Bloomberg BNA

Product Safety & Liability Reporter™

PRODUCT LIABILITY

DISCOVERY

Strategic planning by defense counsel at the outset of discovery in pharmaceutical and medical device liability suits can lead to the preclusion or limitation of treating physician testimony at trial, testimony that jurors frequently find more compelling than that of retained experts who have never treated the plaintiff, say attorneys Carole W. Nimaroff and Stephen Lanza in this BNA Insight. The authors explain that deposition testimony may reveal deficiencies in the physician's qualifications or methodology, which can support motions to narrow trial issues, exclude evidence, and alter outcomes.

Treating Physician Depositions in Pharmaceutical and Medical Device Products Liability Cases: A Road Map for Limiting or Excluding Influential Testimony

By Carole W. Nimaroff and Stephen Lanza

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In pharmaceutical and medical device products liability actions, the fortunes of a plaintiff's case routinely hinges on the specific causation testimony elicited at treating physicians' depositions.

With increasing regularity, plaintiffs are relying upon treating physicians to offer expert testimony at trial, providing defense counsel with opportunities to challenge the qualifications and reliability of the opinions of these non-retained experts under applicable evidentiary standards, including *Daubert*. Strategic planning by defense counsel at the outset of discovery can lead to the preclusion and/or limitation of treating physician testimony at trial, testimony that jurors frequently find more compelling than that of retained experts who have never treated the plaintiff.

Keeping unreliable treating physician testimony from the jury remains a potent weapon in defense counsel's arsenal. Recent federal court products liability cases provide a road map for the vital concessions defense counsel should elicit to successfully challenge the admissibility of the treating physician's testimony. This article offers specific questions to secure admissions critical to a successful dispositive motion. Defense counsel beware—missed opportunities at treater depo-

 ISSN 0092-7732

sitions may result in the admission of unreliable opinion testimony at trial, with costly results.

In products liability litigation, treating physicians are regularly called to testify as to their diagnosis and treatment of a plaintiff in connection with his or her alleged injuries. If a treating physician's testimony ventures beyond this care and treatment, and the diagnoses formed during the course of treatment, into critical areas such as medical causation, defense counsel must be prepared to challenge them using all available tools under Federal Rule of Evidence 702. F.R.E. 702 provides that to testify the expert must *inter alia* have the appropriate credentials, specialized knowledge, and reliable opinions[1]:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court established that district judges are to act as ''gatekeepers'' for expert testimony. 509 U.S. 579, 592–93 (1993). The district judge must weigh the proffered testimony and make a preliminary determination about the scientific validity of the expert's reasoning and methodology. *Id. See Harvey v. Novartis Pharm. Corp.*, No. 2:06–CV–1140–VEH, 2012 BL 262708, at *2 (N.D. Ala. Oct. 4, 2012).

Qualifications

In recent pharmaceutical products liability actions, defendant manufacturers have successfully challenged treating physicians' qualifications to offer specific causation testimony by homing in on the physicians' lack of qualifications. Several tactics have proven successful:

Get Treater to Admit He or She Is Not Expert On the Cause of the Condition at Issue

An admission by the treater that he or she is not an expert on the cause of the medical condition at issue can serve as a basis for a court to find the treater unqualified to render case specific opinions.[2]

Ask Detailed Questions to Unmask Treater's Lack of Scientific, Technical, or Other Specialized Knowledge on Diagnosing Cause of Injury

To establish that the treating physician's expressed opinion on the cause of the injury is not based on any education, training, and/or clinical experience consider the following exemplar questions:

- ''Have you conducted medical or scientific research on [the injury, device or medication at issue]?''
- ''Have you served as an investigator, or otherwise participated in any clinical trials regarding [the medication or device at issue]?''
- ''Have you published or submitted a paper in a peer reviewed journal on [the medication, device or injury at issue]?''
- ''Have you served as a peer reviewer for any articles that involve [the injury, medication or device at issue]?''
- ''Have you ever participated in drafting any clinical guidelines on [the medication, device or injury at issue]?''
- ''Have you been asked to speak by any medical organization on [the medication, device or injury at issue]?''
- ''Have you ever taught on [the medication, device or injury at issue]?''

In *Harvey*, *supra*, a recent lawsuit filed against Novartis Pharmaceuticals Corporation (''Novartis''), plaintiff alleged that her ingestion of the FDA-approved prescription medications Zometa and Aredia caused her to develop ONJ.

The court found that because the treating maxillofacial surgeon had not conducted medical or scientific research, researched ONJ or bisphosphonates, published or submitted a paper on either ONJ or bisphosphonates, or taught on either subject established that he did not have the requisite expertise to offer an opinion on the cause of the plaintiff's ONJ.[3]

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[1] An alternative standard used by many courts is set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and requires that expert testimony must be based on scientific methods that are sufficiently established and accepted in the particular field in which it belongs.

[2] *See, e.g.*, *Parmentier v. Novartis Pharms. Corp.*, No. 1:12-CV-45 SNLJ, slip op. at 11 (E.D. Mo. June 19, 2012) (finding that treating physician's admission that he was not an expert at diagnosing the causes of osteonecrosis of the jaw (''ONJ'') precluded him from testifying as an expert on specific causation); *see also Davids v. Novartis Pharms. Corp.*, 857 F. Supp. 2d 267, 281 (E.D.N.Y. 2012) (treating physician who testified that he did not consider himself an expert in determining the cause of ONJ in patients who have been exposed to bisphosphonates was not qualified to provide an expert opinion on specific causation); *Thomas v. Novartis Pharms. Corp.*, 443 Fed. Appx. 58, 61 (6th Cir. 2011) (stating that while treating physician's self-assessment as to whether he or she is an expert ''is not dispositive as to whether he or she meets the requirements of Rule 702, it is one factor that district courts may consider''); *but see Harvey*, 2012 BL 262708, at *4 (''[T]he court rejects Novartis's contention that Dr. Miller is not an expert simply because he said he does not consider himself an expert. Just as an individual cannot simply declare himself to be an expert, a person cannot simply declare himself not to be an expert. Instead, the court must examine the individual's education, training, and experience, and decide if these credentials make the individual qualified to offer an expert opinion.'').

[3] *See Harvey*, 2012 BL 262708, at *4; *see also Thomas*, 443 Fed. Appx. at 62 (holding that while treating physician was ''unquestionably an experienced oral surgeon with many years of practice and training,'' for physician to qualify as an expert on specific causation, plaintiff had to establish that doctor met

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Regardless of whether the treating physician claims to have expertise in diagnosis of the alleged injury, more often than not physicians will concede that: (i) identifying the cause of the injury is irrelevant to the diagnosis, care, and treatment of a patient with the relevant injury; and (ii) he or she does not possess the required education, training, and clinical experience to determine the etiology of the injury.

To underscore the treater's absence of clinical experience in ascertaining the etiology of the disease, consider asking:

■ ''Over the past [number of years] how many times have you diagnosed this injury?''

■ ''Of those patients in which you have made a diagnosis, have you identified the etiology of the disease?''

If the answer is ''no,'' then ask:

■ ''Is that because identifying the etiology of the disease has no bearing on your care and treatment of the patient?''

■ ''Is it fair to say that your treatment of the patient is the same irrespective of the etiology of the disease?''

If the witness testifies that he has identified the etiology of the disease, then ask:

■ ''How many times have you identified the etiology of the disease?''

Very often treating physicians will have some clinical experience diagnosing the injury at issue but not the cause. Delving deeper into the physician's core patient population may prove fruitful. Specifically, care must be given to examine differences among the patients with the injury who have used the medication or device from those who have not. The inability of a treating physician to clinically differentiate among his or her patients before offering a causation opinion can result in preclusion at trial. The absence of reliable objective features of the injury that a physician can identify that serve as a basis for the diagnosis will undermine the reliability of the diagnosis.

Consider the following questions:

■ ''In your clinical experience how many times have you diagnosed patients with this alleged injury?''

■ ''How many times have you diagnosed patients with that injury outside the setting of [the specific medication or device at issue]?''

■ ''Of those patients who you have diagnosed outside the setting of [the specific medication or device at issue], how many times did you identify the etiology of the disease?''

■ ''Were there any unique symptoms or manifestations of the injury that were specific to the patients diagnosed with the injury that had used the [medication or device]?''

■ ''Did the clinical course of the injury differ in any way among these classes of patients?''

■ ''Did the response to treatment differ in any way among these classes of patients?''

■ ''In the absence of historical information of use [of the medication or device] are there any objective criteria you use to distinguish among these two classes of patients with this injury?''

Equally imperative is to distinguish whether the treating physician is offering an opinion of an ''association'' or of a ''causation'' between the plaintiff's injury and the medication or device at issue. If the treating physician's opinion is only that an association exists between the medication or device and the injury, rather than a causal relationship, some courts would not consider the treater qualified to give an expert opinion as to causation. *See, e.g.*, *Simmons*, No. 11-5053 at 8 (finding that treating physician who found a ''very close association'' between ONJ and bisphosphonates but acknowledged that he ''didn't establish causation'' should not be permitted to testify as to specific causation).

Reliability

Daubert set forth a non-comprehensive checklist for trial courts to consider in determining the reliability of scientific expert testimony. The factors identified by the *Daubert* Court include (1) whether the expert's technique or theory can be or has been tested, i.e., whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) whether the technique or theory has been generally accepted in the scientific community. 509 U.S. at 593–94.

Conducting a Reliable Differential Diagnosis

Differential diagnosis, or diagnosis of exclusion, is the gold standard for a reliable diagnosis. Federal courts have recognized that when performed correctly a differential diagnosis is a proper methodology for determining the cause of a medical condition. *See Tamraz*, 620 F.3d at 674. To garner admissions that challenge the reliability of a case specific causation opinion offered by a treating physician, a defendant manufacturer should explore whether a differential diagnosis was performed, whether it was exhaustive and what criteria were used to exclude potential causes.

The first step to conducting a reliable differential diagnosis is to rule *in* a list of potential causes of the injury. *Nelson v. Matrixx Initiatives*, No. C 09–02904 WHA, 2012 BL 213509, at *6 (N.D. Cal. Aug. 21, 2012). Then, the treating physician must eliminate, or rule out, the identified potential causes until one remains. *Id.* The ''expert must provide reasons for rejecting alterna-

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the requirements to give an expert opinion regarding *the cause of plaintiff's injury*, not just that the physician could recognize and treat the injury); *Simmons v. Novartis Pharms. Corp.*, No. 11-5053, slip op. at 3, 10–11 (6th Cir. June 5, 2012) (finding treating oral surgeon unqualified to give an expert opinion on the cause of plaintiff's injury where treater's testimony revealed that his experience as an oral surgeon may have qualified him to diagnose plaintiff's ONJ, but did not qualify him to explain the etiology of plaintiff's ONJ); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 673 (6th Cir. 2010) (stating that most treating physicians have more training in and experience with diagnosis than etiology).

tive hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation.'' *Id.* at *6-7 (citing *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003)).

This process involves compiling a ''list of possible causes that are generally capable of causing the illness or disease at issue, and then systematically and scientifically ruling out specific causes until a final, suspected cause remains.'' *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1342 (11th Cir. 2010). Of note, defense counsel should make sure to review clinical guidelines that may exist within the practice specialty of the treating physician that pertain to the diagnosis of the medical condition at issue.

Investigate Whether a Reliable Differential Diagnosis Was Performed

Consider these questions:

■ ''Do you routinely practice evidence-based medicine as part of your clinical practice?''

■ ''As part of your evidence-based practice, do you routinely use a differential diagnosis or diagnosis of exclusion?''

■ ''Did you perform a differential diagnosis at the time you were treating plaintiff to determine the cause of the alleged injury?''

If the treating physician did not perform a differential diagnosis, most courts would hold that the physician's opinion does not meet the requirements of F.R.E. 702 and *Daubert*. *See, e.g.*, *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 473 (E.D.N.Y. 2011) (holding that treating physician was not qualified to opine on specific causation where he failed to perform an independent differential diagnosis).

If Treating Physician Confirms Use of Differential Diagnosis, Elicit Specific Testimony as to Potential Causes of Injury Physician Considered

Consider asking the following questions:

■ ''Do you agree with me that there are numerous possible causes of [the alleged injury]?''

Provided the treating physician says ''yes,'' ask him or her to identify all of the possible causes of plaintiff's alleged injury that he or she considered or ruled in as the initiating point of inquiry. If the treating physician omits a cause that may be relevant to plaintiff's injury (e.g., smoking, family history) from the list of differential diagnoses, defense counsel should ask:

■ ''Were you aware that [x] is a potential cause of [plaintiff's alleged injury]?''

If the treating physician answers in the affirmative, ask whether he or she ''considered [x] as a potential cause of plaintiff's alleged injury.''

If the treating physician answers in the negative, make certain to follow up to secure testimony as to why the potential cause was not considered. Most doctors will readily concede that their diagnostic investigation is limited by the information received from the patient.

To the extent he or she did not have knowledge of a relevant potential cause, the witness's credibility is not impugned, but the reliability of the scientific method most certainly is. At a minimum, this approach will either reveal the witness's lack of experience and knowledge or, at best, an unreliable methodology. Defense counsel must be aware of the alternative causes of the condition at issue when taking the deposition so that effective follow up can be pursued.

Consider not only co-morbid conditions, but concomitant medication use by plaintiff with known side effects as possible alternative causes. Inquiry should be made as follows:

■ ''Were you aware that [plaintiff] was on [x medication] at the time of your treatment?''

Investigate the treating physician's knowledge as to duration, dose, and known side effects. If the treating physician testifies that he or she was aware that plaintiff was taking the medication but never considered it as a potential cause, ask:

''Did you include on your list of potential causes the concomitant use of this medication that carried a warning of this precise injury that plaintiff alleges in this lawsuit?''

If the treater says ''yes,'' ask: ''What criteria did you use to exclude this medication as a possible cause of plaintiff's injury?''

If the treating physician says he or she was unaware that plaintiff was taking the medication, make sure to memorialize on the record the following:

■ ''So you did not consider [x medication] as a possible cause for plaintiff's [alleged injury]?''

If, as expected, the treater answers ''no,'' this will seriously undermine the reliability of the treater's differential diagnosis and establish a ground for preclusion of the specific causation opinion.

To Establish Unreliability of Offered Opinion, Get Treating Physician to Acknowledge Failure to Rule Out Other Potential Causes of Injury

In *Harvey*, plaintiff's treating maxillofacial surgeon identified three potential causes of plaintiff's ONJ—bisphosphonates, osteomyelitis, and osteoradionecrosis. 2012 BL 262708, at *6. The Court found that the physician never properly ruled out osteomyelitis (a bone biopsy he ordered to rule it out was inconclusive), and that osteoradionecrosis could have been ruled out by showing that plaintiff had no history of radiation exposure. *See id.*

The treating physician's failure to properly rule out osteomyelitis led the Court to conclude that his opinion was not sufficiently reliable under Rule 702 and *Daubert*. *See id.* at *7; *see also Davids*, 857 F. Supp. 2d at 282 (finding that treating physician's methodology did not pass muster where he testified that his differential diagnosis included ''other factors'' and ''other drugs,'' but he did not identify the ''other factors'' and ''other drugs'' that he ruled out).

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To establish that the treating physician did not properly rule out other potential causes of plaintiff's injury, make sure to ask (for each potential cause identified):

- ''What factors did you consider in ruling out [the other potential cause]?''
- ''What diagnostic testing did you rely on in ruling out [the other potential cause]?''
- ''What literature, if any, did you rely on in ruling out [the other potential cause]?''

If the treating physician did not rule out other potential causes based on any identifiable expertise, medical literature or objective diagnostic testing, his or her differential diagnosis may be excluded as scientifically unreliable under *Daubert*. *Deutch*, 768 F. Supp. 2d at 475.

Although questioning about exclusion of alternative causes that may never have been ruled in may seem a bit unusual, testimony should nevertheless be elicited since there is only one bite at the apple. If the testimony is clear that the physician failed to rule out any of the other potential causes of plaintiff's injury, the foundation for a *Daubert* challenge has been laid to exclude any causation testimony by the treating physician whether designated as an expert or not.[4]

Strategic use of the treating physician deposition remains an important tool that can prevent cases from ever seeing the inside of a courtroom. The landscape of recent federal court *Daubert* decisions confirms that exclusion of the treating physician testimony can be successful when supported by carefully elicited testimony. Because treating physicians are often held by jurors in higher regard than the expert retained solely for litigation, defense counsel cannot afford to miss any opportunity to gain critical admissions.

Even if the *Daubert* motion is denied, deposition testimony that reveals deficiencies in the physician's qualifications or the reliability of his or her opinions can support motions in limine that can narrow trial issues, exclude evidence, and alter outcomes.

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[4] *See Parmentier*, Case No. 1:12-CV-45 SNLJ at 10 (excluding treating physician's specific causation testimony as lacking reliable foundation required under F.R.E. 702 and *Daubert* where physician failed to rule out another known cause of ONJ in performing his differential diagnosis); *Hines v. Wyeth*, No. 2:04-0690, 2011 BL 183816, at *3 (S.D. W. Va. July 14, 2011) (holding that treating physician's differential diagnosis did not satisfy *Daubert* where treating physician did not ''systematically and scientifically'' rule in and rule out specific causes of plaintiff's injury until a final cause remained).