Differential Diagnosis or Distortion?

By Gary Sloboda*

THE CONCEPT OF disease diagnosis is fundamental not only to the practice of medicine but also to the practice of many areas of the law. While “establishing a diagnosis is one of the physician’s most basic tasks[,] . . . which affects the organization and functioning of the entire health care system,”1 the diagnosis of disease plays an important role in non-therapeutic contexts as well—shaping certain anti-discrimination laws and determining the success or failure of tort lawsuits.2 “Diagnostic judgments have become so pervasive and readily accepted in these varied contexts that we may lose sight of their overall significance.”3 One commentator recently argued that as the concepts of disease and diagnosis extend outside the area of the patient-doctor relationship, “closer scrutiny of the diagnostic process is warranted.”4 Indeed, where non-medical decision-makers, such as government agencies, politicians, and judges, use diagnosis for non-therapeutic purposes, new constructs are devised to fit these various forums outside clinical medicine.5 Detaching the diagnostic process from the therapeutic perspective can result in a distortion of the diagnostic process, particularly when medical diagnosis is directed not at healing, but at persuasion and/or profit.6

In the area of tort litigation, the use of diagnosis to prove injuries and causation is routine.7 In fact, without the use of diagnosis in tort actions, many plaintiffs’ causes of action would be almost impossible

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4. Id.
5. See id. at 242–43 (noting that in some situations diagnosis is used to advocate policy and validate complaints).
6. See id. at 243 (noting that where non-medical decision-makers drive the diagnostic process, legitimate concerns arise about the integrity of the medical profession and the costs to society).
7. See Zuchowicz v. United States, 140 F.3d 381, 383–84 (2d Cir. 1998).
to sustain. Thus, although the diagnostic process may be distorted, the continued use of diagnosis in tort actions is crucial to providing a remedy for injured plaintiffs. Therefore, a careful balancing of the varied implications of using diagnostic testimony in tort litigation is necessary. The interests of plaintiffs in being able to prove their causes of action through diagnostic evidence should be weighed against the interest of imposing strict safeguards on the introduction of scientifically unreliable diagnostic testimony.

A great body of law dealing with the introduction of diagnostic testimony has evolved over the last half century. Although the Federal Rules of Evidence and case law attempt to clarify the issue, many unresolved questions remain, particularly in the area of toxic tort and product liability litigation. In these types of lawsuits, the exclusion of medical or expert testimony often determines the entire case. In the Ninth Circuit, in particular, the issue of diagnostic testimony is most troublesome with regard to the use of a "differential diagnosis" to prove causation. Therefore, this Article focuses on cases within the Ninth Circuit involving differential diagnosis and examines relevant cases in other circuits, including a discussion of the therapeutic use of differential diagnosis and its utility in proving causation. This Article promotes a reading of those cases which will provide a way to deal with differential diagnosis causation issues in federal courts by (1) eliminating the requirement of general causation in a differential diagnosis situation, and (2) with regard to specific causation, heightening the level of interrogation of the differential diagnostic process at each step of the diagnosis.

8. See id.
10. See FED. R. EVID. 702.
11. For a description of differential diagnosis, see infra notes 14–16 and accompanying text.
13. Specific causation refers to whether the substance or object actually caused the injury to the particular plaintiff. See id. at 1413.
I. Background

A. Differential Diagnosis and Its Medical Utility

Differential diagnosis, or differential etiology, "is a patient-specific process of elimination" used to identify the cause of a medical problem by eliminating possible causes until the most probable cause is isolated. A differential diagnosis is typically made after the performance of "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests." A differential diagnosis is accomplished by considering the possible causes of a patient's problem and eliminating each of the potential causes "until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." Some courts have noted the widespread acceptance and general reliability of differential diagnosis in the doctor-patient relationship. For example, in In re Paoli Railroad Yard PCB Litigation, the Court of Appeals for the Third Circuit noted that differential diagnosis "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." Similarly, in Heller v. Shaw Industries, Inc., the same court noted that differential diagnosis "consists of a testable hypothesis," has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used outside of the judicial context.

However, the use of a differential diagnosis for therapeutic or healing purposes differs from its use in tort litigation. The purpose of clinical medicine is not theoretical understanding; rather, the aim of

14. Id. (explaining that differential diagnosis is used by "medical practitioners . . . to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes").
16. Westberry v. Gislaved Gummi AB, 178 F.3d 257, 260 (4th Cir. 1999). See also Kannankeril, 128 F.3d at 807 (explaining that "[d]ifferential diagnosis is defined for physicians as the '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'" (quoting STEDMAN'S MEDICAL DICTIONARY 428 (25th ed. 1990))); McElwee v. H.B. Fuller Co., 61 F.3d 1038, 1044 (2d Cir. 1995) (stating that differential etiology or diagnosis is an analysis "which requires listing possible causes, then eliminating all causes but one"); Glaser v. Thompson Med. Co., Inc., 32 F.3d 969, 978 (6th Cir. 1994) (describing differential diagnosis as "a standard diagnostic tool used by medical professionals to diagnose the most likely cause or causes of illness, injury or disease").
17. 35 F.3d 717 (3d Cir. 1994).
18. Id. at 758.
19. 167 F.3d 146 (3d Cir. 1999).
20. Id. at 154–55 (quoting Paoli, 35 F.3d at 742 n.8).
clinical medicine is “the practical goal of therapy, though it uses whatever theoretical science is available.” 21 Historically, “diagnostic perfectionism differed a great deal from one disease to another . . . . [I]n situations where no reasonable treatment was available and where the condition had little effect on life, diagnostic utility would be low and accuracy would be relatively unimportant.” 22 Earlier in the century, for example, when diseases such as tuberculosis and lung cancer were untreatable, “a vague diagnosis of chest disease may have been satisfactory” because effective treatment did not depend on certainty about a patient’s condition. 23

Although medical and scientific knowledge has advanced significantly in the twentieth century, making medical diagnosis more precise, the process of differential diagnosis remains “a mixture of science and art, far too complicated for its accuracy to be assessed quantitatively or for a meaningful rate of error to be calculated.” 24 The use of a differential diagnosis for the purpose of therapy only “follow[s] the causal stream up to a point where intervention is possible” because, typically, physicians “do not care about the disease’s etiology—the theory of its origin or cause—unless understanding causation would assist in diagnosis and treatment.” 25 Therefore, inherent differences exist between the utilization of a differential diagnosis in the clinical setting and its use in the tort arena. Indeed, this tension is indicative of a larger evidentiary problem: How should courts use expert testimony and to what degree should courts pass judgment on the methods and conclusions of medical and scientific professionals? As discussed below, case law and scholarship over the last century have addressed this dilemma from many perspectives. 26 As a result, over the last decade, a new and relatively flexible standard based on the Federal Rules of Evidence has emerged. 27

23. Id. at 95.
25. Herbert A. Simon, Artificial-Intelligence Approaches to Problem Solving and Clinical Diagnosis, in LOGIC OF DISCOVERY AND DIAGNOSIS IN MEDICINE, supra note 21, at 72, 87.
26. See discussion infra Part I.B.
B. The Admissibility of Expert Scientific Testimony in Federal Courts

Before 1993, the "Frye test" governed the admissibility of scientific testimony in a majority of jurisdictions in the United States.\(^{28}\) In *Frye v. United States*,\(^{29}\) the Circuit Court of Appeals for the District of Columbia held a criminal defendant's exculpatory lie detector test inadmissible and established a new standard for the admissibility of scientific evidence: "[T]he thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."\(^{30}\) Therefore, in deciding on the admissibility of scientific evidence, judges were required to determine whether "the expert's methods [were] generally accepted in the relevant scientific community."\(^{31}\) However, in *Frye*, the court admitted that the standard of general acceptance was vague and existed somewhere in the "twilight zone" between experimental and demonstrable scientific principles or discoveries.\(^{32}\) Indeed, the United States Supreme Court later recognized the proliferation of scholarship and debate engendered by the application of *Frye's* inherently vague standard.\(^{33}\)

In 1993, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*\(^{34}\) In *Daubert*, the Court held that Federal Rule of Evidence 702 ("Rule 702") superceded the traditional *Frye* test.\(^{35}\) Rule 702 provides: "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."\(^{36}\)

Therefore, the admissibility of scientific evidence in federal courts depends on a two-pronged inquiry. The evidence must be: (1) scientific, technical, or other specialized knowledge that will (2) aid the trier of fact to understand or resolve a fact in contention.\(^{37}\) The

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28. *See Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923) (holding that the standard for expert scientific testimony is general acceptance in the relevant scientific community).
29. 293 F. 1013 (D.C. Cir. 1923).
30. *Id.* at 1014.
32. *Frye*, 293 F. at 1014.
35. *See id.* at 587, 589.
36. FED. R. EVID. 702.
first prong of this admissibility test, sometimes referred to as the "reliability" prong, "necessitates an examination of whether the reasoning or methodology underlying the expert's proffered opinion is reliable—that is, whether it is supported by adequate validation to render it trustworthy."38 The Daubert Court, although "not presum[ing] to set out a definitive checklist or test,"39 identified some factors that trial judges should consider when they examine the reasoning and methodology behind scientific testimony: (1) whether a theory or scientific technique can be and has been tested;40 (2) whether the work or scholarship the expert relies on has been subjected to peer review;41 (3) in cases relying on scientific techniques, "the known or potential rate of error . . . and the existence and maintenance of standards controlling the technique's operation";42 and (4) whether the work or scholarship relied upon has garnered widespread acceptance in the scientific community.43

The second prong of the Rule 702 admissibility test concerns the relevance of the evidence to the facts in contention.44 The Supreme Court characterized this relevancy requirement as a question of "fit,"45 which "requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."46 In short, the question of "fit" addresses whether the proffered evidence provides useful information about a particular contested fact.47

Further, the Daubert Court specifically noted that in undertaking the "flexible" Rule 702 inquiry,48 trial judges are to focus "solely on principles and methodology, not on the conclusions that they generate."49 This charge has proven easier in theory than in application. Two subsequent United States Supreme Court decisions, General Electric Co. v. Joiner50 and Kumho Tire Co., Ltd. v. Carmichael,51 addressed the difficulty judges face when they reject a particular expert's meth-

38. Westberry, 178 F.3d at 260 (citing Daubert, 509 U.S. at 590 & n.9).
39. Daubert, 509 U.S. at 593.
40. See id.
41. See id. at 593–94.
42. Id. at 594.
43. See id. (folding in the general acceptance standard of Frye).
44. See id. at 591.
45. Id. (citation omitted).
46. Id. at 592.
47. See id. at 591.
48. Id. at 594 n.12.
49. Id. at 595.
odology without passing judgment on the expert’s results. Significantly, the Court in Joiner encouraged judges to consider whether “too great an analytic gap” exists between the underlying research and the expert’s conclusion itself.\textsuperscript{52} \textit{Joiner} apparently serves as an extension of \textit{Daubert}'s judicial “gatekeeping” function.\textsuperscript{53} Under \textit{Joiner}, trial judges, charged with the responsibility of ensuring the relevance and reliability of scientific evidence, are given further license to pass judgment on experts’ conclusions if they appear unreliable in light of the underlying data.\textsuperscript{54} In addition, \textit{Joiner} held that a trial judge’s decision to exclude scientific evidence should be reviewed under the abuse of discretion standard,\textsuperscript{55} making it less likely that the decision will be reversed on appeal.

Similarly, in \textit{Kumho}, the Court further submitted the question of evidentiary reliability to the discretion of the trial judge.\textsuperscript{56} \textit{Kumho} resolved a conflict among the circuits and extended the use of the \textit{Daubert} criteria to testimony based on specialized knowledge in general, not just scientific testimony.\textsuperscript{57} The Court also stated that the trial judge may or may not consider one or more of the \textit{Daubert} reliability factors “depending on the nature of the issue, the expert’s particular experience, and the subject of his testimony.”\textsuperscript{58} Therefore, taken together, \textit{Daubert}, \textit{Joiner}, and \textit{Kumho} provide a relatively flexible framework in which to examine the role of trial judges in excluding or including scientific evidence in federal courtrooms.

The analytical framework established by the Supreme Court over the last several years has the potential to lead to inconsistent or even unfair results. This is due, in part, to the Court’s desire to give trial judges broad discretion regarding the admissibility of scientific evidence. In application, results will differ based on a particular trial judge’s sensibilities and perceptions of the scientific process. In addition, the Court’s fine distinction between scientific “methodology” and “results” often is, in practice, a non-distinction. For example, where a judge rejects an expert’s testimony based on an “analytical gap” between an expert’s data and conclusions, that judge effectively appraises the validity of the expert’s results and opinion, a determina-

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\textsuperscript{52} Id. at 146.
\textsuperscript{53} See \textit{Daubert}, 509 U.S. at 589, 597; see also \textit{Kumho}, 526 U.S. at 141–42.
\textsuperscript{54} See \textit{Joiner}, 522 U.S. at 146–47.
\textsuperscript{55} See \textit{id.} at 139.
\textsuperscript{56} See \textit{Kumho}, 526 U.S. at 147–49.
\textsuperscript{57} See \textit{id.} at 141, 147–49.
\textsuperscript{58} Id. at 150.
\end{thebibliography}
tion specifically proscribed in *Daubert*. However, as discussed below, in the case of the admissibility of an expert's testimony based upon a differential diagnosis, an analytical construct that fits within the Supreme Court's *Daubert*, *Joiner*, and *Kumho* parameters is available; such a construct neither renders the practical distinction between "methodology" and "results" meaningless nor prevents trial judges from effectively ensuring that only reliable scientific testimony is admitted.

II. The Admissibility of Expert Testimony Based on a Differential Diagnosis in Federal Courts Outside the Ninth Circuit

A. Third and Fourth Circuits Lower the Threshold for Admissibility

A number of federal courts of appeal have specifically approved the admissibility of scientific and medical testimony based on a valid differential diagnosis. At least five circuits have concluded that medical testimony based upon a differential diagnosis is admissible to prove causation. Such evidence typically is offered to prove that a particular condition, product, chemical, or substance caused the plaintiff's injuries. Indeed, if the differential diagnosis evidence was not admitted by the trial judge in those cases, the plaintiffs would have been unable to prove causation, and their causes of action would have failed. Although similar in factual and procedural posture, the cases involved differing kinds of diagnostic data, in terms of quality and quantity, upon which the expert testimony was based. Therefore, the


60. See *Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9th Cir. 1998), cert. denied, 526 U.S. 1099 (1999).


62. See *Heller*, 167 F.3d at 154–55; *Westberry*, 178 F.3d at 262–66; *Baker*, 156 F.3d at 252–53; *Zuchowicz*, 140 F.3d at 385–87; *Ambrosini*, 101 F.3d at 140–41.

63. See *Heller*, 167 F.3d at 154; *Westberry*, 178 F.3d at 262–66; *Zuchowicz*, 140 F.3d at 387; *Ambrosini*, 101 F.3d at 140–41.

64. See *Heller*, 167 F.3d at 151–52; *Westberry*, 178 F.3d at 262–66; *Zuchowicz*, 140 F.3d at 385–86; *Ambrosini*, 101 F.3d at 140–41.

65. See *Heller*, 167 F.3d at 153–54, 158 (testimony of allergist and industrial hygienist as to whether organic compounds in carpeting caused plaintiff's respiratory problems based on tests before and after removal of carpet, a series of medical tests, review of medical history, descriptions of plaintiff's activities and environmental living conditions, and temporal relationship between onset of symptoms and installation of carpet); *Westberry*, 178 F.3d at 264–66 (testimony of expert as to whether talc caused sinus condition based on
manner in which the different circuits have evaluated the reliability of a particular expert's differential diagnosis under Daubert and its progeny is crucial to understanding the admissibility of differential diagnoses in federal courts in general. Furthermore, an analysis of the leading cases on the subject illustrates the potential benefits and pitfalls of a wholesale acceptance of differential diagnosis as a reliable methodology for proving causation in complex tort litigation.

Westberry v. Gislaved Gummi AB\textsuperscript{66} involved a tort action brought by a factory worker against Gislaved Gummi AB ("GGAB") based on GGAB's failure to warn of the danger of a talcum powder lubricant it placed on the rubber gaskets it manufactured.\textsuperscript{67} The trial in the district court resulted in a jury verdict for the plaintiff.\textsuperscript{68} GGAB appealed, claiming that the trial court abused its discretion in admitting the expert testimony of the plaintiff's treating physician.\textsuperscript{69} GGAB argued that the testimony of the plaintiff's physician concerning the causal connection between the plaintiff's exposure to the talcum powder and the plaintiff's sinus problems "was inadmissible because it was not based on reliable scientific methodology."\textsuperscript{70} In particular, GGAB contended that the physician's testimony was unreliable because it was not supported by epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data.\textsuperscript{71} In short, GGAB argued that the physician's mere reliance on a differential diagnosis in reaching the conclusion that the plaintiff's sinus problems were caused by his exposure to talc from GGAB's gaskets was insufficient to establish the reliability of the physician's opinion.\textsuperscript{72} The Fourth Circuit rejected evidence of exposure, undisputed evidence that high concentrations of airborne talc could cause irritation to mucous membranes, temporal proximity of exposure and worsening of symptoms, and ruling out other potential causes; \textit{Baker}, 156 F.3d at 249–50 (testimony of two expert gynecologists that pelvic inflammatory disease caused plaintiff's chlamydia based on blood analysis); \textit{Zuchowicz}, 140 F.3d at 385–86 (testimony of physician and pharmacologist as to whether Danocrine caused primary pulmonary hypertension based upon temporal relationship between Danocrine overdose and onset of symptoms and reliance on articles); \textit{Ambrosini}, 101 F.3d at 138–41 (testimony of expert epidemiologist and teratologist as to whether Depo-Provera caused plaintiff's birth defects based on unspecified epidemiological data and scholarship).

\begin{itemize}
\item 66. 178 F.3d 257 (4th Cir. 1999).
\item 67. See id. at 259–60.
\item 68. See id. at 260.
\item 69. See id.
\item 70. Id. at 262.
\item 71. See id.
\item 72. See id.
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GGAB's arguments and held that "a reliable differential diagnosis provides a valid foundation for an expert opinion."73

The real import of the Westberry decision lies not in the broad validation of differential diagnosis as a reliable methodology for purposes of admissibility, but in the court's specific analysis of the physician's differential diagnosis. Essentially, the court addressed two steps of the diagnosis that GGAB argued negated reliability: (1) the lack of scholarship and data "ruling in" talc as a possible basis for the plaintiff's sinus condition,”74 and (2) the failure of the physician to "rule out" other potential causes of the plaintiff's sinus condition.75

On the issue of "ruling in" talc as a possible cause of the plaintiff’s injuries, the Fourth Circuit stated that, "[a]though GGAB is correct that [the physician] had no scientific literature on which to rely to 'rule in' talc as a possible basis for [the plaintiff's] sinus condition,"76 the fact that the plaintiff’s own testimony provided evidence of a substantial exposure, combined with the "temporal proximity of [the plaintiff’s] exposure to talc in his workplace to the onset and worsening of [his] sinus problems,”77 constituted valid support for “ruling in” talc as a causal agent of the injuries.78

On the issue of "ruling out" other potential causes, the court in Westberry noted that "[a] differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation."79 Yet the Fourth Circuit went on to state that "'[a] medical expert’s causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.'"80 The court concluded that the other potential causes of the plaintiff’s sinus condition "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer 'no explanation for why she concluded [an alternative cause] was not the sole cause.'"81 Furthermore, the appellate court noted that the testimony of the plaintiff’s physician on cross-examination ex-

73. 73. Id. at 263.
74. 74. Id. at 264.
75. 75. See id. at 265–66.
76. 76. Id. at 264.
77. 77. Id. at 265.
78. 78. See id. at 264–65.
79. 79. Id. at 265 (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758–61 (3d Cir. 1994)).
80. 80. Id. (quoting Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999)) (alteration in original).
81. 81. Id. (quoting Heller, 167 F.3d at 156–57) (alterations in original).
Despite the physician’s explanation that the cold... developed [near the onset of plaintiff’s symptoms] or the water skiing he did over that summer accounted for his sinus problems.”

Therefore, with a differential diagnosis, an expert may establish that a particular substance could have caused a plaintiff’s injuries merely by an examination of the patient that takes into account: (1) the fact of exposure; (2) the proximity in time between exposure and the onset of symptoms; and (3) a ruling out of other potential causes, after physical examinations and/or testing.

In *Heller v. Shaw Industries, Inc.*, the Third Circuit likewise validated the use of differential diagnosis, but with less sweeping language. In *Heller*, the court reviewed the district court’s exclusion of the plaintiff’s expert medical testimony on the issue of causation. The expert attempted to link organic compounds in the defendant’s carpet to the plaintiff’s respiratory illness. The court of appeals initially found that the district court “was too restrictive in requiring [the plaintiff’s] medical expert to rely on published studies specifically linking [the plaintiff’s] illness with [the defendant’s] product, and in requiring [the] medical expert to rule out all alternative possible causes of [the] illness.”

Nevertheless, the Third Circuit affirmed summary judgment for the defendant, holding that the district court properly excluded the testimony of the plaintiff’s expert on the basis of “a flawed temporal relationship between the installation of the carpet and the presence of [the plaintiff’s] illness.”

The *Heller* decision, issued one month prior to *Westberry*, confirms the *Westberry* analysis of the quality of a differential diagnosis offered to prove causation on three issues. First, in regard to general causation, the lack of published studies relied on by the expert is not enough to exclude an expert’s testimony based upon a differential diagnosis. Second, with respect to specific causation, the failure to “rule out” all other potential causes may not be enough to render an expert’s testimony based upon a differential diagnosis inadmissible.

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82. *Id.* at 266.
83. *See id.* at 264–66.
84. 167 F.3d 146 (3d Cir. 1999).
86. *See id.* at 149–50.
87. *See id.*
88. *Id.* at 149.
89. *Id.* at 149–50.
90. *See id.* at 154–56; *see also* Westberry v. Gislaved Gummi AB, 178 F.3d 257, 264–65 (4th Cir. 1999).
91. *See Heller*, 167 F.3d at 156–57; *see also Westberry*, 178 F.3d at 265.
Finally, a temporal relationship between exposure to the allegedly harmful product or substance and the onset of a plaintiff’s symptoms, combined with proof of exposure and a medical review of a plaintiff’s condition and history, may be enough to establish scientific reliability under Rule 702.92

B. The Benefits and Drawbacks of the Low Threshold Established in Westberry and Heller

Both Westberry and Heller take a fairly liberal approach to the introduction of expert testimony in federal courts based on a differential diagnosis, and, in so doing, extend some deference to accepted diagnostic processes and methodologies of medical and scientific experts. In fact, “[g]iven the liberal thrust of the Federal Rules of Evidence, the flexible nature of the Daubert inquiry, and the proper roles of the judge and the jury in evaluating the ultimate credibility of an expert’s opinion,”93 such a broad reading is called for, particularly where the exclusion of a plaintiff’s causation testimony effectively decides the entire case. Also, as a practical matter, where a particular substance or product is alleged to have caused harm to a plaintiff, finding a pre-existing study, epidemiological or otherwise, which confirms or at least strongly suggests a causal connection between that substance and a plaintiff’s alleged injuries, may be next to impossible.94 In such cases, a low threshold for proving general causation, as in Westberry and Heller, is desirable.95

However, such an approach to general causation may lower the threshold to a point at which dubious expert testimony could be admitted because it was sculpted merely to conform to the analysis in Heller or Westberry. For example, under the most liberal reading of Westberry and Heller, an expert’s testimony may be admissible as long as he or she simply reviews the patient’s medical record and symptoms and determines a close enough temporal proximity exists between exposure and the onset of the patient’s symptoms.96 Although such a view challenges the forthrightness of paid expert testimony, it is a real-

92. See Heller, 167 F.3d at 157–58; see also Westberry, 178 F.3d 264–65.
93. Heller, 167 F.3d at 155.
94. See Westberry, 178 F.3d at 264 (noting that humans rarely are “exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes” and “it is usually difficult, if not impossible, to quantify the amount of exposure” (quoting Federal Judicial Center, Reference Manual on Scientific Evidence 187 (1994))).
95. See id. (noting that information concerning exposure necessary to cause specific harm is not always available).
96. See id. at 264–66; Heller, 167 F.3d at 154–58.
istic one. Complex tort litigation cases, in which millions of dollars may be at stake, produce judicially created thresholds for admissibility that invariably affect the diagnosis, particularly where a diagnosis is made during or in contemplation of tort litigation. The differential diagnosis mode of analysis may increasingly be used as a way for courts to admit testimony which otherwise would have to be excluded under the traditional Frye test. However, there are ways courts may utilize a differential diagnosis analysis, which lower the threshold for general causation, while counterbalancing such leniency with stricter scrutiny of the medical or scientific expert’s evaluative process.

Frequently, legal scholars and practitioners argue for changes in the requirements for expert testimony in general. In the case of toxic torts, one commentator argues quite forcefully that courts should eliminate the requirement of general causation altogether. The essence of the argument is that “conditioning liability on plaintiff’s ability to prove that [the] defendant’s product caused [the] plaintiff’s illness is counterproductive” because it discourages corporations from discovering dangers and informing the public. In addition, it is argued that eliminating proof of causation is not at odds with fundamental principles of tort law because “eliminating causation furthers tort law’s corrective justice rationale that liability [be] linked to moral responsibility.”

Perhaps one of the more interesting proposals for changing the requirements for expert medical testimony is what one commentator terms “delinkage.” The delinkage approach would allow “clinicians...
to testify only about facts elicited during the evaluative interview such as statements by the patient, observed behaviors, and the results of laboratory tests.\textsuperscript{105} Only the fact-finder would make the ultimate inferences from these facts and "[c]linicians could not testify about ultimate issues or even convey their conclusory diagnostic labels which might unduly influence the decisionmaker."\textsuperscript{106} The purpose of de-linkage would be to "encourage more careful role differentiation by medical professionals," thereby reducing "existing incentives to gear diagnoses toward non-therapeutic ends."\textsuperscript{107}

Both of the above approaches, although bold and potentially beneficial, seem to ignore the obvious necessity of expert opinion in complex cases, particularly toxic tort and product liability cases concerning substance exposure and chemical reactions. Without expert testimony and opinions as to causation, courts and juries would be forced to function as \textit{de facto} physicians and scientists. Accordingly, in the case of a differential diagnosis, a more realistic approach to causation would require experts to carefully link their conclusions to their raw data and observations at every step of the diagnosis.\textsuperscript{108}

While trial judges under \textit{Joiner} are required to analyze an expert's methodology in relation to the expert's conclusions, this analysis is typically performed in terms of an expert's ultimate conclusion, that is, whether causation is evident or not.\textsuperscript{109} Courts that recognize differential diagnosis as a valid basis for the admission of expert medical testimony effectively lower the threshold for general causation.\textsuperscript{110} Therefore, a valid differential diagnosis should include a specific linkage of how and why an expert "ruled out" other possible causes of plaintiff's injuries to such a degree that the specific cause of plaintiff's injuries was evident.\textsuperscript{111} While the \textit{Westberry} and \textit{Heller} courts recognized this requirement, the "rule out" threshold was easily met in both cases based on conclusory testimony by the experts, not on testimony that provided medical or scientific linkage or serious explanations for

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105. \textit{Id.} at 304.
106. \textit{Id.}
107. \textit{Id.}
108. \textit{See infra} notes 140–73 and accompanying text.
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either ruling out or ruling in particular causes. In short, because differential diagnosis testimony is subject to a lower threshold for proving general causation, the specific causation requirement of "ruling out" other potential causes, which effectively requires some observation as to how the expert "ruled in" a cause, should be closely scrutinized. As discussed below, a reading of Ninth Circuit case law reveals a variation on this rule for the admission of expert testimony based on a differential diagnosis. This variation effectively eliminates the traditional requirement of general causation, simultaneously heightening the requirements of specific causation.

III. The Admissibility of Expert Testimony Based on a Differential Diagnosis in the Ninth Circuit

The Ninth Circuit Court of Appeals has never used the term "differential diagnosis." In district court cases within the Ninth Circuit, the term appears only in a handful of cases. Indeed, *Hall v. Baxter Healthcare Corp.* is the only district court case in the entire jurisdiction that discusses, at length, the admissibility of medical causation testimony based on a differential diagnosis. Although the Ninth Circuit has never explicitly rejected or validated expert causation testimony based on a differential diagnosis, in *Kennedy v. Collagen Corp.*, it effectively recognized its use as a reliable methodology. In fact, *Westberry* cited *Kennedy* for the proposition that the Ninth Circuit accepts causation testimony based upon a reliable differential diagnosis. Furthermore, both the analysis in *Kennedy* and other cases

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112. *See* Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999) (holding plaintiff's expert's testimony was sufficient even though he did not offer detailed explanations for why he ruled out possible causes of plaintiff's illness); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 266 (4th Cir. 1999) (noting plaintiff's expert merely "considered and excluded" other potential causes without any analysis of how, exactly, other causes were ruled out).

113. *See discussion infra Part III.

114. *See* Kennedy, 161 F.3d at 1228–30; Claar, 29 F.3d at 501–02; Hall, 947 F. Supp. at 1413–14.


117. *See id.* at 1413–14 (excluding the physician’s expert testimony which "by itself, as part... proof of general causation because a single differential diagnosis is a scientifically invalid methodology for such a purpose").

118. 161 F.3d 1226 (9th Cir. 1998).


within the Ninth Circuit, clarifying Rule 702’s judicial gatekeeping function under Daubert and its progeny, establish a fair and reliable approach to the admission of differential diagnosis testimony.121

Hall involved product liability claims against a number of breast implant manufacturers for injuries the plaintiffs allegedly suffered as a result of silicone gel breast implants.122 The defendants filed a number of motions in limine seeking to exclude the plaintiffs’ expert testimony,123 which included testimony purporting to establish a causal link between the breast implants and the plaintiffs’ alleged injuries.124 A treating physician of one of the plaintiffs was prepared to testify, “on the basis of differential diagnosis, that [the plaintiff] suffer[ed] from systemic sclerosis sine scleroderma, manifested by her pulmonary fibrosis, as a result of having silicone gel breast implants.”125 After noting that testimony on the issue of causation requires both general and specific causation, the court stated that “differential diagnosis does not by itself prove the cause, even for the particular patient. Nor can the technique speak to the issue of general causation. Indeed, differential diagnosis assumes that general causation has been proven for the list of possible causes it eliminates.”126

However, general causation issues aside, the court applied a stricter admissibility standard than Westberry and Heller and concluded that the physician’s testimony was inadmissible to prove specific causation because he failed to testify as to “how he eliminated other potential causes of [the plaintiff’s] symptoms.”127 The testimony also failed the relevancy prong of the Daubert test because, without general causation, any specific causation evidence is irrelevant.128 Finally, the court granted all of the defendants’ motions in limine regarding plaintiffs’ general causation testimony and held that all other expert testimony regarding specific causation was moot.129

Hall took a different theoretical approach to the admissibility of causation evidence based on differential diagnosis than Westberry and

121. See Kennedy, 161 F.3d at 1228–30; Claar v. Burlington N. R.R. Co., 29 F.3d 499, 501–02 (9th Cir. 1994); Hall, 947 F. Supp. at 1413–14.
122. See Hall, 947 F. Supp. at 1391.
123. See id. at 1392 n.7.
124. See id. at 1392-95.
125. Id. at 1412.
126. Id. at 1413.
127. Id. at 1414.
128. See id. at 1413.
129. See id.
Differential Diagnosis or Distortion?

Heller, the most recent leading cases on the subject.\textsuperscript{130} Hall extended little deference to the expert opinion of medical professionals.\textsuperscript{131} In fact, by characterizing the physician’s testimony as unreliable, in part because “his conclusion [was] inconsistent with the epidemiology for classical diseases,”\textsuperscript{132} the court gave the nod to the traditional Frye test, which requires general acceptance for the admissibility of scientific evidence. However, Hall’s strict approach to a differential diagnosis is potentially dysfunctional. Indeed, where Westberry and Heller may extend too much deference to medical experts by lowering the threshold for both general and specific causation,\textsuperscript{133} Hall seems to maintain traditional general causation requirements while raising the scrutiny of specific causation beyond that of Westberry and Heller.\textsuperscript{134} If followed by other courts, the Hall approach would place undue burdens on plaintiffs unable to find epidemiological or other studies that link a substance or product to the plaintiff’s symptoms.\textsuperscript{135} In such cases, a plaintiff would not get beyond a defendant’s summary judgment motion.

In addition, Hall rejected the expert’s differential diagnosis testimony even though the expert asserted scientific theories to support both general and specific causation.\textsuperscript{136} Thus, plaintiffs, under Hall, would have to show general causation definitively via other studies and establish specific causation by explaining how the expert ruled out other potential causes.\textsuperscript{137} This approach makes it unlikely that a plaintiff would be able to introduce even specific causation evidence based on a differential diagnosis in the absence of general causation and a delineation of how other potential causes were ruled out by the expert.\textsuperscript{138} As such, the Hall approach would discourage, wholesale, the use of differential diagnosis in expert testimony, abridging the liberal

\textsuperscript{130} Westberry and Heller admitted expert testimony without a showing that the substance at issue caused the alleged injuries in general. See Heller v. Shaw Indus., Inc., 167 F.3d 146, 153-59 (3d Cir. 1999); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 264-66 (4th Cir. 1999). Hall, however, required a showing that the substance at issue caused, in general, the alleged injuries. See 947 F. Supp. at 1413-14.

\textsuperscript{131} See Hall, 947 F. Supp. at 1414.

\textsuperscript{132} Id.

\textsuperscript{133} See Hall, 167 F.3d at 152-59; Westberry, 178 F.3d at 264-66.

\textsuperscript{134} See Hall, 947 F. Supp. at 1414 (requiring expert to show how other potential causes were ruled out). But see Heller, 167 F.3d at 156; Westberry, 178 F.3d at 264-66 (both requiring expert merely to rule out other potential causes without any requirement that the expert explain how the other causes were ruled out).

\textsuperscript{135} See supra notes 94-95 and accompanying text.

\textsuperscript{136} See Hall, 947 F. Supp. at 1413-14.

\textsuperscript{137} See id. at 1414.

\textsuperscript{138} See, e.g., id. at 1413-14.
thrust of the Federal Rules of Evidence and the relatively flexible Daubert standards.\textsuperscript{139}

\textit{Hall} has never been criticized or even distinguished in the Ninth Circuit.\textsuperscript{140} However, in \textit{Kennedy v. Collagen Corp.},\textsuperscript{141} the Ninth Circuit effectively painted over much of the \textit{Hall} analysis in regard to differential diagnosis and created a workable and fair standard for assessing the admissibility of causation evidence based on a differential diagnosis.\textsuperscript{142} \textit{Kennedy} involved a product liability action against the defendant corporation and its employees for alleged injuries sustained by the plaintiff following injections of the defendant’s medical product, Zyderm.\textsuperscript{143} The plaintiff claimed that she developed “atypical systemic lupus erythematosus (SLE), a debilitating and incurable autoimmune disease, as a result of the Zyderm [collagen] injections.”\textsuperscript{144} The plaintiff sought to introduce the affidavit of an expert that established causation.\textsuperscript{145} In forming his opinion, the expert relied “upon a variety of objective, verifiable evidence,”\textsuperscript{146} including: (1) an examination of the plaintiff; (2) the plaintiff’s medical history; (3) her medical laboratory tests; and (4) her medical reports.\textsuperscript{147} The district court rejected the expert’s testimony because the expert had not relied on any specific epidemiological or animal studies proving Zyderm causes SLE and because there existed no consensus in the medical community on the issue.\textsuperscript{148} The Ninth Circuit reversed and remanded, holding that the testimony was reliable, and therefore admissible, because it “was based on [the expert’s] knowledge of a general connection between collagen and various autoimmune disorders, combined with [the expert’s] observation of [the plaintiff’s] injuries and her medical history and

\textsuperscript{139.} See Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 & n.12 (1993); see also Kennedy v. Collagen Corp., 161 F.3d 1226, 1228–29 (9th Cir. 1998) (noting that causation need not be established to a high degree of certainty for expert testimony to be admissible under Federal Rule of Evidence 702), cert. denied, 526 U.S. 1099 (1999).

\textsuperscript{140.} But see Pick v. American Med. Sys., Inc., 958 F. Supp. 1151, 1157 n.18 (E.D. La. 1997) (criticizing the ruling in \textit{Hall} that under \textit{Daubert} “expert testimony at trial relating to the existence and causation of silicone-related autoimmune disease was inadmissible on the basis that [such a conclusion was] at best an untested hypothesis”).

\textsuperscript{141.} 161 F.3d 1226 (9th Cir. 1998).

\textsuperscript{142.} See id. at 1228–30.

\textsuperscript{143.} See id. at 1227. “Zyderm is a substance made from the skin, tendons, and connective tissue of bovine animals.” \textit{Id}. It is injected into facial wrinkles for cosmetic reasons, namely to create a smoother appearance. \textit{See id}.

\textsuperscript{144.} \textit{Id}.

\textsuperscript{145.} \textit{See id.} at 1228.

\textsuperscript{146.} \textit{Id}.

\textsuperscript{147.} \textit{See id}.

\textsuperscript{148.} \textit{See id}.
laboratory tests." Significantly, the court found that the lack of studies linking Zyderm to SLE did not prevent admission of the expert testimony: "The fact that a cause-effect relationship between Zyderm and lupus in particular has not been conclusively established does not render [the expert's] testimony inadmissible." Accordingly, the Ninth Circuit held that the district court "abused its discretion in excluding [the expert's] testimony." Therefore, the plaintiff was able to avoid summary judgment because the expert's testimony was sufficient "to create a genuine issue of material fact as to whether Zyderm caused [the plaintiff's SLE]."

The expert testimony addressed in Kennedy was based on a differential diagnosis—the testimony relied on a physical examination of the patient, her medical history, and laboratory tests. On the basis of these diagnostic steps, the plaintiff's expert concluded that the defendant's collagen product was both the general cause and specific cause of the plaintiff's autoimmune disorder. On the facts of the case, Kennedy appears to overrule Hal's conclusion that a differential diagnosis can never satisfy general causation. Because no cause and effect relationship between Zyderm and SLE was established to a degree that would satisfy general causation, the admissibility of the expert's differential diagnosis to prove causation effectively negates the traditional threshold requirement of general causation. This approach allowed the expert testimony to be admitted based only on the quality of the specific causation evidence. Because the court referred to the specific causation requirement only in passing and by implication, the degree to which specific causation is required in dif-

149. *Id.* at 1229–30.
150. *Id.* at 1230.
151. *Id.* at 1227.
152. *Id.*
153. See *id.* at 1228; cf. Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 807 (3d Cir. 1997) (explaining that the "elements of a differential diagnosis may consist of the performance of physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests").
154. See *Kennedy*, 161 F.3d at 1229. Although the experts did not show by epidemiological or animal studies that Zyderm is a proven cause of autoimmune problems, they used other information and data indicating that the active ingredient in Zyderm produces autoantibodies. See *id.* at 1229. They also presented other evidence that may indicate a link between Zyderm's active ingredient and autoimmune diseases. See *id.*
155. See *id.* at 1229–30.
157. See *Kennedy*, 161 F.3d at 1229–30.
158. See *id.* at 1228–29.
Differential diagnosis testimony is unclear in the Ninth Circuit. However, based on the district court’s analysis in Hall and the prevailing view of Daubert’s judicial gatekeeping function in the Ninth Circuit, a standard emerges which would require fairly strict scrutiny of specific causation evidence based on a differential diagnosis. Furthermore, because Kennedy effectively eliminates the traditional requirement of general causation for the admissibility of differential diagnosis testimony, a stricter scrutiny of specific causation in such cases is required as a matter of policy.

In Claar v. Burlington Northern Railroad Co., the Ninth Circuit interpreted Daubert’s judicial gatekeeping function to mean that district courts are “both authorized and obligated to scrutinize carefully the reasoning and methodology underlying” an expert’s testimony. The court explained that this requirement means district courts have to determine that experts “arrived at their conclusions using scientific methods and procedures, and that those conclusions were not mere subjective beliefs or unsupported speculation.” Hall takes this judicial gatekeeping function even further, stating “Claar itself makes clear that the court must scrutinize the validity of the reasoning leading to the experts’ conclusions, if not the conclusions themselves.” Indeed, based on the Ninth Circuit’s interpretation of Daubert, Hall’s strict approach to specific causation in the case of a differential diagnosis makes sense. Although Kennedy carved out a different approach to testimony based on a differential diagnosis, it did not address the issue of specific causation, that is, “ruling out” other potential causes. Therefore, under Ninth Circuit law, the Daubert stan-

159. See id. at 1228–30.
160. See Kennedy, 161 F.3d at 1228–30; Hall, 947 F. Supp. at 1399 n.29, 1413–14; see also discussion infra notes 163–70 and accompanying text.
162. See Kennedy, 161 F.3d at 1230.
163. 29 F.3d 499 (9th Cir. 1994).
164. Id. at 501.
165. Id. at 502.
166. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1397, 1399 n.29 (D. Or. 1996); see also David E. Bernstein, The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc., 15 CARDOZO L. REV. 2139, 2165–66 (1994) (stating that Daubert not only allows, “but requires, courts to determine whether an expert’s extrapolations from underlying studies or data are proper, or whether the expert has committed scientific or mathematical errors”).
167. See Hall, 947 F. Supp. at 1414. Although Hall’s approach to differential diagnoses was not very useful because it maintained both general and specific causation, Kennedy’s reduction of the general causation threshold in the case of a differential diagnosis tempers the application of Hall’s specific causation requirement. See id.
dard, as enunciated in Claar, applies to the requirement of specific causation where a differential diagnosis is offered to prove causation. In short, in the Ninth Circuit, expert causation testimony based on a differential diagnosis is admissible when: (1) the expert rules out other potential causes of a plaintiff’s condition; and (2) the elimination of other potential causes is founded on more than “subjective beliefs or unsupported speculation.”

However, there are other factors that should affect the admissibility of causation evidence in federal courts based on a differential diagnosis. First, as a matter of policy, because the requirement of general causation is effectively eliminated for a differential diagnosis, the standards for proving specific causation enunciated in Claar and Hall should be carefully scrutinized. Otherwise, plaintiffs may gain an unfair advantage in litigation because the differential diagnosis testimony of one expert could prove causation based only on minimal indicia of general causation and a “ruling out” of potential causes. The proliferation of well-manufactured differential diagnostic testimony is foreseeable in cases where the substance or product is unlikely the causal agent. Therefore, to counterbalance the liberalization of general causation requirements, courts should closely scrutinize the entirety of an expert’s methods and conclusions regarding specific causation, using Claar and Hall as a baseline measurement of reliability.

Second, at least one district court case after Kennedy has considered factors that may limit the application of the Ninth Circuit’s standards for the admissibility of differential diagnoses. In Hickman v. Sofamor-Danek Group, the plaintiff brought a product liability action for injuries allegedly sustained as a result of the defendants’ spinal fixation systems, which were anchored with bone screws into the pedi-

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168. See Claar, 29 F.3d at 501-02.
169. See id.
170. Id. at 502. Because the expert in Kennedy relied to some degree on tentative data linking products similar to Zyderm to symptoms similar to the plaintiff’s disease, courts still may require some evidence of “ruling in” a cause (i.e. minimal indicia of general causation), but not to the degree of the traditional requirements of general causation enunciated in Hall and Claar. See Kennedy v. Collagen Corp., 161 F.3d 1226, 1228 (9th Cir. 1998), cert. denied, 526 U.S. 1099 (1999).
171. See Kennedy, 161 F.3d at 1230.
173. See Kennedy, 161 F.3d at 1228-30; Claar, 29 F.3d at 501-02; Hall, 947 F. Supp. at 1413-14.
cles of the plaintiff's spine. The defendants moved for summary judgment on the grounds that the plaintiff had no evidence of medical causation. The district court granted the defendants' motion because it found that neither of the plaintiff's witnesses—an anesthesiologist specializing in pain management and a psychiatrist specializing in pain medicine with experience in neuropharmacology—were qualified to provide expert testimony about whether the defendants' spinal implant devices caused the plaintiff's pain. The court further reasoned that even if the plaintiff's witnesses were qualified to offer expert testimony on the issue of causation, neither had "provided any evidence that he used an identifiable methodology for reaching his conclusions, or that any such methodology was sufficiently scientifically reliable to satisfy the requirements for expert scientific testimony under Daubert." Although both experts reached their conclusions about the cause of the plaintiff's pain based on a review of the plaintiff's medical records and a review of studies assessing the risks and benefits of internal spinal fixation, neither expert physically examined the plaintiff. However, they did rely on "pain questionnaires" filled out by the plaintiff. Significantly, the court also noted that both of the plaintiff's experts formed their opinions for the sole purpose of litigation.

Whether Hickman involved a differential diagnosis is unclear. Assuming, however, that the expert testimony in Hickman was based on a differential diagnosis, the analysis potentially augments the Kennedy-Hall-Claar synthesis. Hickman raised the issue of whether the manner in which an expert examined a plaintiff can invalidate the differential diagnosis as an unreliable methodology. Although at least one of the experts based his causation conclusions on medical reports, a survey of literature on the subject, and the plaintiff's questionnaire, the court deemed the conclusions inadmissible. If, indeed, this methodology constituted a differential diagnosis, then the examination of specific causation by the court extended beyond the mere "ruling out" of other possible causes, and addressed the context of the differential causation.

175. See id. at *1.
176. See id. at *2.
177. See id. at *3.
178. Id.
179. See id. at *25–26 & n.4.
180. See id.
181. See id. at *25.
182. See id. at *25–26.
183. See id. at *28.
diagnosis. This position was further supported when the court took specific notice of the fact that both experts formed their causation opinions solely for the purposes of litigation, suggesting that the trial court has discretion to include the non-medical or non-scientific context in its assessment of specific evidence based on a differential diagnosis.

Conclusion

The problem of specialized expert testimony in the federal courts will persist. Because the causation issues generally make or break a case at the summary judgment stage, the use of expert medical testimony to prove causation complicates much litigation, which accordingly leads to increased amounts of time and higher litigation costs. A downturn in such litigation practice is unlikely. The law is rapidly evolving on the issue of admissibility of expert causation testimony based on a differential diagnosis. Indeed, in just the last few years, many circuits have established a fairly new approach to the admission of testimony based on a differential diagnosis, which allows for lower general causation standards and, in a few circuits, easier specific causation thresholds. The Ninth Circuit approach to causation testimony based on a differential diagnosis is still developing. By effectively eliminating the traditional general causation requirements and, as a counterweight, imposing strict specific causation standards, the Ninth Circuit approach to testimony based on a differential diagnosis functions as a reliable, useful, and fair standard by which to appraise the admission of medical and scientific causation evidence in federal courts.

184. See id. at *25.