KAYE SCHOLER LLP

About the Authors



Sheila S. Boston is a partner in Kaye Scholer LLP's Complex Commercial Litigation Department and is a member of the firm's Product Liability Group. Ms. Boston has experience representing pharmaceutical and medical device companies and has served as national coordinating counsel of experts, involving the retention, development and preparation of experts for depositions, Daubert/Frye hearings and trials. She received her A.B. from Princeton University in 1990 and her J.D. from Columbia University School of Law in 1993. She can be reached at sboston@kayescholer.com.



Ira Ginsberg is an associate in Kaye Complex Scholer's Commercial Litigation Department and is a member of the firm's Product Liability Group. Mr. Ginsberg has experience representing organizations in general litigation matters, and he has assisted reviewing pharmaceutical compliance programs and counseling clients on applicable state and federal regulations. Mr. Ginsberg received his J.D. from New York University School of Law in 2010. He can be reached at ira.ginsberg@kayescholer.com

This article originally appeared in the April 2012 issue of DRI's RX For The Defense.

When Will Plaintiffs Learn to Let Treating Physicians Be Treating Physicians?

Experienced product liability practitioners know that the treating physician's testimony is often the most important testimony in a personal injury case. Thus, both plaintiff and defense counsel alike attempt to elicit favorable causation testimony from these witnesses. Plaintiff counsel, however, often go a step further: they try to convert non-party treating physicians into experts. Unable to find qualified causation experts in a particular field with the appropriate experience and publications concerning a salient issue, plaintiffs instead often opt to proffer treating physicians as causation experts. And, more often than not, differential diagnosis is the methodology employed by those treating physicians as the basis of their expert opinions.

"Unable to find qualified causation experts in a particular field with the appropriate experience and publications concerning a salient issue, plaintiffs instead often opt to proffer treating physicians as causation experts."

Differential Diagnosis Under Daubert

In product liability personal injury cases brought against drug and medical device manufacturers, the plaintiff must establish general causation and specific causation. To establish general causation, plaintiffs often retain experts in the relevant scientific field. To establish specific causation, plaintiffs often proffer the testimony of treating physicians who base their testimony on the same differential diagnosis doctors routinely employ to treat their patients. "Differential diagnosis refers to the clinical process by which doctors determine the internal disease that is causing a patient's suffering," and when used appropriately it "is an invaluable tool that guides physicians' choices among possible diagnostic tests and treatments." Ian S. Spechler,

Note, *Physicians at the Gates of Daubert: A Look at the Admissibility of Differential Diagnosis Testimony to Show External Causation in Toxic Tort Litigation*, 26 Rev. Litig. 739, 740-43 (2007) ("Spechler Note"). An overwhelming number of courts have held that a medical opinion proffered in support of specific causation, based upon a proper differential diagnosis, is permissible as expert testimony. *See Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178-80 (6th Cir. 2009); *Hines v. Wyeth, Inc.*, 2011 WL 2792436, at *3 (S.D.W.V. July 14, 2011).

"While courts allow treating physicians to testify as experts based on differential diagnosis, such rulings have been based on a misunderstanding of a physician's role."

Expert testimony can be admitted only after careful consideration of Federal Rule of Evidence 702 and the relevant Daubert factors, which require district courts to assess whether proffered expert testimony is both reliable and relevant to a case. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). Courts consider reliability by reviewing "whether the theory or technique had been tested, whether it had been subjected to peer review and publication, the method's known or potential error rate, and the method's general acceptance in the scientific community." Meister v. Med. Eng'q Corp., 267 F.3d 1123, 1127 (D.C. Cir. 2001). Although a treating physician need not be "among the world's foremost authorities" on the causation matter at issue to provide expert testimony regarding a patient's illness, the appropriate diagnosis, and the cause of the illness, a treating physician's expert opinion on causation is subject to the same rigorous standards of scientific reliability that govern the expert opinions of physicians hired solely for purposes of litigation. Thomas v. Novartis Pharm. Corp., 443 Fed. App'x 58, 61 (6th Cir. 2011); see Kumho Tire Co. v. Carmichael 526 U.S. 137, 147 (1999); Bland v. Verizon Wireless, L.L.C., 538 F.3d 893, 897 (8th Cir. 2008). Consequently, the admissibility of a treating physician's "expert" testimony rendered on behalf of a plaintiff is far from a fait accompli. Recent published federal case law demonstrates that plaintiffs in drug and medical device litigations have often struggled to parlay treating physician testimony into admissible expert testimony under Daubert. See Thomas v. Novartis (affirms exclusion of causation testimony of plaintiffs' treating doctors); Hines v. Wyeth (excludes causation testimony of one of plaintiff's surgeons); see also Bland v. Verizon Wireless (affirms exclusion of treating physician's differential diagnosis with a good discussion of Daubert); but see In re Fosamax Prods. Liab. Litig., 647 F.Supp.2d 265 (S.D.N.Y. 2009). Furthermore, although courts find that, at least in theory, a treating physician's differential diagnosis survives Daubert to show specific causation, courts generally find this approach insufficient to demonstrate general causation. See Bickel v. Pfizer, Inc., 431 F.Supp.2d

918, 923 (N.D. Ind. 2006) ("the Plaintiff cannot rely on [differential] diagnosis to establish general causation"); see also In re Rezulin Prods. Liab. Litig., 2004 WL 2884327, at *4 (S.D.N.Y. Dec. 10, 2004) ("differential diagnosis does not 'speak to the issue of general causation. [It] assumes that general causation has been proven for the list of possible causes' that it rules in and out in coming to a conclusion." (quoting Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387, 1413 (D.Or. 1996))); but see Perkins v. Origin Medsystems Inc., 299 F.Supp.2d 45, 57-61 (D. Ct. 2004).

Differential Diagnosis vs. Differential Etiology

While courts allow treating physicians to testify as experts based on differential diagnosis, such rulings have been based on a misunderstanding of a physician's role. Doctors treat symptoms and diseases, so they try to figure out the source of the symptoms and identify the disease or injury so that they may properly treat the patient. Physicians do not, however, routinely engage in differential etiology or an attempt to figure out what external factor caused a disease. Doctors like the one portrayed by actor Hugh Laurie in the Fox network television medical drama "House" are an anomaly. How many doctors make house calls or inspect work and/or home environments as part of their diagnostic practice? There is a significant difference between differential diagnosis and differential etiology. "In a differential diagnosis, a doctor isolates a disease that is causing the patient's symptoms, whereas differential etiology isolates an external factor that has caused the internal disease." Spechler Note at 743. Recently, some courts have demonstrated a clearer understanding of these concepts, and, in assessing the reliability of treating physician testimony, have inquired whether the doctor's differential diagnosis procedure included an emphasis on external causes. *See, e.g., Bickel,* 431 F.Supp.2d at 923-924; *In re Rezulin Prods. Liab. Litig.,* 2004 WL 2884327, at *3-4.

Instructive Defense Victories in 2011

In *Thomas v. Novartis*, three plaintiffs alleged that the defendant's prescription bisphosphonate drugs caused them to develop osteonecrosis of the jaw ("ONJ"). To prove specific causation, plaintiffs proffered the testimony of their respective "expert" treating physicians. The experts of two of the plaintiffs were experienced in the relevant field of medicine, had treated many patients with ONJ, and had engaged in differential diagnosis in support of their specific causation opinions. Furthermore, the plaintiffs presented evidence that the treatment ordinarily used for ONJ actually worsens the condition when used on patients with bisphosphonate-induced ONJ, thus emphasizing the importance of the

treating physician properly determining ONJ's cause. Nonetheless, the court excluded both experts stating that they lacked an adequate basis for showing the defendant's products caused plaintiffs' ONJ. The court noted that "the importance of correctly determining the cause of the osteonecrosis ... does nothing to establish that [the doctor] can in fact, reliably determine the cause of a patient's [ONJ]." *Id.* at 62. The court also stated that showing a doctor could recognize and treat ONJ was insufficient to show that he could adequately determine the condition's external cause. Moreover, the court noted that one of the experts did not consider himself to be an expert in the causes of ONJ, which although not dispositive, did impact the court's assessment of the testimony. The testimony of the third plaintiff's experts were excluded on simpler grounds: both doctors stated that they did not form an opinion about the cause of their patient's condition to a reasonable degree of medical certainty. Furthermore, neither doctor considered himself an expert on the relevant issue.

In *Hines v. Wyeth*, a plaintiff alleged that her ingestion of defendants' hormone replacement therapy (HRT) drugs caused her development of breast cancer. The defendants successfully moved to exclude one of plaintiff's treating physicians from testifying as a specific causation expert. Although the treating physician conducted a differential diagnosis, the court found that his testimony failed to pass the *Daubert* threshold because in addition to not properly ruling out alternative causes of the plaintiff's condition, he did not reliably rule in alternative causes by considering the possibility of such alternatives.

Tips for Defense Counsel

Based on recently published *Daubert* decisions, there are several strategies defense counsel should consider when opposing a plaintiff's attempt to proffer treating physician testimony as expert causation testimony. In addition to arguing that a treating physician lacks certain qualifications and that differential diagnosis is not a suitable methodology for establishing general or specific causation, defense counsel should also:

- Capitalize upon a treating physician's own acknowledgement that he or she is not an expert. See, e.g., Thomas v. Novartis.
- Establish that the treating physician has never published or otherwise presented the causation opinion to professional peers. *See, e.g., Bickel v. Pfizer*.

- Establish that the treating physician is unable to cite any published medical textbook or article that concludes there is a validated medical test, procedure or protocol as the basis for his or her specific causation opinion. See, e.g., Bickel v. Pfizer.
- Obtain an admission from the treating physician that the goal of the differential diagnosis is to determine from what disease a patient suffers, not to determine the external cause of that disease. See Spechler Note.
- Demonstrate that the treating physician failed to adequately "rule in" and "rule out" alternative causes. See, e.g., Hines v. Wyeth.
- Demonstrate that the treating physician not only failed to attempt to rule out other possible causes of the condition but also is unable to rule them out. See, e.g., Meister v. Med. Eng'g.
- Argue that the importance of correctly determining the cause of an alleged injury or disease
 does nothing to establish that the treating doctor could in fact reliably determine the cause of a
 patient's injury or disease. See, e.g., Thomas v. Novartis.
- Always make sure that the treating physician offers more evidence than just a temporal link;
 reliance on temporal proximity, without more, is insufficient to establish causation. See, e.g.,
 Meister v. Med. Eng'g; but see Perkins v. Origin.