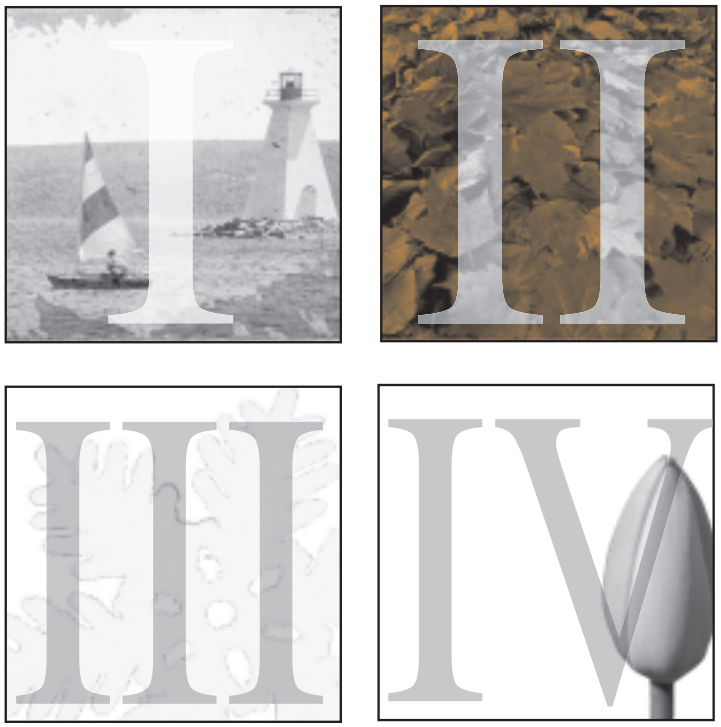
MICHIGAN DEFENSE *Quarterly*

Volume 23, No. 2 October 2006



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THROWING OUT JUNK SCIENCE: THE IMPACT OF MICHIGAN'S ADOPTION OF DAUBERT IN TOXIC TORT LITIGATION

[PART 1 OF 3][1]

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"There is something fascinating about science.
One gets such wholesale returns of conjecture out of such a trifling investment of fact."
Mark Twain, *Life on the Mississippi* (1874).

Executive Summary

In this first of three articles on the *Daubert* standards, the authors discuss the general principles that underlie the *Daubert* requirements.

The requirement that the evidence that is offered must be based on the scientific method establishes a threshold requirement that the courts must apply in exercising their gatekeeper function. *Daubert* sets a minimum requirement. It does not permit expert testimony to be admitted based on anecdotal reports and inferences, nor does it allow courts to lower the bar of scientific reliability based on a perceived lack of relevant scientific evidence. *Daubert* does not establish a "best efforts" test, under which expert testimony can be allowed on the basis that it is the best methodology available under the circumstances, with the jury free to assign the weight it believes the evidence deserves. Instead, the evidence must meet the threshold requirement of being testable and falsifiable, which is the methodology of science.

Introduction

It has now been over two years since Michigan adopted the federal *Daubert* standards for admissibility of expert testimony through the amendment of Michigan Rule of Evidence 702 and the Michigan Supreme Court opinion in *Gilbert v DaimlerChrysler Corp.*[2] *Daubert* has had a dramatic impact in protecting defendants from "junk science" opinions in toxic tort litigation across the country and is now a central weapon for the defense of such claims in Michigan courts as well. While *Daubert's* central tenet is straightforward — expert testimony must be based on scientific evidence that is both reliable and relevant — the task of distilling highly complex and technical scientific testimony so as to expose its legal flaws can appear daunting to even the most seasoned litigator. In this three-part series, we provide a practical guide to both attorneys and courts who are navigating through this brave new world.

Overview

In Part 1, we review the Michigan Supreme Court's adoption of the scientific method as the standard for admissibility of expert testimony and analyze how a court's proper understanding of the scientific method can guide it in evaluating the different types of causation evidence presented in toxic tort litigation, both with respect to general and specific causation. Throughout this discussion, we will draw on our firm's experience as national defense counsel in a series of product liability cases in federal court involving the prescription drug Parlodel®, in which these *Daubert* evidentiary issues have been analyzed in depth in judicial opinions across the country. While prescription drug product liability litigation is limited in Michigan due to the State's statutory protections for manufacturers in compliance with FDA regulations, the lessons drawn from the Parlodel® litigation have broad implications for all types of toxic tort and product liability cases. The Parlodel® litigation has been described in a recent textbook as "the first significant products

liability causation debate of the 21st century" and one that "will serve as a guide to understanding the significant causation issues that will continue to be involved, at increased rates of complexity, in the 21st century products cases."[3]

This discussion will highlight the scientific issues central to the reliability and relevance inquiry of these different pieces of evidence and review some of the federal case law that has properly analyzed this evidence under *Daubert*. Parts II and III, which will appear in the next two issues, will discuss how the *Daubert* standards should be applied in considering the specific categories of evidence routinely presented by plaintiffs' experts in toxic tort litigation, i.e., epidemiology, animal studies, chemical analogies, regulatory findings and other secondary sources, anecdotal case reports, and clinical reasoning.

The *Daubert* Directive: Expert Testimony Must be Derived By the Scientific Method.

Ever since the United States Supreme Court's landmark ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[4] federal judges have been tasked with the obligation to serve as gatekeepers to keep scientifically unreliable and irrelevant expert testimony out of the courtroom. In 2004, with the Michigan Supreme Court's ruling in *Gilbert*, Michigan judges assumed this same obligation. The standards set forth in *Daubert*, which the U.S. Supreme Court has described as "exacting,"[5] have had a significant impact on numerous areas of legal dispute, but perhaps no area has been more affected than toxic tort and product liability litigation. Under *Daubert* and its progeny, *General Electric v. Joiner*[6] and *Kumho Tire Co., Ltd. v. Carmichael*,[7] a plaintiff can no longer get a toxic tort claim before a jury based solely on an expert's subjective opinion that the plaintiff's injury was caused by a particular product or exposure. Rather, the plaintiff must demonstrate that the expert's opinion is scientifically valid, both on the general causation question of whether the substance at issue could potentially cause the injury in any person and the specific causation question of whether the substance in fact did cause the particular plaintiff's injury.[8]

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Daubert has imposed a significant new obligation on trial courts, and many judges across the country have struggled to understand the scientific principles that they must follow in their new role.[9] Many Michigan state court judges are likely to face similar difficulties. Plaintiffs' counsel and like-minded legal observers have sought to take advantage of this uncertainty by arguing that the U.S. Supreme Court provided ambiguous guidance regarding the admissibility of medical causation testimony and that courts should defer to the judgment of medical experts so long as they follow the same "differential diagnosis" reasoning in their expert testimony as they do in their clinical practice.[10] These arguments are wrong. The guidance provided by the U.S. Supreme Court and adopted by the Michigan Supreme Court is clear: expert testimony that an exposure caused an adverse event is admissible only if it is based on the scientific method, i.e., evidence properly derived through the generating and testing of hypotheses. This guidance provides a simple framework for courts considering the variety of evidence generally put forth by causation experts in toxic tort and product liability litigation.

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The *Daubert* Requirements: Scientific Reliability and Relevance

In *Daubert*, the United States Supreme Court held that scientific testimony is not admissible unless it satisfies the dual requirements of scientific reliability and relevance. Scholarly debate regarding *Daubert* has often focused on the four factors suggested by the court in determining scientific reliability: (1) testing, (2) peer review, (3) error rate and standards, and (4) general acceptance. However, a rote discussion of these factors misses the point. These factors are relevant only insofar as they assist the trial court in applying the overarching directive of *Daubert* that expert testimony must be based on the scientific method. The court explained that "in order to qualify as 'scientific knowledge' an inference must be derived by the scientific method."[11]

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The court defined the scientific method as follows: "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry."[12] Moreover, "[s]cientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes."[13] In other words, expert testimony is admissible only if empirical testing validates the specific theory to which the expert opines.[14]

Daubert also explains that while admissible expert testimony must be based on the scientific method, "there are important differences between the quest for truth in a courtroom and the quest for truth in the laboratory."[15] "[S]cientific conclusions are subject to perpetual revision. Law on the other hand, must resolve disputes finally and quickly."[16] Accordingly, expert testimony must be judged based on the current state of scientific knowledge, not on the possibility that additional knowledge may emerge in the future. The court recognized that the requirement of existing empirical evidence "on occasion will prevent the jury from learning of authentic insights and innovation" but held that this "is the balance struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for particularized resolution of legal disputes."[17]

Four years after *Daubert*, the United States Supreme Court provided further guidance on how judges should use the scientific method in evaluating expert testimony. In *Joiner*, the plaintiffs' experts contended that their opinion (that PCBs can cause lung cancer) should be admitted because they relied on epidemiology and animal studies, which are standard tools used by scientists in testing causal hypotheses. The court rejected this contention, explaining that a faithful application of the scientific method requires more: "whether animal studies can ever be the proper foundation for an expert's testimony was not the issue. The issue was whether these experts opinions were sufficiently supported by the animal studies on which they purport to rely."[18] In other words, expert testimony must be based on empirical testing that *validates* the conclusions reached.[19]

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The *Joiner* court held that the research cited by plaintiffs' experts did not validate their conclusions because the epidemiological studies did not report a statistically significant causal link between PCBs and lung cancer, lacked proper controls, and examined substances other than PCBs, and because the animal studies involved massive doses of PCBs and a different type of cancer and could not be properly extrapolated to humans. Plaintiffs' experts could not support their opinions under the scientific method because their conclusions ultimately rested on subjective leaps from the scientific evidence. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and opinion proffered."[20]

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Two years later, in *Kumho Tire*, the Supreme Court held that the *Daubert* requirements of reliability and relevance apply to all expert testimony, including experience-based testimony. Even in areas where the four factors proposed in *Daubert* are inapplicable, the court explained that the overarching question remains the same: Is the expert's testimony supported by a methodology that has been objectively validated and supports the conclusions offered?[21] In evaluating this question, the court instructed that courts should consider whether the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of the expert in the relevant field."[22]

The Parlodel® Litigation

Over the past decade, a number of product liability cases involving the prescription drug Parlodel® have been working their way through the courts. The Parlodel® litigation has resulted in a body of *Daubert* case law that squarely addresses the issues of medical causation expert testimony and provides a detailed analysis of "all of the components of the 'causation' argument that are available to experts in the most contentious of products liability case[s]."[23]

There is now an emerging judicial consensus that plaintiffs' experts' causation opinions in the Parlodel® litigation do not satisfy the requirements of *Daubert*. Three federal appellate courts, the Eighth, Tenth and Eleventh Circuits, have unanimously affirmed district court opinions excluding the causation opinions of plaintiffs' experts, and four other published dis-

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trict court opinions excluding this testimony were not appealed.[24] A few earlier federal district court opinions, two of which were drafted by the same magistrate judge, have gone the other way.[25] The Parlodel® opinions thus provide a useful *Daubert* case study of courts that properly evaluated medical causation testimony based on the scientific method and those that do not.

Plaintiffs' Allegations Regarding Parlodel®

Parlodel® (bromocriptine mesylate) is an FDA-approved drug used for a variety of indications, including Parkinson's Disease, amenorrhea/galactorrhea (lack of menses), infertility, and acromegaly (a growth disorder). From 1980 to 1994, Parlodel® was also approved for the prevention of postpartum lactation ("PPL") in women who elected not to breast-feed. The manufacturer of Parlodel® withdrew the drug from the market for this PPL indication following receipt of a number of case reports of strokes, seizures and myocardial infarctions and an FDA advisory committee determination that there was limited need for pharmaceutical treatment for PPL. The FDA withdrew its approval of Parlodel® for the PPL indication in 1995, based on its conclusion that the limited utility of the drug for PPL did not outweigh the possible risks.[26]

Plaintiffs' experts allege that Parlodel® causes vasoconstriction (a narrowing of blood vessels) which they allege can cause stroke, seizures, and myocardial infarction. Plaintiffs' experts concede that the epidemiological studies conducted on the drug have not established a causal link with these injuries and that there is a body of controlled clinical research in humans that has found that Parlodel® has the exact opposite effect of causing vasodilation (a widening of blood vessels). Plaintiffs' experts also concede that controlled intact animal research has not shown a causal link between Parlodel® and strokes, seizures, or myocardial infarctions in animals. Plaintiffs' experts base their causation opinion on anecdotal case reports (including alleged dechallenge-rechallenge reports), animal research involving limited endpoints, chemical analogies, a variety of secondary source materials, and differential diagnoses.[27]

Opinions Admitting Plaintiffs' Experts' Causation Opinions

The district courts that have admitted plaintiffs' experts' causation opinions have relied primarily on differential diagnoses and the determination that lesser scientific evidence of general causation should be accepted because it allegedly would not be possible to conduct an epidemiological study of sufficient strength to adequately test plaintiffs' experts' causation hypothesis. Thus, one magistrate judge dismissed the lack of any direct scientific evidence supporting plaintiffs' experts' causation opinion, reasoning that "[s]cience, like many other human endeavors, draws conclusions from circumstantial evidence, when other, better forms of evidence [are] not available."[28] In a subsequent opinion, the same magistrate judge sounded a similar theme: "In science, as in life, where there is smoke, fire can be inferred, subject to debate and further testing."[29] The court was similarly deferential in its review of plaintiffs' experts' specific causation opinions. While noting that there were a number of alternative causes for the injuries at issue, the court found that the "debate creates a question about the weight to be accorded the plaintiffs' experts' opinions, but it does not affect the admissibility."[30]

Daubert does not permit expert testimony to be admitted based on the smoke of anecdotal reports and inferences, nor does it allow courts to lower the bar of scientific reliability based on a perceived lack of relevant scientific evidence.

Missing in these opinions is any recognition of the requirement in *Daubert* that the experts' causation opinions be based on the scientific method of testing and validating hypotheses. *Daubert* does not permit expert testimony to be admitted based on the smoke of anecdotal reports and inferences, nor does it allow courts to lower the bar of scientific reliability based on a perceived lack of relevant scientific evidence. In accepting plaintiffs' experts' lower showing of evidence, these courts abdicated their gatekeeping responsibility.

Opinions Excluding Plaintiffs' Experts' Opinions

By contrast, in the Parlodel® cases in which courts have evaluated plaintiffs' experts' opinions based on the scientific method, the experts' testimony has been excluded. These courts have conducted detailed analyses of each of the different categories of evidence mentioned above, and their reasoning and conclusions are incorporated in the remaining articles in this series. The overarching theme in these opinions is the courts' recognition that medical causation

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opinions are not admissible unless they are based upon scientifically tested and validated hypotheses.

As these courts have explained, *Daubert* does not establish a "best efforts" test.[31] An expert cannot satisfy *Daubert* by arguing that he or she has "used the best methodology available under the circumstance,"[32] or has "done the best [he or she] could with the available data and the scientific literature."[33] Rather, the expert must answer the "key question," whether the "theory being advanced by the expert is testable or has been tested, the methodology of which is what distinguishes science from other fields of human inquiry."[34] "The hallmark of [*Daubert*'s] reliability prong is the scientific method, i.e., the generation of testable hypotheses that are then subjected to the real world crucible of experimentation, falsification-validation, and replication."[35] The "testing of hypotheses" is "a critical aspect of the application of the scientific method."[36] Expert opinions "reposed in the realm of 'may cause' or 'possibly could cause'" must be excluded.[37] "While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination of whether liability exists."[38]

These Parlodel® cases forcefully answer critics of *Daubert* who argue for a lower standard based on deferential review of medical causation testimony:

> The *Daubert* trilogy, in shifting the focus to the kind of empirically supported, rationally explained reasoning required in science, has greatly improved the quality of the evidence upon which juries base their verdicts. Although making determinations of reliability may present the court with the difficult task of ruling on matters that are outside its field of expertise, this is less objectionable than dumping a barrage of scientific evidence on a jury, who would likely be less equipped than a judge to make reliability and relevancy determinations.[39]

The scientific method serves as a bulwark against subjective judgments and inspired guesswork masquerading as scientific knowledge.

The scientific method serves as a bulwark against subjective judgments and inspired guesswork masquerading as scientific knowledge. Courts that ignore the scientific method in their review of medical causation opinions do a disservice to the legal system and disregard the Supreme Court's mandate.

Conclusion

It is one thing to state what courts are supposed to do in applying the *Daubert* standards in toxic tort litigation; it is quite another to explain for a court how it is to properly go about meeting its obligation. The next two articles in this series will lay out the scientific and legal arguments that defense counsel can use in helping to guide Michigan courts in fulfilling their new gatekeeping role.

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Endnotes

1. Editor's Note: Earlier versions of this series have appeared as an article in the *Journal of Health Law*, published by the American Health Lawyers Association, and will be included in the *Drug Abuse Handbook*, 2nd Edition, published by Taylor and Frances/CRC Press and edited by Steven Karch and Michael Peat (expected publication December 2006, available at www.crcpress.com and through other distributors.) Both AHLA and Frances/CRC Press have granted permission for the publication of this series.
2. 470 Mich. 749, 685 N.W.2d 391 (2004).
3. Terence F. Kiely, Science and Litigation: Products Liability in Theory and Practice 177 (CRC Press 2002).
4. 509 U.S. 579 (1993).
5. *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000).
6. 522 U.S. 136 (1997).
7. 526 U.S. 137 (1999).
8. *See, e.g., Raynor v. Merrell Pharms. Inc.*, 104 F. 3d 1371, 1376 (D.C. Cir. 1997).
9. A recent survey of 400 state trial judges found that while a large majority of judges agreed that the role of "gatekeeper" was an appropriate one for a judge, most judges did not have a proper understanding of the scientific principles set forth in *Daubert*. *See* Sophia I. Gatowski, *et al.*, *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-Daubert World*, 25(5) Law and Human Behavior 433 (2001).
10. *See, e.g.*, J. Kassirer & J. Cecil, *Inconsistency in Evidentiary Standards for Medical Testimony: Disorder in the Courts*, 288(11) JAMA 1382-87 (Sept. 2002); M. Berger, *Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation*, 64 SUM Law & Contemp. Probs. 289 (Spring/Summer 2001).
11. 509 U.S. at 590.
12. *Id*. at 593. The Court cited to two philosophical texts on the nature of scientific evidence. See id. (citing C. Hempel, The Philosophy of Natural Science 49 (1966) ("[T]he statements constituting a scientific explanation must be capable of an empirical test"); K. Popper, Conjectures and Refutations: The Growth of Scientific Knowledge 37 (5th ed. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability")).
13. *Id*. at 591.
14. The four factors discussed in *Daubert* provide different methods by which an expert's opinion can be analyzed for adherence to the scientific method. Two of the factors, testing and error rates, are integral parts of the scientific method itself. The other two factors, peer review and general acceptance, can provide independent sup-

port that the opinion was properly derived by the scientific method. Peer review, however, should not be mindlessly equated with publication. As the Court noted, publication "is but one element of peer review." *Daubert*, 509 U.S. at 593. Peer review, like general acceptance, refers more broadly to the concept that the theory at issue has been subjected to and found valid through empirical testing by the broader scientific community. *See generally* W. Anderson, et al., *Daubert's Backwash: Litigation-Generated Science*, 34 U. Mich. J.L. Reform 619 (2001); E. Chan, *The "Brave New World" of Daubert: True Peer Review, Editorial Peer Review, and Scientific Validity*, 70 N.Y.U. L. Rev. 100 (1995).

15. *Id*. at 596-97.
16. *Id*. at 597.
17. *Id*.
18. 522 U.S. at 145.
19. *See id*. at 146 ("conclusions and methodology are not entirely distinct from one another").
20. *Id*.
21. *See* 526 U.S. at 157 (noting with respect to challenged tire expert's testimony that "despite the prevalence of tire testing," plaintiffs did not "refer to any articles or papers that validate [the expert's] approach").
22. *Id*. at 152.
23. Kiely, *supra* note 8. In addition to being used as a case study for legal scholars, the Parlodel® litigation was discussed in an article published in the Journal of the American Medical Association by an unsuccessful amicus for plaintiffs appealing a Parlodel® *Daubert* exclusionary ruling to the Eleventh Circuit Court of Appeals in *Rider*. *See* J. Kassirer & J. Cecil, *supra* note 7.
24. *Rider*, 295 F.3d 1194; *Hollander*, 289 F.3d 1193; *Glastetter*, 252 F.3d 986; *Dunn*, 275 F. Supp 2d 672; *Soldo*, 244 F. Supp. 2d 434; *Caraker*, 188 F. Supp. 2d 1026; *Brumbaugh*, 77 F. Supp. 2d 1153; *see also Revels*, 1999 WL 644732 (excluding Parlodel® causation opinions on Texas analog of *Daubert*).
25. *Brasher v. Sandoz Pharms. Corp.*, 160 F. Supp. 2d 1291 (N.D. Ala. 2001) (Putnam, M.J.); *Globetti v. Sandoz Pharms. Corp.*, 111 F. Supp. 2d 1174 (N.D. Ala. 2000) (Putnam, M.J.); *Eve v. Sandoz Pharms. Corp.*, 2001 U.S. Dist. LEXIS 4531 (S.D. Ind. Mar. 7, 2001), *see also Gunderson v. Sandoz Pharms. Corp.*, Nos. 2004-CA-001536-MR, 2004-CA-001537-MR, 2005 WL 2694816 (Ky.App. Oct. 21, 2005), *appeal pending* (holding that trial court did not abuse discretion in admitting causation testimony).
26. *See Caraker*, 188 F. Supp. 2d at 1028, 1040.
27. *See generally Rider*, 295 F.3d 1194; *Glastetter*, 252 F.3d 986; *Caraker*, 188 F. Supp. 2d 1026.
28. *Globetti*, 111 F. Supp. 2d at 1180; *see also Eve*, 2001 U.S. Dist. LEXIS 4531, at *75 (quoting *Globetti*).
29. *Brasher*, 160 F. Supp. 2d at 1296; *see also id.* at 1297 ("Given the practical unavailability of other forms of scientific evidence, reliance on those that are available is all the more reasonable.").
30. *Id*. at 1299.
31. *Siharath*, 131 F. Supp. 2d at 1373.
32. *Id*. at 1371.
33. *Hollander*, 289 F.3d at 1213.
34. *Brumbaugh*, 77 F. Supp. 2d at 1156.
35. *Caraker*, 188 F. Supp. 2d at 1030.
36. *Soldo*, 244 F. Supp. 2d at 529.
37. *Glastetter*, 107 F. Supp. 2d at 1025.
38. *Dunn*, 275 F. Supp 2d at 684.
39. *Rider*, 295 F.3d at 1197.