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Admissibility of an expert's opinion under *Daubert v. Merrell Dow Pharmaceuticals Inc.* and Federal Rule of Evidence 702 requires more than the invocation of an accepted methodology, says attorney Katharine R. Latimer: The expert's opinion must ''in fact be derived from a scientifically sound method.'' Courts have begun to recognize this, and pierced the veil of the ''differential diagnosis mantra'' to determine whether the expert adhered to, and his opinion is the product of, that methodology.

A Good Bedside Manner Wouldn't Be Enough, Either: Differential Diagnosis Under *Daubert*

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An Expert Needs More Than A Method

Federal Rule of Evidence 702 leapt to center stage with the U.S. Supreme Court's landmark decision in *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993).[1] The *Daubert* Court explained that Rule 702

[1] Effective Dec. 1, 2000, Federal Rule of Evidence 702 provides: ''Testimony by Experts—If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data,

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allows the district court to admit only that expert testimony which is scientifically reliable and which will assist the jury.[2]

In exercising what the Court described as a gatekeeping function, the district court must make ''a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts at issue.''[3]

Every *Daubert* practitioner by now knows the ''methodology'' mantra: faced with a *Daubert* challenge to the scientific reliability (and, hence, the admissibility) of an expert's opinions, the first-line response—perhaps bolstered by affidavits and textbook references—is that ''all experts in the field use this method'' or that ''this method has been used for decades.'' The line works, proponents of the expert's opinion say, because *Daubert* teaches that the trial court's sole focus must be on ''methodology'' rather than ''conclusions.''[4] But identifying the expert's methodology—even as a standard and accepted one—only frames the *Daubert* question, it does not answer it. The trial judge's obligation is to assess whether the expert has stayed true to the method in a way that enables him to offer opinions that are fairly derived.[5]

Examples are plentiful and include the safety testing methodology used by the expert in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999), a case often cited only for the proposition that the *Daubert* reliability screen applies to all types of expert testimony. In *Kumho Tire*, the Court acknowledged that the visual and tactile inspection method employed by the expert might be accepted in the tire industry.[6] But ''contrary to respondents' suggestion, the specific issue before the court was not the reasonableness in general of a tire expert's use of a visual and tactile inspection . . . . Rather, it was the reasonableness of using such an approach, along with [the expert's] particular method of analyzing the data thereby obtained, to draw a conclusion regarding the particular matter to which the expert testimony was directly relevant.''[7]

In short, laying claim to an accepted methodology is simply not enough.

Differential Diagnosis as ''Method''

One of the best illustrations of the rule is found in the fast-growing library of cases dealing with medical expert testimony. As described below, *Daubert* can and should exclude many a medical expert opinion purportedly reached using the well-recognized, well-accepted methodology of ''differential diagnosis.'' In these cases, the opponent of the opinion is not challenging the differential as a methodological concept; rather, he is challenging the execution or application of the concept to the case at hand.

The trial judge must ''assess whether the expert has stayed true to the method in a way that enables him to offer opinions that are fairly derived.''

Experts and laypersons (other than lawyers) long have recognized differential diagnosis as a standard clinical technique by which to make ''the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings.'' STEDMAN'S MEDICAL DICTIONARY 428 (25th Ed. 1990).[8]

Perverted in the courtroom with a consequential sleight of phrase, differential diagnosis is now routinely defined in the case law as ''a standard scientific technique of identifying the *cause* of a medical problem, by eliminating the likely causes until the most probable one is isolated.'' *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999) (emphasis added).[9]

Even in the courtroom, however, it is important to remember that differential diagnosis is a ''patient-specific process of elimination,'' *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1362 (N.D. Ga. 2001); in other words, it can help answer the question of whether a chemical ''did cause'' an illness in a particular patient, but it is not designed to answer the more fundamental question of whether a chemical ''can cause'' the illness in the first place, *id*.

Whatever its definitional origins, differential diagnosis as an accepted technique by which to search for causation-of-injury is comfortably settled in the case law.[10] Proponents of expert opinions grounded in differential diagnosis then argue that the opinions are *per se* admissible under *Daubert*.

They are wrong:

> The process of differential diagnosis is undoubtedly important to the question of 'specific causation.' If other possible causes of an injury cannot be ruled out, or at least the possibility of their contribution to causation minimized, then the 'more likely than not' threshold for proving causation may not be met. *But it is also important to recognize that*

(2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.''

Prior to the amendment, Fed. R. of Evid. 702 provided: ''If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.''

[2] *Daubert*, 509 U.S. at 589-93.

[3] *Id.* at 592-93.

[4] *See id.* at 595.

[5] As explained in *General Electric Co. v. Joiner*, 522 U.S. 136,146 (1997): ''[C]onclusions and methodology are not entirely distinct from one another.''

[6] *Kumho Tire*, 526 U.S. at 156.

[7] *Id.* at 153-54. The *Kumho Tire* Court found that the expert failed to apply the methodology in a sound way, and so it was not an abuse of discretion for the district court to have excluded his opinion testimony.

[8] *Quoted in Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997).

[9] *See also, e.g., Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 252-53 (1st Cir. 1998); *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995).

[10] *See, e.g., Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000) (''causation opinion based upon a proper differential diagnosis . . . satisfies *Daubert*''); *Westberry*, 178 F.3d at 263 (''reliable differential diagnosis provides a valid foundation for an expert opinion'') (collecting cases).

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> *the final, suspected 'cause' remaining after this process of elimination must actually be capable of causing the injury.* That is, the expert must 'rule in' the other suspected cause as well as 'rule out' other possible causes. And, of course, expert opinion on this issue of 'general causation' must be derived from scientifically valid methodology.

Siharath, 131 F. Supp. 2d at 1362-63 (*emphasis in original*).[11]

An Example: *Glastetter v. Novartis Pharms. Corp.*

On June 8, 2001, the U. S. Court of Appeals for the Eighth Circuit issued a sweeping *Daubert* opinion in *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986 (8th Cir. 2001) (*per curiam*) (petition for rehearing and rehearing *en banc* denied July 13, 2001). The plaintiff in *Glastetter* had suffered a stroke in 1993 shortly after the birth of her third child; her experts opined that her stroke was caused by the medication Parlodel, which had been prescribed to her to prevent physiological lactation because she had elected not to breastfeed.

In a unanimous decision, the Court affirmed the district court's entry of summary judgment in favor of Novartis, 107 F. Supp. 2d 1015 (E.D. Mo. 2000). The court of appeals observed that each of plaintiffs' experts had conducted a differential diagnosis that concluded that Parlodel caused her stroke. 252 F.3d at 989. The court further observed that in the Eighth Circuit ''a differential diagnosis is presumptively admissible.'' *Id.*[12] As applied, however, the diagnoses were ''scientifically invalid'' because the experts ''lacked a proper basis for 'ruling in' Parlodel as a potential cause of [stroke] in the first place.'' *Id.*; *see also id.* at 991 (noting ''threshold question posed in this appeal: whether Glastetters' experts properly 'ruled in' Parlodel as a cause of [strokes]'').

The court of appeals rejected plaintiffs' experts' reliance on case reports, 252 F.3d at 989-90; [13] on textbook statements that lacked support, *id.* at 990;[14] on chemical analogies, *id.* at 990;[15] on ''rechallenge'' and ''dechallenge'' events,*id.* at 990-91; [16] on animal studies, *id.* at 991;[17] on comments in internal corporate documents, *id.* at 991;[18] and on FDA's regulatory pronouncements and actions, *id.* at 991.[19] These things, the court said, whether viewed in ''isolation'' or in the ''aggregate,'' *id.* at 992, did not supply a scientifically sound basis by which to ''rule in'' Parlodel as a cause of stroke, and therefore the differential was improper and the expert opinions inadmissible.

Other Recent Representative Cases

Well-heeled *Daubert* practitioners plainly know that a generally accepted methodology is the safest starting place from which to withstand a challenge: An online research query on ''differential diagnosis'' and ''*Daubert*'' identifies more than 100 federal cases.

Expert testimony grounded on differential diagnosis is often admitted;[20] in those case where the issue is analyzed, however, the *Glastetter* cautionary approach is held to be the preferred one. For example:

In *Cooper v. Smith & Nephew Inc.*, 2001 U.S. App. LEXIS 15408 (4th Cir. 7/9/01), the U.S. Court of Appeals for the Fourth Circuit affirmed the exclusion of the testimony of an orthopedic surgeon who conducted a differential diagnosis and proffered the opinion that a pedicle screw caused plaintiff's injury. While the court readily agreed that a ''reliable differential diagnosis provides a valid foundation for an expert opinion under Rule 702,'' the expert's inferences of causation and failure to consider alternative causes rendered his particular differential defective.[21]

In *Black v. Food Lion Inc.*, 171 F.3d 308 (5th Cir. 1999), the U.S. Court of Appeals for the Fifth Circuit held that the district court abused its discretion in admitting the testimony of a medical doctor who opined that a fall caused plaintiff's fibromyalgia syndrome. The doctor could rule out various possible causes of the injury, but had no sound scientific basis by which to rule in the fall. ''This analysis amounts to saying that because [the expert] thought she had eliminated other possible causes of fibromyalgia, even though she does not know the real 'cause,' it had to be the fall . . . . This is not an exercise in scientific logic but in the fallacy of post-hoc propter-hoc reasoning, which is as unacceptable in science as in law.''[22]

And in *Raynor v. Merrell Pharms, Inc.*, 104 F.3d 1371, 1375 (D.C. Cir. 1997), a Bendectin case, the court's approach ably predicted the current trend:

> [T]he primary question can properly be formulated as whether it is methodologically sound to draw an inference

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[11] *Quoting Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996) (further internal quotations omitted).

[12] *Citing Turner*, 229 F.3d at 1208.

[13] ''A case report is simply a doctor's account of a particular patient's reaction to a drug or other stimulus, accompanied by a description of the relevant surrounding circumstances. Case reports make little attempt to screen out alternative causes for a patient's condition. They frequently lack analysis. And they often omit relevant facts about the patient's condition.'' *Glastetter*, 252 F.3d at 989-90. The temporal associations documented in case reports therefore are ''not scientifically valid proof of causation.'' *Id.* at 990.

[14] The Court found that the texts relied on case reports or other anecdotal information, or referred to diseases other than stroke, or cited studies on chemicals other than the one at issue. *Id.* at 990.

[15] The ''generic assumption that [one chemical] behaves like other [chemicals in a class] carries little scientific value. Even minor deviations in molecular structure can radically change a particular substance's properties and propensities.'' *Id.* at 990 (citing *Schudel v. General Electric Co.*, 120 F.3d 991, 996-97 (9th Cir. 1997)).

[16] The Court credited the district court's ''considerable discretion'' in rejecting the ''paucity of examples,'' particularly given that the data involved conditions ''quite distinct'' from stroke. *Glastetter*, 252 F.3d at 990-91.

[17] None of the studies associated Parlodel and stroke in any animal. Moreover, plaintiffs' experts had ''acknowledged the difficulty in extrapolating from the results of studies on small animals to effects on much larger humans.'' *Id.* at 991.

[18] The court concluded: ''Glastetter lifted these statements out of context from longer memoranda.'' *Id.* at 991.

[19] The court observed that FDA's risk-utility balancing test was ''irrelevant'' to the medical causation question in the case. ''The methodology employed by a government agency results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances.'' *Id.* at 991 (quoting *Hollander v. Sandoz Pharms. Corp.*, 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000) (internal quotations omitted)).

[20] *See, e.g., Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255 (6th Cir. 2001).

[21] *Cooper.*, 2001 U.S. App. LEXIS 15408 at *12-20.

[22] *Black*, 171 F.3d at 313.

that a drug causes human birth defects from chemical structure, in vivo animal studies, and in vitro studies when epidemiological evidence is to the contrary. The *secondary* question is whether one expert's ''differential diagnosis,'' which apparently seeks to determine cause by process of elimination, is *methodologically sound in this context*.

* * *

Although we found testimony ruling out alternative causes admissible . . . , that testimony on specific causation has legitimacy only as follow-up to admissible evidence that the drug in question could in general cause birth defects. That first step, establishing a link between Bendectin and human birth defects (general causation) is missing here.

(*Emphasis added*.)

Conclusion

Glastetter and most other significant decisions that address differential diagnosis make clear that the ''methodology'' mantra will not suffice. To be admissible, an expert's opinion must *in fact be derived from* a scientifically sound method. As it was invited to do in *Joiner* and in *Kumho Tire*, the district court will consider more than the *ipse dixit* of the expert to assess whether the differential, as applied, can survive a *Daubert* challenge.

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