IADC Committee Newsletter

DRUG, DEVICE AND BIOTECHNOLOGY AND MEDICAL DEFENSE AND HEALTH LAW

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IN THIS ISSUE

This month's article focuses on issues that can arise when a plaintiff names both a drug/device manufacturer and a treating physician as defendants. The authors offer suggestions for recognizing the potential for conflict and taking an early and aggressive approach to managing a cooperative defense.

Overcoming Tensions between Drug/Device Defendants and Treating Physicians

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ABOUT THE COMMITTEES

The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. In the future, the Drug, Device and Biotechnology Committee will be focusing on increasing its use of technology to make it an even more valuable resource for its members.

Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

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I. Introduction

As any attorney who has participated in multi-party litigation knows, the risk for finger pointing and infighting among co-defendants looms large. This is especially true in the medical malpractice and product liability realm where doctors and manufacturers can be pitted against each other either by savvy plaintiff's counsel or through their own desire for self-preservation. Additionally, divergent interests between a plaintiff's treating physicians (who are also often defendants) and the manufacturer defendants, almost always benefits the plaintiff. While conventional wisdom is that the defendants should make every effort to present a unified defense, such collaboration is usually easier said than done.

This article will briefly outline, from both the physician and the manufacturer's perspective, the problems often encountered in product liability/medical malpractice litigation and some suggestions for minimizing the inevitable conflicts.

II. Bickering Benefits No One (Except The Plaintiff)

In our fervor to aggressively defend our clients, defense lawyers sometimes find themselves intentionally or inadvertently pointing fingers at co-defendants in defense of their case. It is easy to succumb to this approach. For instance, the client or insurer may be pushing for it after having been burned by a co-defendant in prior litigation. Or, counsel may suspect the co-defendant is already plotting to engage in the same tactic and does not want to be caught unprepared. In other situations, counsel might (mistakenly or not) believe the plaintiff will show leniency to one defendant in exchange for providing favorable testimony against the co-defendants.

Regardless of the motivation, finger pointing inevitably leads to the old adage – you might win the battle, but you'll lose the war. While shifting blame or offering harmful testimony against a co-defendant might, in the short term, advance your client's cause, it potentially hurts all defendants in the end. A fractionalized defense scenario where co-defendants are blaming each other results in nothing more than each defendant acting as a plaintiff with regard to the other defendants. Rather than having to address and unravel the defendants' defenses himself, plaintiff's counsel can sit back and reap the benefits as the co-defendants pick each other apart. Such discord among the defendants muddies the trial, creates confusion for jurors, and can ultimately drive up the settlement value or a verdict. In contrast, if the physician and manufacturing defendant work together, the burden is placed back on the plaintiff (where it rightfully belongs) to actually establish liability and causation in the case.

III. Problems Encountered From The Doctor Defendant's Perspective

In order to defend a plaintiff's medical malpractice claim, the physician defendant needs to demonstrate that the decision to use a device or drug, or the manner in which to use the device or drug, met the applicable standard of care. Expert witnesses are commonly employed to develop this defense. Normally, defense counsel only has to worry about the expert witnesses identified by the plaintiff testifying against their physician client. Unfortunately, in litigation involving a drug or device manufacturer, that is not always the case. Below are some examples of situations in which the co-defendant

manufacturer either inadvertently or, at times, intentionally creates conflict with the physician defendant through its witnesses.

A. The Ill-Prepared Corporate Representative

Innocent actions on the part of the manufacturer can just as easily create problems for a physician defendant as would aggressive and intentional finger pointing. This commonly arises during the deposition of the manufacturer's 30(b)(5) or (6) representative. If counsel for the manufacturer has only equipped the witness to defend their own device/drug and has not substantively prepared the witness on how to handle or deflect standard of care related questions, the physician's counsel will have no choice but to treat the witness as hostile. Take, for instance, the following summary of an actual scenario encountered by defense counsel:

Defendant physician was a board certified general surgeon. In performing the excision of a facial lesion on a patient, she utilized a new electrocautery device. During the procedure, the electrical current arced from the tip of the device to a gauze pad placed on the patient's face, causing an operative fire which resulted in second and third degree burns to the patient. A 30(b)(6) representative for the device manufacturer was identified and deposed by the plaintiff. The manufacturer's corporate representative was not well-prepared regarding the case against the physician and gave several poor answers which had the net effect of insinuating that the doctor misused the device and failed to follow the manufacturer's warnings. As a result of these equivocal answers, counsel for the physician was forced to aggressively cross-examine the representative. The ill-prepared representative got even further turned around and eventually ended up testifying that the company's fire warnings were ambiguous for any surgeon that read their manual. What should have been an innocuous deposition eventually resulted in the manufacturer paying a hefty sum of money in settlement.

B. The Similarly Situated "Causation" Expert

Red flags often go up when a co-defendant manufacturer identifies a "causation" expert who is similarly situated[1] to the defendant physician. Even in states where standard of care criticisms do not need to come from a similarly situated physician, the fact that a manufacturer has identified a physician expert at all can create tension. Even more so than a 30(b) witness, a poorly prepared expert witness can deal a devastating blow to a co-defendant physician. Often, plaintiff's counsel will take advantage of the manufacturer's identification and use that expert to backdoor standard of care testimony about the physician defendant. Below is an example of how this scenario can play out:

Defendant physician is an internist treating a Coumadin patient. The internist draws INR values on the Friday before Labor Day and sends them off to the laboratory for a report to be run. The lab detects a panic value and faxes a copy of the report to the internist's office at 4:00 a.m. on Saturday morning. The lab claims it also tried to call the physician's office, but the office's answering message

[1] In some states, such as Alabama, an expert witness must be certified in the same specialty as the defendant physician and must have practiced in the same discipline during the year preceding the date of the alleged breach in order to offer standard of care testimony.

simply directed callers to follow up with the emergency room if medical care was needed. The internist returns to his office after the weekend and finds the lab report. However, by that time, the patient has already died. The plaintiff files suit against the internist and the laboratory. During litigation, the laboratory identifies an expert witness who is anticipated to testify on the issue of causation. However, the lab's expert is also an internist and, during deposition, is not asked a single question by plaintiff's counsel about causation. Rather, the lab's expert is solely questioned on the internist's decision to order INR values on a Friday and the office's procedure for handling lab emergencies. The physician's counsel had to cross-examine the lab's expert as if he was the plaintiff's and both the internist and the lab eventually were forced to settle because they could not present a unified defense and were concerned that the finger pointing would potentially result in a large verdict if the case tried.

Whether the laboratory defendant purposefully identified an internist to shift blame to the physician defendant is unknown. Perhaps the lab's counsel simply misjudged the direction plaintiff's counsel would take with questioning. Nevertheless, through the physician's eyes this situation strongly suggested that the laboratory defendant knew the plaintiff would go lightly on the issue of causation in exchange for obtaining harmful standard of care testimony from the lab's expert.

These situations highlight how dangerous the manufacturer's witnesses can be to the physician defendant, regardless of whether there is deliberate finger pointing or not. The physician's counsel must, on one hand, remain ready to defend against purposeful attacks, and on the other hand, maintain an open channel of communication with the manufacturer's counsel to assist in recognizing and minimizing potentially risky witnesses. In addition, as set out below, counsel for the physician (even if the physician is not a named defendant in the litigation) needs to be attuned to the special problems faced by the manufacturer defendants and prepared to offer assistance when able.

IV. Problems Encountered From The Device/Drug Manufacturer's Perspective – Causation Testimony and the Treating Physician

In pharmaceutical mass torts, plaintiffs often like to focus on the "bad company" story, while defendant manufacturers like to focus on causation either by showing alternative causation or no causation. Expert causation testimony is obviously important, and a great deal of time, effort and money is spent developing experts. But the testimony of the uncompensated treating physician (interpret as unbiased) is key. It goes without saying that testimony from a treating physician can help a plaintiff show the existence of a claimed disease, help substantiate claims for pain and suffering, and demonstrate that the plaintiff made efforts to seek treatment for the alleged injuries. At the same time, defendants can develop testimony from a treating physician to support a statute of limitations defense, demonstrate no causation or alternative causation, or refute the severity of the plaintiff's claimed injury. In order to develop such potentially critical testimony, co-defendants must work together. Doctors often like their patients, and do not want to harm their case or get into a finger pointing battle on causation. This may be particularly true when the doctor is not a defendant, but hopefully less likely when the doctor has been

sued.

The requirements governing the types of opinions offered by paid experts, as well as the form in which they are offered, have been codified by Rule 26(a)(2) of the Federal Rules of Civil Procedure following the Supreme Court's decision in *Daubert*. They require any witness who is retained to deliver expert testimony to provide a signed report which includes a complete statement of all opinions the expert will offer and the basis and reasons for them; the facts or data considered by the expert in forming those opinions; any exhibits that will be used to summarize or support them; the expert's qualifications, including a list of all publications authored in the previous 10 years; as well as a statement of the compensation to be paid for the study and testimony in the case. Fed. R. Civ. P. Rule 26(a)(2)(B).

It is important to understand how, and to what extent, these rules apply to treating physicians who are asked to offer their expert testimony at trial. The Federal Rules of Evidence note that if the testimony from a treating physician is limited to "opinions or inferences which are rationally based on the[ir] perception[s]," then they would be considered lay witnesses and would not have to disclose an expert report. Fed. R. of Evid. 701. But they must be opinions that were acquired from observations or actions within the course of treating the particular patient. *See Fielden v. CSX Transp., Inc.,* 482 F.3d 866, 871 (6th Cir. 2007) (non-retained treating physician may testify "within a permissive core on issues pertaining to treatment, based on what he or she learned through actual treatment and from the plaintiff 's records up to and including that treatment," without having to disclose an expert report per Rule 26(a)(2)(B)); *Krischel v. Hennessy*, 533 F.Supp.2d 790, 795 (N.D. Ill. 2008)("When a treating physician limits his testimony to his observation, diagnosis and treatment, there is no need for a Rule 26(a)(2)(B) report").

Some courts have allowed treating physicians to testify regarding causation without first submitting an expert report if they have formed their opinions on causation during the course of their treatment of the plaintiff. *See Fielden v. CSX Transp., Inc.*, 482 F.3d at 871 (holding that a formal report is not required when determining causation is an integral part of treating a patient); *Goodman v. Staples the Office Superstore, LLC,* 644 F.3d 817, 825-26 (9th Cir. 2011) ("a treating physician is only exempt from Rule 26(a)(2)(B)'s written report requirement to the extent that his opinions were formed during the course of treatment."); *Meyers v. National R.R. Passenger Corp.,* 619 F.3d 729, 734-35 (7th Cir. 2010) ("a treating physician who is offered to provide expert testimony as to the cause of the plaintiff 's injury, but who did not make that determination in the course of providing treatment, should be deemed to be one 'retained or specially employed to provide expert testimony in the case,' and thus is required to submit an expert report in accordance with Rule 26(a)(2)").

However, if physician testimony goes beyond the care and treatment of the plaintiff, such as by offering opinions resulting from the application of the treating physician's medical knowledge to a broader set of facts, some courts consider this "expert" testimony that must withstand the rigors of Daubert. *See Brooks v. Union Pac. R. Co.*, 620 F.3d 896, 900 (8th Cir. 2010) (requiring the disclosure of a written report for a party seeking to have a treating physician testify as to the causation of a medical condition, as opposed to merely the existence of the condition).

The Eleventh Circuit recently excluded certain testimony from one victim's treating doctors, ending her case. *See Williams v. Mast Biosurgery USA, Inc.,* 644 F.3d 1312 (11th Cir. June 30, 2011). The plaintiff did not retain any experts, instead attempting to make a case solely through the testimony of her four treating physicians. The court observed that:

Much of the testimony proffered by treating physicians is an account of their experience in the course of providing care to their patients. Often, however, their proffered testimony can go beyond that sphere and purport to provide explanations of scientific and technical information not grounded in their own observations and technical experience. When such a situation presents itself, the trial court must determine whether testimony not grounded in the physician's own experience meets the standard for admission as expert testimony.

Id. at 1316-17. Consequently, the court found that major parts of these physicians' testimony was excludable as incompetent expert testimony.

In December 2010, the Federal Rules were amended to address concerns arising from situations where plaintiffs attempted to satisfy their causation burden through undisclosed experts who had not been subject to deposition. *See* Notes of Advisory Committee on 2010 Amendments to Fed. R. Civ. Proc. 26(a)(2)(C). The Rules now require that a party wishing to present testimony from non-retained experts at trial (such as treating physicians), must file a disclosure on "(i) the subject matter on which the witness is expected to present evidence under Federal Rules of Evidence 702, 703, or 705; and (ii) a summary of the facts and opinions to which the witness is expected to testify." *See* FRCP 26(a)(2)(C).

This amendment played a key part in excluding expert testimony from a plaintiff's treating physician in *Schutter v. Wyeth Inc.*, 2011 U.S. Dist. LEXIS 110764 (N.D. Ill, 2011). In a lawsuit filed against the manufacturer of hormone replacement therapy for allegedly causing plaintiff's breast cancer, the treating doctor merely discussed general risk factors for breast cancer. The court struck the testimony of the physician because he did not offer specific testimony about how hormone therapy was a risk factor or "a potential cause of breast cancer," *Id.* at *9-10. The court found that the testimony did not put forth a methodology for stating the cause of breast cancer, nor did it rely on any experience beyond the general qualifications of a doctor who treats breast cancer, and that a party could be foreclosed from introducing causation testimony by a doctor if it was based on knowledge gained outside of his capacity as the plaintiff's treating physician, unless he was designated as an expert under Rule 26(b)(2). *Id*. at *10.

These new rules enable defendants to seek admission of the "expert" alternative cause or no causation testimony, and, if it goes awry, challenge the admissibility of the testimony of treating physicians. Should defendants obtain favorable alternative or no causation testimony, plaintiffs must seek to obtain testimony that the doctor formed his or her opinions outside the course of the plaintiff's treatment. If plaintiff is successful, defendants must seriously consider having the doctor prepare an expert report in order to guarantee that the doctor can favorably testify at trial on the key causation issue. Conversely, if plaintiff develops favorable causation

testimony, defendants must be guided by the rules in seeking to exclude the testimony while at the same time attempting to remain aligned with their co-defendant.

Keeping the rules and law in mind, phrasing of questions at the deposition can become key. Straight forward phrases such as "during your care and treatment" or "you made the following note in your records which I assume supports your opinion in this case" can sometimes get you over the admissibility hurdle or set up a challenge to admissibility. Similarly, "I did not see anything in your records concluding my client's product caused plaintiff's injury" together with the foundational Daubert methodology type questions, and all of a sudden your case becomes more than just a battle of the experts. Your defense is now aligned with the uncompensated treating doctor. To state the obvious, working with co-counsel (or the doctor where permitted) in advance of the deposition will help flush out potential problems on such key issues. Without that level of cooperation, the deposition becomes a potential mine field.

V. Minimizing Conflicts and Finding Common Ground

At one point in time, both the physician and the manufacturer were working together for a common end – good patient care. Litigation, however, quickly can drive a wedge into that collegial spirit. The strategies for mitigating the potentially disastrous consequences of co-defendant finger pointing begin early in litigation and must continue throughout trial.

- **Meet with co-defense counsel early on**.

Striking an alliance with co-defense counsel early on is essential. One factor to bear in mind when trying to develop this alliance is which attorney your efforts should be directed towards. Manufacturing defendants often have several layers of counsel, from local to national to corporate. While a physician's counsel might be most familiar with the manufacturer's local counsel, that individual may not be in the best position to make decisions regarding future collaboration or information sharing. As such, make sure you go as far up the chain as needed in order to develop a mutually beneficial relationship.

- **Develop common ground for your defenses.**

Find a way to make the facts of the case work for all defendants if possible or, at least, do not make your defense rest primarily on shifting the blame to a co-defendant. From the physician's perspective, the best outcome for all defendants would be the following: (1) the manufacturer defendant testifies that it stands behind its device/drug and the product worked like it was supposed to; and (2) the manufacturer defendant acknowledges that it must defer to the physician's clinical judgment on how the product was used in this particular patient and avoid commenting on the standard of care of the physician. In such a situation, the manufacturer is still able to advocate for its product/drug without stepping on the toes of the physician's medical assessment.

- **If physicians are to be used as causation witnesses, select them jointly**.

Coordination and communication are key when selecting and preparing witnesses. Make sure to consider whether your identification of an expert witness will have

ramifications on the co-defendants. If it is unavoidable that your causation expert will be the same medical specialty as the defendant physician, consider allowing the physician's counsel to assist in the vetting of the expert.

- **Know the Treating Physicians -- and meet with them beforehand (if you can!).**

Any opportunity for defense counsel to have a conversation with a plaintiff's treating doctor outside of a deposition or trial could be extraordinarily valuable. States are split over the issue of allowing a defendant to engage in ex parte medical contact with a plaintiff's physician. Some courts construe the privacy rules of HIPAA as creating a physician-patient privilege that preempts a defendant from engaging in either formal or informal discovery. However, the status of informal defense access to treating physicians varies from state to state. While several courts acknowledge that a plaintiff waives any physician-patient privilege when they bring personal injury actions because they affirmatively place their mental or physical condition at issue, others have refused to allow this contact. As a result, it is vitally important to be aware of the rules that apply in the state where the litigation is taking place. Defense counsel may be entitled to this invaluable opportunity!

- **Consider a Joint Defense Agreement**.

Regardless of whether it is formal or informal, joint defense agreements can prove to be valuable collaborative tools. The key to getting the most out of these agreements is understanding how your jurisdiction will treat them. For instance, some courts consider the agreements inadmissible, but still discoverable. Other courts require that the agreements be in writing before they are enforceable. Thus, researching local law before proceeding is paramount.

- **Beware the Indemnity Agreement.**

Indemnity may be appropriate in certain situations, but beware the benefit that plaintiff's counsel can gain from such an agreement. The "don't believe the doctor because he or she is in bed with the manufacturer" can resonate with the jury.

While forming an alliance with the co-defendant is not advisable in every situation, if the situation is appropriate a unified effort can promote efficiency, enhance effectiveness, and reduce risk. By understanding the problems physician and manufacturing defendants can create for each other, counsel will be better prepared to develop a strategy for minimizing that conflict and, in the end, increase the chances of winning the war.

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