid plaintiff's lawyer wants to take on the drug juggernaut alone, she can usually avoid sharing her fee with the committee members. But unless she agrees to share her fee, she will not be given access to the committee's work product.

Bellwether trials: Once discovery is completed and common legal issues resolved, the lawyers are left to try their

own cases. But before that happens, the court will almost always select some cases to be tried as "bellwethers." The hope is that the results of a few test cases will aid the parties' settlement efforts. There are always disputes concerning which of the cases are appropriate as "bellwethers." Furthermore, once the bellwethers are reduced to verdict, there is the inevitable controversy over whether the results are useful in predicting the results of other claims. Usually, however, after a sufficient number of verdicts are handed down, the path to settling the remaining cases grows easier.

Getting involved

The novice drug attorney can reach out to seasoned drug lawyers for case review and background knowledge. She can jump into the fray or associate with another firm. As part of coordinated proceedings, there's a lot of committee work to do and the plaintiffs' bar welcomes diligent workers. To handle a drug case successfully, the attorney needs to have an interest in the science; the organization, patience, and tenacity to deal with the administrative structure; the ability to work well with other plaintiffs' lawyers; and the ability to try the client's case when the time comes.



Meredith

A partner at the Danko Law Firm, Kristine Meredith works in personal injury and product liability litigation which currently includes, In Re: Yaz/Yasmin MDL No. 2100. She began her career defending medical device manufacturers in mass tort

litigation before making the switch to plaintiffs work eight years ago. Visit the Web site: www.dankolaw.com

Endnotes

- ¹ See, *Nelson v. Indevus Pharmaceuticals, Inc.* (2006) 142 Cal.App.4th 1202, 1206; *In re Trasylol Products Liab. Litig.*, 2010 WL 6098571 (S.D. Fla. Mar. 16, 2010).
- ² *Valentine v. Baxter Healthcare Corp.*, (1999) 68 Cal.App.4th 1467, 1482; CACI No.1205 (Spring 2011).
- ³ *Stevens v. Parke, Davis & Co.*, (1973) 9 Cal.3d 51, 68-69.
- ⁴ *Carmichael v. Reitz*, (1971) 17 Cal.App.3d 958.