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THE ADMISSIBILITY OF MEDICAL TESTIMONY IN OHIO:
 DAUBERT, JOINER AND OHIO'S RELEVANCE-RELIABILITY
 STANDARD

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I. INTRODUCTION

Amidst the decline of public confidence in the capacity of the American legal system to resolve complex and technical issues, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceutical, Inc.*² In this landmark decision, the Supreme Court replaced the "general acceptance" test³ and formulated a criterion that established scientific validity as the measure for reliable opinions based on scientific explanations.⁴ Rule 702 of the Ohio Rules of Evidence follows the course charted by *Daubert* and challenges judges and lawyers to appreciate how science works and, to some degree, engage intellectually in the methodology of scientific thinking.⁵

²*Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). The interpretive disagreements over *Daubert* have been intense. Since *Daubert*, articles and public commentary on the admissibility of scientific evidence have flooded law reviews and journals. One year after the decision, the Federal Judicial Center published THE REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (Federal Judicial Center ed., 1994) (hereinafter "*Reference Manual*"). The *Reference Manual* was designed to assist federal judges in dealing with issues of science and technology; and it too has been subjected to heavy criticism. See, e.g., Lee Loevinger, *Commentary on Evidentiary Framework*, 36 JURIMETRICS J. 149-58 (1996) (arguing that the Reference Manual's chapter on evidentiary framework fails to adhere to the rigorous discipline inherent in the scientific process).

³See *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (holding that expert opinions based on scientific principles or techniques are inadmissible unless the scientific principle or discovery has gained general acceptance in the relevant scientific community).

⁴See discussion *infra* Part II.A. For an excellent description of the difference between validity and reliability see *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 n.9 (5th Cir. 1991); see also Bert Black, *A Unified Theory of Scientific Evidence*, 56 FORDHAM L. REV. 595 (1988). Black explains that validity and reliability "are very different concepts." *Id.* at 599. "Reliability means that a successful outcome, or a correct answer, is sufficiently probable for a given situation In contrast . . . , validity means that which results from sound and cogent reasoning. An invalid conclusion cannot be reliable, yet valid reasoning does not necessarily lead to reliable conclusions." *Id.* Black asserts, [T]he scientific question [should be viewed] as a matter of validity, with the answer depending on accepted scientific practice and the soundness and cogency of the entire pattern of reasoning leading to the expert's conclusion. In contrast, the legal question relates to how much reliability the law requires, with the answer depending on legal standards. *Id.* at 600.

⁵The Court determined that the liberal thrust of the Federal Rules of Evidence were at odds with the rigid "general-acceptance" requirement enunciated in *Frye*. Thus, the

The State of Ohio amended Rule 702 in 1994 to include *Daubert's* concept of scientific reliability. Notice, however, the staff note to amended Rule 702 maintains that case law prior to *Daubert* provides an acceptable basis for establishing reliability.⁶ Consequently, current Ohio law differs somewhat from federal law and the *Daubert* Court's focus on empirical analysis. This article looks at the differences between the federal system and Ohio's more flexible management of scientific evidence and the interplay between state and federal case law.

Legal commentators trumpeted *Daubert* as the definitive anti-junk science decision.⁷ *Daubert* emphasized that the focus of a federal judge's inquiry "must be solely on principles and methodology, not on the conclusions that they generate."⁸ However, in *General Electric Co. v. Joiner*,⁹ the Supreme Court backed away from this position and permitted a federal judge to examine the reasoning process linking methodology to the expert's conclusions.¹⁰ *Joiner* affirmed the discretionary authority of a federal judge to reject an expert's rationale, even where the methods and principles which formed the expert's opinion are

Court concluded that the "general acceptance" standard was incompatible with the Federal Rules: "That austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials." *Daubert*, 509 U.S. at 589.

⁶Although the staff notes to Rule 702 of the Ohio Rules of Evidence intend otherwise, these passages have generated confusion regarding the interpretation and application of Rule 702:

[W]ith the intention to do no more than codify existing holdings on the admissibility of expert testimony, the amended rule does not attempt to define the standard of reliability but leaves that to further development through case law. The amendment also leaves unchanged Ohio's rejection of *Frye* as the exclusive standard of reliability. Similarly, the amendment does not purport to supplant existing case law as to the acceptable means of showing reliability, whether through judicial notice or testimony. Further, the law remains unchanged that the inquiry as to reliability is appropriately directed, not to the correctness or credibility of the conclusions reached by the expert witness, but to the reliability of the principles and methods used to reach those conclusions.

⁷"*Daubert* came to the right result; it's an anti-junk science opinion." Paul Reiding, *They Blinded Me with Science*, ABA J. 58, 59 (1996) (quoting Professor Imwinkelreid, law professor at the University of California, Davis, and prolific author on scientific evidence). Professor Imwinkelreid adds that if an expert's opinions are based on scientific evidence, then the witness must show the court that the opinions were reached in a manner similar to other scientists in the same discipline. *Id.*

⁸*Daubert*, 509 U.S. at 595. The majority opinion expressed confidence that federal judges possess the capacity to assess the validity of whether reasoning or methodology underlying scientific testimony is valid and whether the reasoning or methodology can be applied to the facts at issue. *Id.* A close review of the *Reference Manual* suggests otherwise. See *Reference Manual supra* note 2.

⁹*General Elec. Co. v. Joiner*, 118 S. Ct. 512 (1997).

¹⁰*Id.* at 519 (citing *Daubert*, 509 U.S. at 595).

recognized as valid. Finally, in *Kumho Tire Co. Ltd. v. Carmichael*,¹¹ the Supreme Court applied *Daubert* not only to scientific testimony, but to all expert witnesses including non-scientific experts who rely on skill or experience to formulate opinions.¹²

Ohio's approach to the admissibility of expert opinions differs from the federal system's approach to the admissibility of expert opinions.¹³ Under the federal system, the determination of scientific validity rests exclusively with the trial judge, whereas Ohio divides the responsibility of determining reliability between judge and jury.¹⁴ Moreover, Ohio's definition of reliability is less restrictive and scientific than *Daubert*. Ohio measures the reliability of expert opinions by applying a relevancy standard and inquiring into the validity of the principles or methods upon which the opinions are based.¹⁵ In stark contrast to the approaches taken in *Joiner* and *Kumho*, Ohio courts do not evaluate the validity of the logic behind the expert's conclusions. Here's another important difference between the federal and Ohio systems: federal juries are afforded liberal access to learned treatises; and consequently, they have access to critical insight and information about new, advanced medical and scientific knowledge.¹⁶ By contrast, the Ohio Supreme Court has only recently eased the restrictions on courtroom use of learned treatises.¹⁷ Note too, that the *Daubert* Court evaluated the admissibility of expert testimony taken only from experts in the fields of the basic sciences, which commonly employ

¹¹*Kumho Tire Co. v. Carmichael*, No. 97-1709, 1999 WL 152455, at *1 (U.S. Mar. 23, 1999).

¹²*Id.* at *1.

¹³See discussion *infra* Part II.B. regarding the relevance/reliability approach.

¹⁴In *McCubbin v. Michigan Ladder Co.*, 679 N.E.2d 1142 (Ohio Ct. App. 1996) the court noted a conflict between Ohio's amended Rule 702(c) and prior case law. *Id.* 643-45. The court found the staff note confusing because prior case law compels the trial court to submit questions of reliability of the opinion of expert witnesses to the jury. *Id.* The *McCubbin* decision raises questions about a greater role for trial judges in admitting scientific testimony, in view of the amendment that added the word "reliability" to Rule 702 and encouraged reliance on *Daubert*. See *id.* at 643-44.

¹⁵See *State v. Nemeth*, 694 N.E.2d 1332, 1338 (Ohio 1998). See also discussion *infra* Section II(B)(5).

¹⁶See FED. R. EVID. 803 (18):

Learned Treatises. To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

Id.

¹⁷See OHIO EVID. R. 706. See also discussion *infra* Section IV.A.

the principles of empirical analysis.¹⁸ Ohio Rule 702, however, comprehends the admissibility of all expert testimony, especially physician opinions, and the methodology underlying their opinions.¹⁹ Finally, Ohio's case-by-case method of determining the threshold level of reliability of expert testimony differs from the federal requirement that all expert testimony must pass the *Daubert* test to be admissible. This distinction marks the major difference between Ohio's approach to the admissibility of expert opinions and *Daubert's* approach to the admissibility of expert opinions.

This article specifically examines the reliability standard imposed under Rule 702 of the Ohio Rules of Evidence and its application to medical expert testimony in Ohio. Section II reviews *Daubert*, its progeny, and Ohio law. This analysis reveals tension between Ohio's flexible relevance/reliability standard and the more exacting demands of *Daubert*. Section III examines the scientific basis of clinical diagnosis and treatment of illness and disease. This section argues that judges should take judicial notice of the conventional methodology underlying the clinical practice of medicine, and thus the preliminary question of reliability of medical expert testimony should rarely require a *Daubert* hearing. Section IV discusses the reliability of medical and scientific literature and the criteria establishing its use by experts and attorneys in the courtroom.

II. DAUBERT AND ITS PROGENY—IMPACT ON OHIO LAW

A. The *Daubert* Decision

To better appreciate the rationale of *Daubert*, it is useful to review Petitioner-Plaintiff's scientific basis for associating the drug Bendectin to birth defects. At trial, Plaintiff's expert employed three forms of scientific evidence to establish Bendectin's role in causing Plaintiff's injury: *in vitro* (test tube) and *in vivo* (live animal) studies linking Bendectin to malformations;²⁰ chemical structure analysis comparing the similarities between substances known to

¹⁸See, e.g., *Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303-05 (6th Cir. 1997) (noting that empirical testing distinguishes science from other fields of inquiry); *United States v. Starzeczyzel*, 880 F. Supp. 1027, 1038-41 (S.D.N.Y. 1995) (asserting that *Daubert* is limited to scientific testimony).

¹⁹Incidentally, *Kumho* applied a *Daubert* analysis to all types of expert witnesses, just as Ohio analyzes scientific and non-scientific witnesses. See discussion *infra* Section III.A. Commentators fortified with a scientific background clarify their focus on scientific evidence by separating science from other forms of knowledge. They also concentrate on how scientists establish validity. See, e.g., Bert Black et al., *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 754-55 (1994) (outlining three characteristic traits distinguishing scientific knowledge from other forms of knowledge). Science seeks systematic organization of information; it tries to explain why observed conditions and events occur; and it requires that "[s]cientific explanations . . . be formulated in such a way that they can be subjected to empirical testing, a process that has to include the possibility of empirical falsification." *Id.* at 755.

²⁰*Daubert*, 509 U.S. at 582-85.

cause birth defects and Bendectin;²¹ and a reanalysis of previously published epidemiology studies.²² On appeal to the United States Supreme Court, Respondent-Defendant asserted that Petitioner-Plaintiff's expert failed to employ sufficient scientific evidence to support the expert's opinion that Bendectin caused Plaintiff's birth deformities. The United States Supreme Court sided with Petitioner-Plaintiff, rejected the *Frye* Court's "general acceptance" standard²³ as the sole test of reliability, and presumably expanded the parameters for admission of scientific evidence.

Where scientific knowledge provides the foundation of an expert's opinion, *Daubert* requires the trial judge to investigate whether the expert relied on scientifically valid methodology.²⁴ To aid in this determination, the Supreme Court discussed a non-exhaustive list of factors: 1) whether the principle and methodology is subject to empirical testing; 2) whether the principle and methodology has been subject to peer review and publication, noting that publication is a lesser element of peer review; 3) the known or potential rate of error of a particular scientific method; and 4) general acceptance, or at least the degree in which the relevant scientific community supports the methodology or principle, may carry great weight.²⁵

General Electric v. Joiner,²⁶ however, undermined the assumption that *Daubert* relaxed the admissibility standard for scientific evidence. The *Joiner* Court reviewed a district court's findings with respect to the animal and epidemiology studies used by Respondent's expert to support the theory that exposure to PCBs promoted the development of Respondent's lung cancer.²⁷ Restating the findings of the district court, the Supreme Court noted that the results of the animal studies showed PCBs caused tumors identified as alveologenic adenomas, a type of cancer not typically found in the lung.²⁸ The Court also reiterated the district court's conclusion that the epidemiology studies failed to demonstrate a "statistically significant link between lung cancer and PCBs."²⁹

²¹*Id.*

²²*Id.* The expert relied on data in published epidemiology studies that found no causal link between the drug and birth defects. In the courtroom, the expert used the same data to draw a conclusion different from conclusions drawn by the authors. *Id.*

²³See *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

²⁴"In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity." *Daubert*, 509 U.S. at 590 n.9.

²⁵*Id.* at 591-93.

²⁶*General Elec. Co. v. Joiner*, 118 S. Ct. 512 (1997).

²⁷*Id.* at 518.

²⁸*Id.*

²⁹*Id.* at 519.

The Supreme Court consequently reversed the Eleventh Circuit Court of Appeals and concluded that it was not an abuse of discretion for the district court to reject the expert's reliance on those studies.³⁰ The Court permitted the trial court to investigate the validity of the methods employed by an expert or the validity of the reasoning process or inferences drawn from available data. The Court observed: "The studies were so dissimilar to the facts presented in this litigation that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them."³¹ The *Joiner* Court finally held, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered That is what the District Court did here, and we hold that it did not abuse its discretion in so doing."³² After *Joiner*, only an abuse of discretion gives an appellate court grounds to reverse the decisions of a trial judge. Consequently, whenever the trial judge detects any analytical gaps in the extrapolation between "data and opinions proffered," a legitimate reason to exclude the testimony exists, and thus, the testimony may be excluded.³³

The Supreme Court's most recent foray into the issues surrounding the admissibility of expert testimony took place in *Kumho Tire Co. Ltd. v. Carmichael*.³⁴ This case seems to have momentarily ended the debate over the application of *Daubert's* factor test to expert testimony grounded in the soft sciences and experience or skill-based methodology. In *Kumho*, the right rear tire of a minivan driven by Mr. Carmichael blew out, causing an accident that killed one passenger and severely injured others.³⁵ The Carmichael family brought a diversity suit against the tire maker and its distributor, claiming that the tire was defective.³⁶ At trial, the Carmichaels produced an expert who had a master's degree in engineering and ten years experience in the tire industry. Although the tire was badly worn and, in some spots, treadbare, the expert relied on a visual and tactile test to determine that the tire lacked signs of abuse.³⁷ Consequently, he testified that, based on his experience, the tire failure was caused by a design defect.³⁸

³⁰*Id.* at 519.

³¹*Joiner*, 118 S. Ct. at 518.

³²*Id.* at 519 (citing *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992), *cert. denied*, 506 U.S. 826 (1992)).

³³*Id.* The petitioners also appealed the Eleventh Circuit's application of a uniquely stringent standard of review of the District Court's exclusion of expert testimony. The Supreme Court found, "[a]buse of discretion—the standard ordinarily applicable to review of evidentiary rulings—is the proper standard by which to review a district court's decision to admit or exclude expert scientific evidence." *Id.* at 514.

³⁴*Kumho Tire Co. v. Carmichael*, No. 97-1709, 1999 WL 152455, at *1 (U.S. Mar. 23, 1999).

³⁵*Id.* at *4.

³⁶*Id.*

³⁷*Id.*

The Carmichaels rested the bulk of their case on the testimony of their expert. It was no surprise then that the defendants moved the district court to exclude the expert's testimony on the ground that his methodology failed the reliability requirement of Rule 702 of the Federal Rules of Evidence.³⁹ Applying the reliability-related factors found in *Daubert*, the trial court agreed with the defendants that it should act as a gatekeeper and keep out the expert's technical, rather than scientific, evidence.⁴⁰ The Eleventh Circuit reversed, saying that *Daubert* explicitly applies only where an expert relies on the application of scientific principles, rather than on skill or experience-based observations.⁴¹ The Supreme Court reversed the Eleventh Circuit and agreed with the trial court, noting that *Daubert's* relevancy factors should be considered whenever they are reasonable measures of the reliability of expert testimony.⁴² In instances where empirical analysis may not be suitable to determine the reliability of an expert's methodology, for example, experience and skill-based methodology, the court must make certain that the witness employs the same "intellectual rigor" that defines the expertise of practitioners in the relevant field.

Undoubtedly, after *Kumho*, treacherous terrain lies ahead for expert witnesses. Because the *Kumho* Court directs judges to consider whether the *Daubert* factors constitute a "reasonable measure" of the reliability of an expert's methodology, judges are free to exclude any expert testimony that lacks a reasonable measure of reliability.

Under *Daubert*, innovative theories premised on valid laboratory tests and experiments were in all likelihood safe from judicial review.⁴³ *Joiner* and *Kumho*, however, grant federal judges enormous discretion to reject any expert opinion they dislike.

B. The Development of Ohio's Relevance/Reliability Standard

In Ohio, although the guidelines covering the admissibility of most expert testimony—including physicians—falls under the first sentence of Rule 702(C), confusion persists because Ohio case law decided before the amendment of

³⁸*Id.*

³⁹*Kumho*, WL 152455, at *6.

⁴⁰*Id.* at *6.

⁴¹*Id.* at *7.

⁴²*Id.* at *9.

⁴³Of course, this statement assumes that innovative theories premised on valid laboratory tests and experiments, with nothing more, satisfy the focus of Rule 702.

The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate. *Daubert*, 509 U.S. at 594-95. See also discussion *infra* Part III.A.

Rule 702 continues to be an acceptable means of establishing the reliability of expert opinions.⁴⁴ The staff note announced "there is no intention to change existing Ohio law determining the reliability of expert testimony."⁴⁵ Thus, when considering the admissibility of scientific and medical evidence in Ohio, one must look to the law prior to the amendment of Rule 702 to understand how *State v. Williams*,⁴⁶ *State v. Pierce*,⁴⁷ and *State v. Bresson*⁴⁸ have shaped Ohio's evidentiary framework.

1. *State v. Williams*—The Birth of Ohio's Relevance/Reliability Standard

Over a decade before the amendment of Rule 702, the Ohio Supreme Court abandoned the *Frye* test⁴⁹ in *State v. Williams*.⁵⁰ In *Williams*, the court addressed the admissibility of spectrographic voice analysis used to convict a defendant on charges of aggravated burglary, felonious assault, and attempted rape. The body of the decision cited Professor McCormick's criticism of *Frye*: "general scientific acceptance is a proper condition for taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence."⁵¹ The court endorsed a more flexible approach, the "relevance/reliability" standard.⁵² The

⁴⁴Rule 702 of the Ohio Rules of Evidence states in relevant part:
Testimony by Experts

. . . .

(C) The witness' testimony is based on reliable scientific, technical, or other specialized information. To the extent that the testimony reports the result of a procedure, test, or experiment, the testimony is reliable only if all of the following apply:

- (1) The theory upon which the procedure, test, or experiment is based is objectively verifiable or is validly derived from widely accepted knowledge, facts, or principles;
- (2) The design of the procedure, test, or experiment reliably implements the theory;
- (3) The particular procedure, test, or experiment was conducted in a way that will yield an accurate result.

OHIO EVID. R. 702. Thus, the amendment to Rule 702 seems to apply to all expert witnesses and the basis underlying expert opinions, whether or not their conclusions have anything to do with science.

⁴⁵OHIO EVID. R. 702 staff note.

⁴⁶*State v. Williams*, 446 N.E.2d 444 (Ohio 1983).

⁴⁷*State v. Pierce*, 597 N.E.2d 107, 115 (Ohio 1992), superseded by rule as stated in *State v. Nemeth*, 694 N.E.2d 1332 (Ohio 1998).

⁴⁸*State v. Bresson*, 554 N.E.2d 1330 (Ohio 1990).

⁴⁹*See Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

⁵⁰*Williams*, 446 N.E.2d at 444. The opinion notes that the Supreme Court never formally adopted the *Frye* test. However, "general acceptance" was the standard followed by the lower courts. *Id.* at 447 n.5.

⁵¹*Id.* at 447.

⁵²According to Professor Giannelli, the birth of the relevance/reliability approach can be traced to Professor McCormick. *See* Paul C. Giannelli, *The Admissibility of Novel*

court summed up its position by asserting that "any relevant conclusions which are supported by a qualified expert witness should be received unless there are other reasons for exclusion."⁵³ Following the trend set by a few federal jurisdictions, the Ohio Supreme Court sought to avoid the harsh restriction of *Frye's* "general acceptance" test.⁵⁴

Rules 402, 403, and 702 of the Ohio Rules of Evidence constituted the basis of *Williams's* version of the relevance/reliability standard.⁵⁵ Rule 402 provided that all relevant evidence was admissible unless excluded by constitutional mandates or in conflict with statutes or other rules.⁵⁶ Rule 702, prior to the 1994 amendment, authorized the admissibility of scientific evidence by qualified witnesses if the testimony assisted the trier of fact to understand the evidence or determine a fact in issue.⁵⁷ Finally, Rule 403 operated to exclude scientific

Scientific Evidence: Frye v. United States a Half Century Later, 80 COLUM. L. REV. 1197, 1223 (1980). Giannelli explains that the first step in applying the relevance/reliability approach is the determination of the probative value of the evidence, which turns on a determination of whether the evidence has a tendency to make the existence of a fact more or less probable. *Id.* Secondly, the potential to mislead the jury must be evaluated, and lastly this danger must be balanced against the probative value of the proffered evidence. *Id.* at 1232-1239. In contrast to the approach taken in *Daubert*, the relevance/reliability approach limits the trial judge to screening scientific evidence while the jury must evaluate the reliability of the evidence and ultimately its probative value. For further commentary on the relevance/reliability approach and its limitations to effectively deal with scientific evidence, see Bert Black et al., *supra* note 19 (arguing that the relevance/reliability approach is a flawed shortcut to determining the probative value of scientific evidence); see also Jay P. Kesan, *An Autopsy of Scientific Evidence in a Post-Daubert World*, 84 GEO. L.J., 1985 (1996) (analyzing flaws found in the relevance/reliability approach). "By admitting all relevant scientific evidence, any disagreements or significant doubts about a testifying expert's methodology are treated as issues going to weight and credibility, rather than admissibility, of the evidence." *Id.* at 1995.

⁵³*Williams*, 694 N.E.2d at 447.

⁵⁴See, e.g., *United States v. Williams*, 583 F.2d 1194 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1978) (rejecting strict application of *Frye* and substituting it for the relevancy test); *Christopherson v. Allied-Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (questioning the development of a homemade test for admissibility when the expert opinion testimony was correctly excluded because the majority found it substantially more prejudicial than probative); and *United States v. Jakobetz*, 747 F. Supp. 250 (D. Vt. 1990) (holding the reliability of DNA evidence outweighed increased potential of unfairly prejudicing the jury).

⁵⁵*Williams*, 694 N.E.2d at 447-49. Professor Giannelli makes the point that the issue of probative value begins with the definition of relevant evidence found in Federal Rule 401. The federal rule is identical to rule 401 of the Ohio Rules of Evidence. Both define relevant evidence to mean: "Evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Giannelli, *supra* note 41, at 1235-36.

⁵⁶OHIO EVID. R. 402.

⁵⁷See OHIO EVID. R. 702, staff note (discussing that the "assist the trier of fact" standard had been uninformative and had misled judges and attorneys). In short, the note states that a threshold standard of reliability determined by references to the methods and

evidence only in the rare occasion where the evidence's probative value is substantially outweighed by unfair prejudice.⁵⁸

In comparison to *Daubert*, the *Williams* relevance/reliability standard weighs a preliminary finding of the relevance of scientific evidence against its prejudicial effect. Given this approach, scientific validity lacks significance because the trial judge balances probity against prejudice rather than investigating the validity of the methods relied upon by the experts to reach an opinion. Commentary critical of the relevance/reliability approach seems even more constructive after *Daubert*.⁵⁹ The relevance/reliability standard treats "reliability of the evidence and the validity of the underlying scientific methodology as aspects of relevancy."⁶⁰ Since this approach relegates scientific validity to a secondary role, the qualifications of the expert witness surfaces as the principal influence on resolving the issue of reliability.⁶¹ Consequently, from a practical standpoint, highly qualified experts possess more persuasive power with juries. Thus, the more qualified the expert, the more reliable the testimony. Because the application of Ohio's relevance/reliability standard relies so heavily on the qualifications of experts, only a broader latitude in the cross-examination of experts can illuminate the long shadow of impeccable credentials potentially hiding speculative conclusions.⁶²

2. *State v. Pierce*—Generally Recognized Test

Daubert did not "read the requirements of Rule 702 to apply to all scientific techniques."⁶³ Prior to *Daubert*, the Ohio Supreme Court in *State v. Pierce*

principles employed by experts in reaching their conclusions replaces "assist the trier of fact" language. If, as the staff note states, Ohio case law remains unchanged, the threshold question of reliability must be balanced against undue prejudice.

⁵⁸Rule 403 of the Ohio Rules of Evidence permits exclusion of relevant evidence on grounds of prejudice, confusion or undue delay. See OHIO EVID. R. 403. Nearly identical to the Federal Rule, Ohio's Rule 403 is rarely applied to scientific evidence because the result usually ends in summary judgment for the defendant. See Margaret A. Burger, Evidentiary Framework, in THE REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 37, 113-116 (Federal Judicial Center ed., 1994).

⁵⁹Giannelli, *supra* note 52, at 1250 (concluding that the relevance/reliability screening process of complex scientific principles leads to the admission of "insufficiently valid data techniques" and, thus, an inappropriate test for the admissibility of scientific evidence).

⁶⁰Kesan, *supra* note 52, at 1994.

⁶¹*Id.* at 1995 (citing Michael H. Gottesman, *Admissibility of Expert Testimony After Daubert: The "Prestige" Factor*, 43 EMORY L.J. 867, 884 n.44 (1994)).

⁶²See OHIO EVID. R. 706. "Learned Treatises for Impeachment." *Id.* Rule 706 permits the impeachment of expert witnesses through the use of publications not only relied upon by the expert but determined as authoritative by other expert testimony or by judicial notice. *Id.*; see discussion *infra* Section IV.A.

⁶³*Daubert*, 509 U.S. at 592.

Of course, well-established propositions are less likely to be challenged

reached similar conclusions.⁶⁴ The court upheld the admission of DNA evidence but limited the application of the relevance/reliability standard to novel or new scientific theories.⁶⁵ After reviewing literature on the validity of DNA typing, the court expressed its belief that DNA testing had risen to the level of a generally recognized test.⁶⁶ Quoting a passage signaling a progressive approach to the admissibility of scientific evidence, the court endorsed the language of one commentator, saying that all expert testimony based on generally recognized tests was presumptively admissible.⁶⁷ The term

than those that are novel, and they are more handily defended. Indeed, theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under Fed. Rule Evid. 201.

Id. at 592 n.11. While being mindful of the above dicta, note that federal courts often refuse to apply *Daubert* when faced with engineers alleging defects in products liability cases relying upon general engineering principles,—i.e., math and physics—rather than new or unconventional methodologies. *See, e.g.,* Compton v. Subaru of America, Inc., 82 F.3d 1513 (10th Cir. 1996) (finding *Daubert* inapplicable to an engineer's testimony on crashworthiness); *Officer v. Teledyne Republic/Spray*, 870 F. Supp. 408 (D. Mass. 1994) (refusing to apply a *Daubert* analysis to assess the reliability of an engineer's testimony on the defective design of a hydraulic jack); *Tassin v. Sears Roebuck Co.*, 946 F. Supp. 1241 (N.D. La. 1996) (*Daubert* factors are irrelevant to a case involving alternative product designs); Lisa M. Agrimonti, *The Limitations of Daubert and Its Misapplication to Quasi-Scientific Experts*, 35 WASHBURN L.J. 134 (1995) (making a case that engineers are quasi-scientific experts because their methodology consists of basic principles of math, physics and engineering typically learned by engineers during their training); *Cf.,* Cummins v. Lyle Industries, 93 F.3d 362 (7th Cir. 1996) (applying a *Daubert* analysis to an engineer's opinion that was based on generally accepted—though not proffered—engineering principles); FRANCIS H. HARE & ALLWIN E. HORN, EXPERT OPINION TESTIMONY—THE DAUBERT ANALYSIS IS NOT APPLICABLE TO ESTABLISHED PRINCIPLES OF SCIENCE (Indep. Counsel Resources Monograph Series 011, 1997).

⁶⁴*State v. Pierce*, 597 N.E.2d 107, 115 (Ohio 1992). Writing for a unanimous court, Judge Moyer reaffirmed the relevancy standard for the admission of scientific evidence and firmly rejected the defendant's request that the court adopt the *Frye* test for the admissibility of DNA evidence. *Id.*

⁶⁵*Pierce*, 597 N.E.2d at 107. After the amendment of Rule 702 of the Ohio Rules of Evidence, trial judges must apply the relevance/reliability standard to the foundations of any expert's opinion, even where an expert opinion is based on generally recognized tests—an instance warranting the mere formality of judicial notice. *See* OHIO EVID. R. 702.

⁶⁶*Pierce*, 597 N.E.2d at 112. "Although irrelevant for the determination of admissibility under Ohio law, the theory and procedures used in DNA typing are generally accepted within the scientific community." *Id.*

⁶⁷*See id.* (quoting Note, *United States v. Two Bulls: Eighth Circuit Addresses Admissibility of Forensic DNA Evidence*, 37 LOY. L. REV. 173, 177 (1991)).

The relevancy standard balances the probativeness, materiality, and reliability of the evidence against the risk of misleading or confusing the jury or unfairly prejudicing the defendant. This approach makes all expert testimony on generally recognized tests presumptively admissible and places the burden of excluding the evidence on the opponent.

"presumptively admissible" in this context may be misleading. A review of the citations supporting this statement discloses that state and federal courts take judicial notice of scientific evidence generally accepted within the scientific community rather than presume admissibility.⁶⁸

Rule 702 now requires information forming the basis of expert opinion to undergo a "reliability determination." Although Rule 702 supersedes *Pierce*,⁶⁹ the case recognized judicial notice as a time-saving procedure to eliminate unnecessary hearings over undisputed methodology. After *Pierce*, a court, in its discretion, may take judicial notice of the reliability of all generally accepted tests.

3. *State v. Bresson*—Soft Science

Although *Daubert* explicitly applied its analysis to conclusions derived from scientific knowledge, a number of legal commentators prior to *Kumho* question whether *Daubert* applies to non-scientific testimony.⁷⁰ In contrast to opinions based on science, opinions based on specialized knowledge, skill, or training lack the scientific foundations that can be empirically tested.⁷¹ Arguably, the relevance/reliability approach is better suited to the determination of reliability of expert opinions drawn from personal experience and specialized knowledge.

Id. (citing *State v. Woodall*, 385 S.E.2d 253, 259 (W. Va. 1989)).

⁶⁸The *Woodall* court applied the relevancy standard, stating "Rule 702 [of the West Virginia Rules of Evidence] makes all expert testimony concerning generally recognized tests presumptively admissible and casts the burden of excluding such testimony upon the side seeking exclusion." *Woodall*, 385 S.E.2d at 259. The court also stated, "[a]s to DNA typing analysis, we find that the reliability of these tests is now generally accepted by geneticists, biochemists, and the like. Thus, no *Frye* hearing will be required in the future for judicial notice of reliability." *Id.* at 260 (citation omitted).

⁶⁹See *State v. Nemeth*, 694 N.E.2d 1332, 1338 (Ohio 1998). "Since *Pierce*, . . . Evid.R. 702 [sic] was amended, specifically adding the requirement that the information forming the basis of the expert testimony be 'reliable.'" *Id.*

⁷⁰See Burger, *supra* note 58, at 84-88, for discussion regarding the well argued debate over whether the stringency of empirical validation is appropriate to methodology which lacks a close resemblance to the traditions of the scientific method. See also *Developments in the Law—Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481 (1995). This article suggests the application of the same standard of reliability for all types of expert testimony by applying maximum flexibility rather than a rigid set of criteria. *Id.* at 1527.

⁷¹See *Developments in the Law—Confronting the New Challenges of Scientific Evidence*, *supra* note 70, at 1525 n.133 (citing John Monahan & Laurens Walker, *Judicial Use of Social Science Research After Daubert*, 2 SHEPARD'S EXPERT & SCI. EVIDENCE Q. 327, 332 (1994)). Monahan and Walker propose a more relaxed standard for evaluating the reliability of social science research. *Id.*

In *State v. Bresson*,⁷² a case that dealt with "soft science,"⁷³ the Supreme court of Ohio reversed the Franklin County Court of Appeals and affirmed the trial court's judgement convicting the defendant of driving under the influence of alcohol.⁷⁴ On appeal to the supreme court, the Franklin County Court of Appeals certified the following question: "Whether a court may admit evidence of a defendant's performance on a horizontal gaze nystagmus test in the absence of expert testimony establishing the scientific foundation of the test."⁷⁵ The *Bresson* court declined to characterize the HGN test as scientific in nature, thereby negating the need for an expert witness to lay a scientific foundation for the validity of the test.⁷⁶ Ultimately the court held,

[a] properly qualified officer may testify at trial regarding a driver's performance on the horizontal gaze nystagmus test as it pertains to the issues of probable cause to arrest and whether the driver was operating a vehicle while under the influence of alcohol However, such testimony may not be admitted to show what the exact alcohol concentration level of the driver was for purposes of demonstrating a violation of R.C. 4511.19(A)(2), (3), or (4).⁷⁷

Bresson illustrates the analysis favored by the Ohio Supreme Court when dealing with tests and procedures incapable of validation through an empirical process. First, consistent with the relevance/reliability approach, the court conducted only a preliminary review focusing on corroborative findings of probity and accuracy of the test.⁷⁸ Second, the court examined medical journals for some evidence verifying the accuracy of the HGN test.⁷⁹ Thus, the court applied the relevance/reliability standard to non-scientific evidence and took

⁷²*State v. Bresson*, 554 N.E.2d 1330 (Ohio 1990).

⁷³For an explanation of the difference between hard and soft science see Cathleen C. Herasimchuk, *A Practical Guide to the Admissibility of Novel Expert Evidence in Criminal Trials Under Federal Rule 702*, 22 ST. MARY'S L.J. 181, 194 (1990). "The types of novel expertise currently offered in courts run the gamut from the highly subjective, 'soft' sciences of psychology and psychiatry to the highly objective 'hard' sciences of microbiology, chemistry, and nuclear physics." *Id.*

⁷⁴*Bresson*, 554 N.E.2d at 1331.

⁷⁵*Id.* at 1332.

⁷⁶*Id.* at 1335. The HGN test was admissible after an initial showing of the officer's qualifications and that proper techniques were performed.

⁷⁷*Id.* at 1330-31 (syllabus).

⁷⁸*Id.* at 1332-34.

⁷⁹*Bresson*, 554 N.E.2d at 1332-34. The court appears to take judicial notice of medical literature to establish reliability. Typically, the Ohio Supreme Court has looked to learned treatises to find reasonable assurances that the methodology in question has been subject to favorable peer review. See, e.g., *Miller v. Bike Athletic Co.*, 687 N.E.2d 735 (Ohio 1998); and *Nemeth*, 694 N.E.2d at 1332.

judicial notice of learned treatises establishing the validity of the expert's methodology.⁸⁰

4. *Miller v. Bike Athletic Co.*—Limitations of Relevance/Reliability Approach

*Miller v. Bike Athletic Co.*⁸¹ underscores the difficulty of assimilating Daubert into a jurisdiction that applies the balancing process of the relevance/reliability standard to screen all types of expert opinion. In *Miller*, the court held that "a trial court's role in determining whether an expert's testimony is admissible under Evid. R. 702 focuses on whether the opinion is based upon scientifically valid principles, not whether the expert's conclusions are correct or whether the testimony satisfies the proponent's burden of proof at trial."⁸² The majority opinion ruled that the lower court abused its discretion when it excluded expert testimony that a properly inflated football helmet liner would have prevented a neck fracture and permanent paralysis in a high school football player.⁸³ In *Miller*, the expert relied on an outdated theory and formed an opinion that ignored a large base of medical literature⁸⁴ showing the true culprit behind severe spinal injuries to be hyperflexion of the neck and axial loading—the transmission of forces from the skull to the spinal cord and supporting vertebrae—initiated by striking an opponent with the crown of the helmet.⁸⁵ A well-fitting, defect-free helmet protects against head injuries but affords

⁸⁰With respect to taking judicial notice, the *Bresson* court's conduct is consistent with commentary under Rule 706 of the Ohio Rules of Evidence. "The common law rule restricted the use of a learned treatise to impeachment A possible expansion of the common law rule concerns the use of judicial notice to establish the treatise as a reliable authority. A court taking judicial notice of Gray's Anatomy illustrates this aspect of the rule." OHIO EVID. R. 706 staff note (citation omitted).

⁸¹*Miller v. Bike Athletic Co.*, 687 N.E.2d 735 (1998).

⁸²*Id.* at 736 (syllabus).

⁸³*Id.* at 738. Plaintiff, a high school football player, was rendered quadriplegic while attempting to tackle another player running at him full speed. Plaintiff's expert, a mechanical and biomedical engineer, examined the helmet and found that the energy-absorbing liner that protected the top of the head had not been properly inflated at the time of Plaintiff's injury. Plaintiff's expert opined that proper inflation would have sufficiently absorbed the force of impact and avoided a fracture of the fifth cervical vertebrae. *Id.*

⁸⁴See, e.g., Note, *Injuries Resulting from Nonintentional Acts in Organized Contact Sports: The Theories of Recovery Available to the Injured Athlete*, 12 IND. L. REV. 687 (1979); Philo & Stine, *The Liability Path to Safer Helmets*, TRIAL 38 (Jan. 1977); *Practical Trial Suggestions: Products Liability of Sports Equipment Suppliers*, 28 DEF. L.J. 332 (1979).

⁸⁵See Gerald J. Todaro, *Allocation of Risk Based on Mechanics of Injury in Sports: A Proposed Presumption of Non-Fault*, 10 HASTINGS COMM. & ENT. L.J. 33 (1987) (discussing the development of rule changes on the use of a helmet to intentionally butt, ram, spear or strike an opponent with the crown or top of the helmet resulting from medical research establishing that the compression effect from the force of the impact can result in fractures of the vertebrae).

minimal protection from neck fractures and spinal injuries.⁸⁶ The plaintiff's expert in *Miller* relied upon an antiquated theory that had lost credence in sports medicine.⁸⁷ However, the majority admitted the expert's opinion because the testimony could aid the trier of fact.⁸⁸

The majority apparently applied the reliability factors found in *Daubert* to determine a minimal level of reliability for the basis of the expert's opinion. Yet, without articulating the relevance/reliability approach, the majority ruled that Plaintiff's out of court experiments testing the helmet were sufficiently reliable to aid the trier of fact.⁸⁹ Endorsing *Daubert*, the dissent strongly recommended a gatekeeping role for Ohio trial judges, especially where the basis of the testimony ought to comply with Rules 702(C)(1), (2), and (3) of the Ohio Rules of Evidence.⁹⁰

Unfortunately, the majority in *Miller* relied upon *Joiner* as decided by the Eleventh Circuit Court of Appeals.⁹¹ The Eleventh Circuit decision limited its focus to whether an expert's opinions were based on scientifically valid principles, not the conclusions and opinions drawn from tests, methodology, and principles.⁹² As stated above, it was later overturned by the United States Supreme Court.⁹³

Whether an expert's theory is innovative or controversial, reliability is compromised when numerous medical or scientific studies compel a conclusion contrary to the one advanced by the expert. Applying a *Joiner* analysis (as exercised by the United States Supreme Court) to the facts in *Miller*, the expert's opinion, contradicted by a virtual consensus of medical and scienti-

⁸⁶See Todaro, *supra* note 85, n.19-25.

⁸⁷See *id.*

⁸⁸How helpful is testimony contrary to the prevailing view founded on medical and scientific research? See discussion *infra* Section IV.B, suggesting that one expert opposing another—out of the context of the complete framework of medical literature—permits a the jury to mistakenly believe that a legitimate schism exists in a given medical field.

⁸⁹*Miller*, 687 N.E.2d at 742. "Dr. Lafferty's theory is not so complicated that it would overwhelm a jury. We find that his testimony could aid the trier of fact in determining whether the football helmet was a cause of injury to appellant's neck." *Id.* The *Miller* court's conclusion is confusing. The majority seems to apply Rule 702 in its unamended form while applying *Daubert* which provided the impetus for the amendment. See OHIO EVID. R. 702 staff note (explaining the rationale for eliminating the "aid the trier of fact" language).

⁹⁰*Miller*, 687 N.E.2d at 744 (1998) (Cooke, J., dissenting).

⁹¹*Id.* (citing *Joiner v. General Elec. Co.*, 78 F.3d 524, 530 (11th Cir. 1996)).

⁹²See *Joiner*, 78 F.3d at 530.

⁹³By reversing the Eleventh circuit Court of Appeals, the Supreme Court established that reliability determinations *may* include a review of the expert's calculations and ultimate conclusions. See *Joiner*, 118 S. Ct. at 512.

fic research,⁹⁴ arguably lacks sufficient reliability to aid the trier of fact.⁹⁵ Consequently, *Miller* is at odds with recent federal case law, and thus it leaves unsettled the depth of the trial court's investigation into the reliability element of the relevance/reliability standard.

Assuming Ohio's continued dedication to the relevance/reliability standard and its deference to the jury's determination of reliability, jurors will need more access to learned treatises to gain greater perspective on an expert's opinion. Courtroom availability of medical and scientific literature seems necessary to prevent jurors' "uncritical acceptance" of expert opinions that defy prevailing views in medicine or science.⁹⁶

5. *State v. Nemeth*—Ohio Judges' Limited Gatekeeping Role

The recent decision of *State v. Nemeth*⁹⁷ endorsed a preliminary judicial determination of the reliability of expert opinions. However, the decision ultimately continues the relaxed standard imposed by the relevance/reliability approach: "Courts should favor the admissibility of expert testimony whenever it is relevant and the criteria of Evid. R. 702 [sic] are met."⁹⁸

In *State v. Nemeth*, Defendant, a 16 year old boy, was tried for killing his alcoholic and abusive mother by shooting her five times in the head and neck with a compound bow and arrow.⁹⁹ The trial court had excluded the testimony of a Ph.D. psychologist on the "battered child syndrome" proffered by Defendant to support his claim of self-defense or justification for the instruction on the lesser included defense of murder.¹⁰⁰ Although faced with an expert whose methodology was less exacting than a medical doctor, the supreme court reviewed and cited learned treatises to validate the principles underlying the psychologist's opinion of a defendant suffering from battered child syndrome. In one sentence, the Supreme Court provided the clearest definition of

⁹⁴Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After Daubert*, 78 MINN. L. REV. 1387, 1412-1417 (1994). Sanders notes that, in Bendectin cases, the courts often excluded opinions based on in vitro and in vivo studies because of the overwhelming body of contradictory epidemiological evidence. *Id.* at 1413-1414 nn.144-47.

⁹⁵*Id.* at 1438 (citing Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 32 JURIMETRICS J. 345, 347-348). See also Charles J. Walsh & Beth S. Rose, *Increasing the Useful Information Provided by Experts in the Courtroom: A Comparison of Federal Rules of Evidence 703 and 803(18) with the Evidence Rules in Illinois, Ohio and New York*, 26 SETON HALL L. REV. 183 (1995) (concluding that the failure to adopt Federal Rule of Evidence 803(18) governing the admission of learned treatises prevents the maximum receipt of information to jurors).

⁹⁶Sanders, *supra* note 94, at 1438.

⁹⁷*State v. Nemeth*, 694 N.E.2d 1332 (Ohio 1998).

⁹⁸*Id.* at 1336.

⁹⁹*Id.*

¹⁰⁰*Id.* at 1334.

reliability currently available: "Relevant evidence based on valid principles will satisfy the threshold reliability standard for the admission of expert testimony."¹⁰¹ The remaining paragraph places the judge's preliminary role as a gatekeeper in perspective:

The credibility to be afforded these principles in the expert's conclusions remain a matter for the trier of fact. The reliability requirement in Evid. R. 702 is a threshold determination that should focus on a particular type of scientific evidence, not the truth or falsity of an alleged scientific fact or truth. 'In other words, the Court need not make the initial determination that the expert testimony or the evidence proffered is true before submitting the information to the jury.'¹⁰²

Nemeth articulates the evidentiary framework by which Ohio judges determine the admissibility of scientific evidence under Rule 702 of the Ohio Rules of Evidence. First, under Rule 401 of the Ohio Rules, the evidence must be relevant.¹⁰³ Second, pursuant to amended Rule 702: the testimony must relate to a matter beyond the knowledge or experience of a layperson;¹⁰⁴ the witness must be qualified as an expert by specialized knowledge, skill, experience, training or education;¹⁰⁵ and the witness' testimony must be based on reliable scientific, technical or other specialized information.¹⁰⁶ Lastly, the court must determine if the probative value of the expert's opinion is substantially outweighed by the danger of unfair prejudice, confusion or undue delay in accordance with Rule 403 of the Ohio Rules of Evidence.¹⁰⁷

In contrast to the federal system, Ohio's evidentiary framework precludes judges from plumbing the depths of an expert's analytical arguments to determine if any gap exists between principles and courtroom conclusions. Nor is the judge called upon to consider the truth or falsity of the conclusions rendered by the expert. *Nemeth* draws a fine line between principles and conclusions—identical to the line penciled-in by *Daubert*. But *Nemeth* stiffens

¹⁰¹*Id.* at 1339.

¹⁰²*Nemeth*, 694 N.E.2d at 1339 (citations omitted).

¹⁰³*Id.* at 1336 (noting the requirement under Rule 401 that evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."). See also *infra* text accompanying note 107.

¹⁰⁴See *Nemeth*, 694 N.E.2d at 1336 (quoting OHIO EVID. R. 702).

¹⁰⁵See *id.* (quoting OHIO EVID. R. 702).

¹⁰⁶*Id.*

¹⁰⁷Though not specifically mentioned by the *Nemeth* court, Rule 403, defining an aspect of relevancy, functions as a companion to the relevancy analysis applied under Rule 401. This requirement is inferred from the supreme court's caveat that "[c]ourts should favor the admissibility of expert testimony whenever it is relevant." *Nemeth*, 694 N.E.2d at 1336.

the flexibility of the relevance/reliability approach by providing the trial judge a limited gatekeeper role. How long will Ohio judges resist the temptation to analyze the rationale of experts they dislike? If *Joiner* is any indication of judicial restraint, Ohio judges may soon emulate federal judges and seek to examine the validity not only of methods and principles but the logic underlying the expert's reasoning process.

III. ADMISSION OF PHYSICIAN TESTIMONY UNDER THE RELEVANCE/RELIABILITY STANDARD

Under rule 702 of the Ohio Rules of Evidence and the relevance/reliability standard, no longer may judges admit physician testimony solely on the basis of the physician's education, training, and medical licensure. Consequently, courts should now make preliminary reliability assessments of an expert's opinions in the courtroom, in addition to the usual predicates of admissibility under the Ohio Rules of Evidence. Courts should take judicial notice of the reliability of the long established practice, known as differential diagnosis, except for the unusual circumstance where no support is found in medical training, research, or epidemiology studies for a physician's opinion on the issue of causation.

Historically, Ohio courts have seldom questioned the physician's methodology underlying diagnosis and treatment or, more importantly, the forensic opinions derived from a treating physician's management of a patient. Indeed, a state medical license and an active practice qualifies the physician to render a series of medical opinions about the patient's condition, necessary treatment, and future medical care.¹⁰⁸

As seen in this section, the medical reasoning process consists of the systematic accumulation of patient information, medical research, and medical literature. Physicians use methodology on a daily basis to form medical conclusions in the practice of medicine. *Daubert* and *Joiner* changed the

¹⁰⁸See, e.g., *Ishler v. Miller*, 384 N.E.2d 296 (Ohio 1978) (rejecting the contention that an expert in a medical malpractice case must be board certified in the same specialty as the defendant doctor); see also *Rouse v. Riverside Methodist Hosp.*, 459 N.E.2d 593 (Ohio Ct. App. 1983) (holding that a physician licensed to practice medicine is competent to testify on medical issues, including the causal relationship of medical expenses to a particular injury). Evidence that a physician practices in a different specialty of medicine has a bearing on the weight of the testimony, not its admissibility. *Id.*

For example, a cardiologist or an internist may testify about a family practice physician's mismanagement of a patient's unstable angina, but an orthopedist, although duly licensed, would likely lack the requisite qualifications. See *Alexander v. Mount Carmel Med. Ctr.*, 383 N.E.2d 564 (Ohio 1978) (finding podiatrist competent to testify against an orthopedic surgeon on the issue of proper casting of a fracture); *Steel v. Buxton* 639 N.E.2d 861 (Ohio Ct. App. 1994) (holding that general practitioner serving as a surgical assistant was competent to testify because of overlapping specialties).

The exception involves standard-of-care issues in medical malpractice cases. Physicians who devote less than one-half of their time to the active clinical practice of medicine lack the qualifications to give competent expert testimony. See OHIO EVID. R. 601(D). The Federal Rules of Evidence lack a similar competency requirement.

emphasis on the evidentiary foundations of opinions forged by medical experts. Similarly, Rule 702 of the Ohio Rules of Evidence and the relevance/reliability standard requires the witness to produce not only a valid medical license but methodology, as well. Clearly, as seen in this section, courts should take judicial notice of the long-established clinical practice of differential diagnosis. Especially on complex issues of medical causation, differential diagnosis provides a reliable method upon which to base the physician's opinion on causation and damages.

A. *The Methodology of Diagnosis*

Today technology—in the form of diagnostic studies, quantitative clinical reasoning, and statistically validated treatment outcomes—attests to the role of science in the practice of medicine.¹⁰⁹ Medical opinions fit somewhere between the 'soft' and 'hard' sciences.¹¹⁰ Physicians rarely reach a definitive diagnosis without first interpreting data generated from sophisticated medical technology.¹¹¹ More than ever, clinical decisions are supported by data,

¹⁰⁹Thomas A. Lang & Michael Secic, *How to Report Statistics in Medicine*, in AMERICAN COLLEGE OF PHYSICIANS 147, 147-169, (1996). The role of technology in the form of diagnostic testing is so essential to diagnosis that guidelines for reporting characteristics of new tests have been established to help physicians evaluate their validity. *Id.*

¹¹⁰In the introductory chapter of *Harrison's Principles of Internal Medicine*, the editors articulate the relationship between art and science:

Science-based technology is the foundation for the solution to many clinical problems; the dazzling advances in biochemical methodology and in biophysical imaging techniques that allow access to the remotest recesses of the body are the products of science Yet skill in the most sophisticated application of laboratory technology and in the use of the latest therapeutic modality alone does not make a good physician. The ability to extract from a mass of contradictory physical signs and the crowded computer printouts of laboratory data those items that are of crucial significance, to know in a difficult case where to treat 'or to watch,' to determine when a clinical clue is worth pursuing or when to dismiss it as a 'red herring,' and estimate in any given patient whether a proposed treatment entails a greater risk than the disease are all involved in the decisions that the clinician, skilled in the practice of medicine, must make many times each day.

ANTHONY S. FAUCI et al., HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 1 (McGraw Hill 14th ed. 1998).

¹¹¹*Harrison's Principles of Internal Medicine* defines the concept of evidence-based medicine as clinical decisions formally supported by data, especially data from randomized, controlled clinical trials. See FAUCI *supra* note 110. The text cites a 1995 study concluding that 82% of primary treatments administered at a university-affiliated hospital had previously been scientifically validated by randomized controlled clinical trials or by unanimous agreement that such studies were unnecessary. FAUCI *supra* note 110, at 4. See also R.O. BRANDENBURG ET AL., *CARDIOLOGY FUNDAMENTALS AND PRACTICE*, 33 (Yearbook Med. Publishers, Inc. 1997) (tracing the evolution of cardiac instrumentation resulting in more precise information leading to increased accuracy of diagnosis).

particularly data derived from controlled clinical trials reported in medical journals.

The cognitive model of making medical decisions is a five-step process: 1) investigation of the complaint by means of clinical examination (history and physical examination); 2) ordering of diagnostic tests, each with its own intrinsic accuracy and usefulness; 3) integration of clinical findings with test results to assess diagnostic probabilities; 4) weighing of comparative risks and benefits of alternative courses of action; and 5) determination of patient's preferences and development of a therapeutic plan.¹¹²

As soon as a doctor performs an examination on a patient, differential diagnosis provides the means by which physicians reach a conclusion on a patient's illness or disease. The process of prioritizing the causes of a patient's signs and symptoms and treating the most likely cause of the patient's illness describes the operation of differential diagnosis.¹¹³ Once the patient's malady is identified, treatment begins. In the process of clinical reasoning, physicians systematically formulate medical opinions and select treatment alternatives.¹¹⁴ Thus the clinical practice of medicine necessarily depends on technology, medical research, and differential diagnosis.

Daubert and its followers rarely quibble with a physician's diagnosis. The skirmish line is drawn where the physician relies on differential diagnosis to causally connect the medical condition of a patient to a product or chemical substance. In *Joiner*, for example, one of the experts, a medical toxicologist, testified at trial that he formed his opinion through the process of differential diagnosis.¹¹⁵ Despite the expert's reliance on differential diagnosis, the trial court rejected the expert's opinion on causation, and the *Joiner* Court ultimately

¹¹²See FAUCI *supra* note 110, at 9 (noting the five phases of clinical reasoning in Table 3-1).

¹¹³Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in THE REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 181, 214 (Federal Judicial Center ed., 1994). Technically, differential diagnosis is a process of elimination, forcing physicians evaluating chest pain, for example, to think about diagnosis in the following fashion: "Dx [diagnosis] myocardial infarct R/O (rule out) pulmonary embolus and aortic dissection." Differential diagnosis is defined as a method by which a physician determines what disease process has caused a patient's symptoms. *Id.* The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on physical examination, clinical tests and a thorough case history. *Id.*

¹¹⁴Diagnosis and medical treatment of a patient's condition almost always depends on diagnostic testing. The clinical management of patients combines the education and training of a physician with a battery of laboratory studies, x-rays, and invasive imagery. Essentially, science provides the data, but the physician must interpret the data. Similar to lawyers, physicians cannot afford the luxury of certainty that drives the scientist in the laboratory. Although science and technology provide a sound basis for the treatment of a patient, good clinical decision making is a skill not solely dependent on science or art. In short, technology has yet to replace judgment. See generally FAUCI *supra* note 110.

¹¹⁵*Joiner*, 118 S. Ct. at 522 n.4 (Stevens, J., concurring and dissenting in part).

found that the trial court's decision was not an abuse of discretion.¹¹⁶ However, *Joiner* left unresolved a split in the lower courts over the admission of causation opinions on the basis of differential diagnosis.¹¹⁷

Differential diagnosis remains a valid method of reaching causation opinions, unless the epidemiology studies, lab studies, and medical literature providing the data to support the expert's opinion is deemed unreliable. In short, *Joiner's* concern over "analytical gaps" translates into a problem well known to trial lawyers: Insufficient facts fail to support an expert's conclusion. After *Daubert* and *Joiner*, at least in the federal court system, what used to be a question of weight is now solely a question of admissibility.

B. Medical Research and Epidemiology

Epidemiology is the study of the incidence, distribution, and etiology of disease in human populations.¹¹⁸ Epidemiologists make the assumption that disease is not distributed randomly within groups of people.¹¹⁹ Epidemiological evidence comes into play in the courtroom when people exposed to an agent or chemical are compared to an unexposed group and the results show that the exposed group contracted a particular illness or disease more readily than others. Through a comparison of the exposed population group to the unexposed group, epidemiologists draw conclusions to establish relationships between exposure to an agent and a particular illness. From a litigation standpoint, the problem arises when experts use epidemiological findings as a basis to infer a causal connection between a chemical (or drug) and the plaintiff's injury.¹²⁰

¹¹⁶*Joiner*, 118 S. Ct. at 523.

¹¹⁷For circuit opinions holding that a clinical physician may express an opinion based on clinical medical methodology that a toxic substance caused the patient's disease, see *Moore v. Ashland Chem.*, 151 F.3d 269 (5th Cir. 1998). *Moore* sheds light on the enormous discretion involved in the admissibility of clinical physicians' opinion on causation. The majority opinion excluded the testimony of a non-treating physician relying on differential diagnosis, yet it found the testimony of the treating physician reliable, even though he relied on essentially the same scientific information. *Id.* For additional cases excluding physician testimony, see *Schmaltz v. Norfolk & W. Ry.*, 896 F. Supp. 180 (N.D. Ill. 1995); *Cavallo v. Star Enter.*, 892 F. Supp. 756 (C.D. Va. 1995), *aff'd* in part and *rev'd* in part 100 F.3d 11, 50 (4th Cir. 1996); *O'Connor v. Commonwealth Edison*, 13 F.3d 1090 (7th Cir. 1994), *cert. denied*, 114 S. Ct. 2711 (1994). For decisions finding opinions based on clinical methodology unsupported by hard science, see *Zuchowicz v. United States*, 140 F.3d 381 (2d Cir. 1998); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995); *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968 (8th Cir. 1995).

¹¹⁸Linda A. Bailey, et al., *Reference Guide on Epidemiology*, in THE REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 121, 125 (Federal Judicial Center ed., 1994).

¹¹⁹*Id.*

¹²⁰Bert Black & Patrick W. Lee, *Guide to Epidemiology in Statistics*, in EXPERT EVIDENCE, A PRACTITIONER'S GUIDE 77-78 (West Group 1997).

In all medical fields only well controlled clinical trials truly measure the value of new treatment modalities.¹²¹ Clinical trials are medical experiments designed to reach scientific conclusions.¹²² However, the validity of the inferences drawn from clinical studies depends on the scientific model. Statisticians recognize three classes of scientific study in a descending order of validity: experiments, quasi-experiments, and observational studies.¹²³ As the research travels down this continuum, the level of uncertainty increases, due to the lack of control over potential variables unaccounted for in the study.¹²⁴

The results of randomized clinical trials presents the best evidence of improvements in the treatment of illness and disease. A randomized clinical trial consists of a treatment group and a control group, in which subjects are randomly selected and assigned to each group.¹²⁵ The control group is not treated. If the two groups have very similar characteristics, a difference in response is probably a result of the treatment.¹²⁶ However, if the treatment group differs from the control group by one or more factors, "the effects of the factors are likely to be "confounded" with the effects of the treatment."¹²⁷ In cancer research, anything less than a randomized, well controlled clinical trial offers a weak basis for causal inferences about effective treatment.¹²⁸

¹²¹See FREEDMAN ET AL., STATISTICS 3, 4-6 (3d ed. 1998). The authors provide an excellent description of a randomized clinical trial involving the effectiveness of the Salk vaccine:

A new drug is introduced. How should an experiment be designed to test its effectiveness? The basic method is *comparison*. The drug is given to subjects in a *treatment group*, but other subjects are used as controls—they are not treated. Then the responses of the two groups are compared. Subjects should be assigned to treatment or control *at random*, and the experiment should be run *double-blind*: Neither the subjects nor the doctors who measure the response should know who was in the treatment group and who was in the control group.

Id. at 3-9.

¹²²See *id.*

¹²³See Stephen E. Fienberg et al., *Understanding and Evaluating Statistical Evidence in Litigation*, 36 JURIMETRICS J. 1 (1995).

¹²⁴See *id.* (elaborating on some of the more common misunderstandings in statistical reasoning).

¹²⁵FREEDMAN ET AL., *supra* note 121, at 1-11.

¹²⁶*Id.* at 11.

¹²⁷*Id.* (emphasis added).

¹²⁸1 VINCENT T. DEVITA ET AL., CANCER: PRINCIPLES AND PRACTICE OF ONCOLOGY 3, at 513 (5th ed. 1997) (quoting B. MACMAHAN & T.F. PUGH, EPIDEMIOLOGY: PRINCIPLES AND METHODS (1970) for the proposition that statistical associations from observational studies are often not dependable).

Only a minority of statistical associations are causal Once a statistical association has been demonstrated, how can it be determined whether or not it is causal The most satisfactory procedure is a direct experiment The evaluation of the causal nature of a rela-

Controlled clinical trials that lack randomization constitute quasi-experiments,¹²⁹ because the investigator controls which subjects receive treatment. Whenever the judgment of the medical investigator enters into the process of patient selection for either the true treatment or control group, the loss of randomization destroys the true experimental status of a clinical trial.¹³⁰ For example, a surgeon selecting patients eligible for a study of a new surgical technique may exclude sicker or older patients. This leads to "confounding," meaning a hidden factor caused the difference seen in patient response to treatment.¹³¹ Surprisingly, a good number of published studies of medical research fit into the category of non-randomized controlled trials.

Observational studies provide the least valid inference between treatment and improvement of patient outcomes. For example, by considering factors common to a group of cancer patients (such as tumor grade, stage, age and sex), a clinician may *retrospectively* compare the survival rate of those patients who underwent cancer radiation treatment and those who underwent chemotherapy.¹³² The list of cancer patients in an observational study may be compiled from a tumor registry or a database tracking patient outcomes.¹³³ Since the investigator did not control which patients received radiation treatment, nor the makeup of patients treated with chemotherapy, the investigator lacked control over confounding factors.

Although randomized clinical trials far outweigh the evidentiary value of observational studies, the former are rarely done because of ethical and practical restrictions.¹³⁴ Consequently, observational studies provide the bulk of articles appearing in medical literature. Statisticians warn that observational studies establish only associations, not causal relationships.¹³⁵ Because

tionship, in the absence of direct experiment, is neither easy nor objective The field of cancer therapy is replete with examples of new modalities that were taken up with enthusiasm and proved worthless only after they had resulted in many years of futile cost and suffering.

Id.

¹²⁹Fienberg et al., *supra* note 123, at 15.

¹³⁰*Id.*

¹³¹FREEDMAN ET AL., *supra* note 121, at 20. Observational studies are the usual vehicle for the study of the causes of cancer. *Id.* However, in terms of contributing to the treatment of future cancer patients, observational studies are poor substitutes for prospective clinical trials. See DEVITA ET AL., *supra* note 128, at 513.

¹³²DEVITA ET AL., *supra* note 128, at 513 (devoting an entire chapter on the design and analysis of clinical trials because randomized clinical trials are the true vehicle of advancing new treatments).

¹³³*Id.* at 231.

¹³⁴*Id.* at 234.

¹³⁵FREEDMAN ET AL., *supra* note 121, at 27. "Observational studies can establish association: one thing is linked to another. Association may point to causation: if exposure causes disease, then people who are exposed should be sicker than similar

scientists respond cautiously to findings reported in observational studies, causal inferences drawn from such studies are controversial. However, a consensus of observational studies reporting similar findings may furnish compelling evidence. For example, the enormous evidence linking tobacco use to lung cancer comes from observational studies dating back to the 1950s.¹³⁶ As the number of observational studies increased, so did the strength of the evidence identifying smoking as a cause of lung cancer.

1. Medical Literature—Publishing Medical Research and Reporting Statistical Significance

This section explores the basic concepts represented by the numerical values which appear in medical and scientific literature.¹³⁷ Statistical calculations affect the physician's evaluation of whether the conclusions contained in medical and scientific research are valid. Like the physician, lawyers and judges concerned about reliability should appreciate that statistical significance does not mean "statistically important." Rather, "significance" signifies a numerical value.¹³⁸ In statistics, mathematical formulas yield precise numerical information that lawyers and judges all too frequently overgeneralize to satisfy burdens of proof.¹³⁹ Because statistical reasoning is often presented in a counter-intuitive manner, the concept of random variation, essential to understanding statistics, eludes most lawyers.

people who are not exposed. But association does not scientifically prove causation." *Id.*

¹³⁶DEVITA ET AL., *supra* note 128, at 158. The authors state that the epidemiological data on smoking and lung cancer meets the criteria for establishing causal association in an observational study, i.e., "the consistency of the results across studies, the strength of the relationship [relative risk ratio], its specificity, the correct temporal sequence between exposure and disease, and the coherence of the association as evidenced by dose-response relation." *Id.* (citation omitted).

¹³⁷I would like to express my gratitude to Professor Panickos Palettas from the Department of Statistics at Ohio State University for his helpful comments on statistical reasoning. Any errors in the translation of statistical concepts are my own.

¹³⁸DAVID S. MOORE & GEORGE P. MCCABE, *INTRODUCTION TO THE PRACTICE OF STATISTICS*, 454 (2d ed. 1993). Notice, the majority in *Joiner* appears to use the term "statistically significant" to mean "statistically important" in discussing the scientific articles supporting the plaintiff's theory of causation. *See Joiner*, 118 S. Ct. at 519.

¹³⁹A warning about the nature of statistical reasoning seems appropriate here. The argument that trial lawyers and judges should understand statistics well enough to reason like statisticians is analogous to asking an English teacher to read the Bill of Rights and then argue a First Amendment case before an appellate court. *See Fienberg et al., supra* note 123, at 18 (offering a discussion on statistical confusion between probability of sample identification and probability of guilt, referred to as "the fallacy of the transposed conditional").

a. P Value

To medical researchers, the design of a clinical trial or study evaluating the benefits of a new treatment carries more weight than statistical significance. Since clinical trials are the principal vehicle of medical research, the medical community demands an assurance that treatment effects reported in a clinical trial were not due to chance.¹⁴⁰ Statisticians use a "test of significance" (a probability value commonly shown as *P-value*) to calculate the possibilities that the treatment result is a chance occurrence.¹⁴¹ Statisticians have universally decided that a significance level limiting a chance occurrence to 5% or less means the results of the study have achieved "statistical significance."¹⁴² For example, a *P-value* of 5% or less ($P \leq .05$) means that patient improvement observed in the study could not happen by chance except in 5 (or less) of 100 similar studies.

Even with a $P \leq .05$, statisticians caution against inferring too much from statistical significance.¹⁴³ This warning is predicated on a reverse logic not easily discernible by non-statisticians.¹⁴⁴ In his introductory text, *Statistics: Concepts and Controversies*, David Moore describes this unusual twist of statistical reasoning:

A statistical test begins by supposing for the sake of argument that the effect we see is *not* present. We then look for evidence against this supposition and in favor of the effect we hope to find. The first step in a test of significance is to state a claim that we will try to find evidence *against* . . . a statement being tested in a test of significance, [it's] called the *null hypothesis*. The test of significance is designed to assess the strength of the evidence against the null hypothesis Usually the null hypothesis is a statement of "no effect" or "no difference."¹⁴⁵

¹⁴⁰DEVITA ET AL., *supra* note 128, at 234.

¹⁴¹FREEDMAN ET AL., *supra* note 121, at 475-502 (discussing the question of "tests of significance" which analyzes the issue of whether observed differences are real or just a chance variation).

¹⁴²*Id.*

¹⁴³David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, in THE REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 331, 380-381 (Federal Judicial Ctr. ed., 1994)

¹⁴⁴See Fienberg et al., *supra* note 123, at 23. See also MOORE & MCCABE, *supra* note 138, at 449 (describing the crucial first step of statistical reasoning). "[W]e ask whether some effect is present. . . . To do this, we begin by supposing for the sake or argument that the effect is not present." *Id.*

¹⁴⁵See DAVID S. MOORE, STATISTICS: CONCEPTS AND CONTROVERSIES, 486 (4th ed. 1997); see FREEDMAN ET AL., *supra* note 121, at 482 (stating that *P-values* are determined by the hypothesis being based on an absurd conclusion then finding evidence against it). "Test of significance" is an argument by contradiction. *Id.* at 482.

$P \leq .05$ does not say that treatment is effective 95% of the time. This numerical expression does mean, however, that the observed treatment effects in the clinical trial were unlikely due to chance.

Keep in mind the admonition of David Kaye and David Friedman: "Statistical significance depends upon the p-value [sic], and the p-value depends upon sample size."¹⁴⁶ A small sample size rarely provides the statistician enough information to draw credible inferences.

b. Confidence Intervals

The business of statistics centers on drawing inferences, i.e., conclusions from samples of a particular population group that accurately apply to the entire group. P-values represent one type of statistical inference; confidence intervals are another. Because sample size affects P-value, some statisticians argue that calculation of *confidence* intervals conveys more useful information:

a statistical device known as a confidence interval permits a more refined assessment of appropriate inferences about the association found in an epidemiology study. The advantage of a confidence interval is that it displays more information than P-values. What a P-value does not provide is the magnitude of the association found in the study or an indication of how numerically stable that association is.¹⁴⁷

A confidence interval estimates a range of the values within which the results of a study would likely fall if the study were repeated numerous times.¹⁴⁸ Thus, a confidence interval of 95% means that if a particular study was repeated twenty times, 19 out of 20 times the results would fall within a specified range.¹⁴⁹ Statisticians usually reserve statistical confidence for levels of 95% or

¹⁴⁶Kaye & Freedman, *supra* note 143, at 384.

¹⁴⁷Bailey et al., *supra* note 118, at 154. Professor Palletas takes issue with the proposition that confidence intervals generate stronger inferences than P-values. In his view, P-values and confidence intervals provide the same information. *Id.* Confidence intervals seem easier to follow because of the direct manner in which the information is presented.

¹⁴⁸Bailey et al., *supra* note 118, at 173.

¹⁴⁹FREEDMAN ET AL., *supra* note 121, at 385. In Professor Moore's introductory text, he periodically provides clear and concise definitions of statistical concepts to help the student stay the course:

A 95% confidence interval is an interval obtained from the sample data by a method that in 95% of all samples will produce an interval that captures the true population parameter.

We call 95% the confidence level. It is the probability that the method gives an interval that captures the true parameter. 95% confidence is short for "I got this result by a method that gives correct results 95% of the time."

Id. See also MOORE, *supra* note 145.

better.¹⁵⁰ Today, whenever statistical methods appear in reports of medical studies, software capabilities also permit confidence interval estimates.

Although confidence intervals plot the results of a clinical trial or medical study, assuming the studies were done a number of times, confidence intervals must be interpreted with caution. A confidence interval says that we got these numbers by a *method* that gives correct results 95% of the time.¹⁵¹ A high confidence level without regard to sample size limits the ability of the statistician to interpret the value of the confidence interval.

c. Relative Risk/Odds Ratio

In epidemiology studies, typically, investigators examine the degree to which the risk of disease increases when individuals are exposed to chemicals, drugs, or other agents. Epidemiologists, for example, calculate the danger of exposure from a certain stimulus in terms of a *relative risk ratio*.¹⁵² Epidemiologists define relative risk as follows:

The ratio of the risk of disease or death among the exposed to the risk among the unexposed. For instance, if 10% of all people exposed to a chemical develop a disease, compared with 5% of people who are not exposed, the disease occurs twice as frequently among the exposed people: The relative risk is $10\%/5\% = 2$. A relative risk of 1 indicates no association.¹⁵³

Considerable conflict arises over the appropriate use of epidemiology studies on the subject of causation.¹⁵⁴ Given the above passage, should courts accept a relative risk of 2.0 (a 50% increase of contracting a disease if exposed) as sufficient proof of causation? The authors of the epidemiology section of *The*

¹⁵⁰See MOORE, *supra* note 145, at 457-482 (assuming that confidence comes with 95% confidence interval).

¹⁵¹*Id.* at 466. See MOORE & MCCABE, *supra* note 138, at 440. Professor Moore states that the purpose of a confidence interval is to estimate an unknown parameter, such as a mean SAT-M score for California students, with an indication of how accurate the estimate is and how confident we are, whether 85% or 95%, that the result is correct. See also MOORE, *supra* note 145.

¹⁵²See Bailey et al., *supra* note 118, at 148 n.64 (citing *Gaul v United States*, 582 F. Supp. 1122, 1125 (N.D. Del. 1984)). Relative risk ratio was defined by the court as "the relationship between the risk of an occurrence, such as contracting a disease, in a population exposed to a certain stimulus, and the risk of the occurrence in a population not exposed to the stimulus." *Gaul*, 582 F. Supp. 1122, 1125. The court later used the example of comparing the likelihood of suffering from stomach cancer when a comparison is made between meat-eaters and vegetarians. *Id.*

¹⁵³Bailey et al., *supra* note 118, at 176.

¹⁵⁴Diana B. Petitti, *Reference Guide on Epidemiology*, 36 JURIMETRICS J. 159-168 (1996). Among her many criticisms, she is most troubled by the *Reference Guide's* apparent endorsement of a finding of a relative risk of greater than 2.0 as sufficient to satisfy plaintiff's burden of proof on causation. *Id.* The author claims that no academic or scientific studies are available to support this statement. *Id.*

Reference Manual on Scientific Evidence state that the threshold for "concluding that an agent was more likely the cause of a disease than not is a *relative risk* rated at 2.0."¹⁵⁵ When experts use a relative risk of 2.0 or greater in the exposed group as the basis for an opinion that the plaintiff's illness was caused by a chemical agent, commentators vehemently argue that proof of individual causation based solely on an epidemiology study exemplifies junk science.¹⁵⁶

In the interest of being thorough, it should be noted that the strength of an association between exposure to a stimulus and disease can be calculated not only by *relative risk* ratio but also an *odds ratio*.¹⁵⁷ The design of the study designates which formula statisticians use. *Relative risk* ratios express the strength of the association between exposure and disease in cohort studies,¹⁵⁸ whereas *odds ratios* describe a similar relationship in case control studies.¹⁵⁹

¹⁵⁵See Bailey et al., *supra* note 118, at 147 (acknowledging that relative risk states the strength of an association between exposure and disease; emphasizing that a high relative risk ratio does not permit one to conclude scientifically that a causal relationship exists).

¹⁵⁶*Id.* The authors footnote a number of cases that have evaluated the role of epidemiology in proving individual causation. *Id.* at 167-170 nn.122-132. In particular, see *DeLuca v. Merrell Dow Pharm., Inc.*, 911 F.2d 941 (3d Cir. 1990) (holding epidemiology studies did not provide direct evidence that a particular plaintiff was injured); *Kehm v. Procter & Gamble Co.*, 580 F. Supp. 890 (N.D. Iowa 1982) (finding epidemiology studies to be probative on the issue of initial causation); *Ellis v. International Playtex, Inc.*, 745 F.2d 292 (4th Cir. 1984) (finding certain epidemiological studies admissible despite criticism toward the studies' methodology); *In re Joint E. & S. Dists. Asbestos Litig.*, 758 F. Supp. 199 (S.D.N.Y. 1991), *rev'd*, 964 F.2d 92 (2d Cir. 1992) (holding that relative risk less than 2.0 may be sufficient to prove causation). See also, Michael Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV. ENVTL. L. REV. 429 (1983); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion and Statistical Evidence*, 96 YALE L.J. 376 (1986); Kenneth S. Abraham & Richard A. Merrill, *Scientific Uncertainty in the Courts*, ISSUES SCI. & TECH. (Winter 1986). See generally DEBORAH G. MAYO & RACHELLE D. HOLLANDER, ACCEPTABLE EVIDENCE: SCIENCE AND VALUES IN RISK MANAGEMENT (Oxford Univ. Press 1991) (exposing the entrance of individual and social values in the collection, interpretation, communication and evaluation of evidence of risk; and showing how individual and social values bear on the acceptability of the evidence of risk in our society).

¹⁵⁷See Bailey et al., *supra* note 118, at 149. The authors describe odds ratio as a comparison of the odds of having a disease when exposed to a suspected agent compared to the odds of getting the same disease with no exposure. *Id.* For example, although many people do not smoke nor are they exposed to secondary smoke, a certain number of people in this group will get lung cancer.

¹⁵⁸See Bailey et al., *supra* note 118, at 134-136. A cohort study is defined as prospective or follow-up study, for example, on the effects of secondary smoke. *Id.* Researchers will identify one group exposed to secondary smoke, and another group that is not. Thereafter they will follow both groups for a specified period of time looking for an increase in illness in the exposed group. *Id.*

¹⁵⁹See Bailey et al., *supra* note 118, at 136. Case-control studies are less expensive and involve less time. Here the researcher might begin with a group of lung cancer patients, then select a group that does not have lung cancer to form the control group. The

Odds ratios work like risk ratios. Researchers compare the odds of getting a disease when exposed to a suspected agent against contracting the disease without exposure.¹⁶⁰ Likewise, inferring individual causation in litigation from an *odds ratio* greater than 2 suffers from the same infirmities that curb the use of the strength of associations calculated by *relative risk* ratios.¹⁶¹

In summary, physicians make medical judgments through a highly disciplined process. Once a physician makes a diagnosis, the treatment plan consists of up-to-date therapies driven primarily by clinical experience and medical research. Publication of medical research serves as one of the main channels for updating physicians on rapidly changing methods of treatment. Physicians usually consider the quality of the science backing a publication; thus, expert witnesses' opinions on diagnosis, causation and damages depends to some degree on information found in medical literature usually never admitted into evidence. Federal as well as Ohio courts routinely examine the medical literature upon which the expert has relied when determining the reliability of a medical expert witness's opinion.¹⁶² On what basis can judges determine the reliability of medical literature relied upon by the expert? We examine this question in the next section.

IV. ASSESSING RELIABLE MEDICAL LITERATURE

A. Comparing Federal Practice to Amended Rule 706 of the Ohio Rules of Evidence

This section addresses the reliability of learned treatises admitted for the limited purpose of impeachment under newly amended Rule 706 of the Ohio Rules of Evidence. Indeed, courts have not only reviewed medical literature in

case-control study is retrospective in nature when the investigators compare each group's past exposure to cigarette smoking.

¹⁶⁰The calculation of odds ratios is similar to relative risk ratios. But the design of a cohort study allows the estimation of risk when comparing groups of exposed versus unexposed individuals. This direct estimation cannot be made in a case-controlled study, therefore researchers use the odds ratio because it approximates relative risk, if the disease under study is uncommon in the population, and all cancers fit the meaning of "uncommon." DEVITA ET AL., *supra* note 128, at 235.

¹⁶¹Epidemiologists consider seven factors when determining whether an association between a stimulus and a condition or illness is causal: (1) the strength of the association; (2) temporal relationship; (3) consistency of the association; (4) biologic plausibility (coherence with existing knowledge); (5) consideration of alternative explanations; (6) specificity of the association; and (7) dose-response relationship. See Bailey et al., *supra* note 118, at 156-170.

¹⁶²See, e.g., Bresson, 554 N.E.2d at 1333 (citing *The New Zealand Medical Journal and The American Journal of Optometry & Physiological Optics* to verify accuracy of test used to determine defendant's driving under the influence); Pierce, 597 N.E.2d at 114-116 (reviewing the scientific literature on the soundness of the calculation of frequency probability in DNA evidence); Nemeth, 694 N.E.2d at 1339 (referencing the *Handbook of Clinical Child Psychology* to determine the reliability of the defense of battered child syndrome).

determining reliability, but specifically noted whether the findings were statistically significant.¹⁶³ Only recently have commentators begun to look at the reliability of opinions expressed in literature that serve as the basis of medical or scientific expert testimony.¹⁶⁴

Under the Federal Rules of Evidence, hearsay opinions contained in medical literature gain entrance to the courtroom through either Rule 703 or Rule 803(18). Rule 703 of the Federal Rules allows a medical expert witness to rely on facts, data or opinions commonly relied upon by physicians when diagnosing and treating patients.¹⁶⁵ Rule 803(18) of the Federal Rules recognizes as an exception to hearsay all "statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art established as reliable authority."¹⁶⁶ Consequently, this Rule acknowledges that specialists who qualify as experts in the courtroom often rely on medical or scientific literature to formulate opinions in their field of expertise. Furthermore, Rule 803 allows this information to be used to impeach an opposing expert's testimony.¹⁶⁷ Both Rule 703 and 803(18) of the Federal Rules of Evidence take into account the expert's daily experience with and exposure to medical and scientific literature, and both permit experts to reach conclusions and opinions in court (just as they do on a daily basis out of court) that would otherwise be inadmissible.

¹⁶³*Joiner*, 118 S. Ct. at 519 (noting whether the epidemiology studies supporting the expert's opinions showed statistically significant increase in lung cancer deaths with exposure to PCBs).

¹⁶⁴See Walsh & Rose, *supra* note 95, at 226 (stating that publications do not become learned treatises by a talismanic pronouncement of a testifying expert and noting that the rules for determining reliable authorities are not clear). See also Robert F. Magill Jr., *Issues Under Federal Rule of Evidence 803(18): The "Learned Treatise" Exception to the Hearsay Rule*, 9 ST. JOHN'S J. LEGAL COMMENT. 49 (1993).

¹⁶⁵*Moore v. Ashland Chem. Inc.*, 126 F.3d 679 (5th Cir. 1997). The court was faced with the testimony of a well-qualified pulmonologist, who testified that the plaintiff's reactive airway disease had been caused by chemicals contained on the defendant's premises. The pulmonologist relied on differential diagnosis and a standard medical text regarding diseases and occupational medicine. The expert's opinion regarding causation was ruled admissible under Federal Rule 703 on the basis that opinions not in evidence, even if inadmissible, may form the basis of an expert's opinion "if reasonably relied upon by experts in the particular field," quoting Michael H. Graham, *Handbook of Federal Evidence*, 109-110 n.18 (4th ed. 1996). *Id.* at 691.

¹⁶⁶FED. R. EVID. 803(18).

¹⁶⁷Rule 803(18) of the Federal Rules of Evidence states the following:

To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert in direct examination . . . statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art established as a reliable authority by the testimony or admission or the witness or by other expert testimony or by judicial notice. If admitted, the statement may be read into evidence but may not be received as an exhibit.

Id. (emphasis added).

Recent developments, however, show Ohio is catching on to the idea that physicians are exposed to reliable data, information, and opinion in the daily practice of medicine. Reacting against an old regime that allowed medical witnesses to theorize in court with impunity for both plaintiffs and defendants,¹⁶⁸ the Ohio Supreme Court amended the Ohio Rules of Evidence to add Rule 706.¹⁶⁹ This Rule codified Ohio's common law rule which restricted the use of learned treatises to impeachment.¹⁷⁰ It also incorporates the essence of Federal Rule 803(18), because it operates to prevent experts - especially physicians and scientists - from offering theories unsupported by prevailing concepts in their particular field. Since the introduction of Rule 706, witnesses may no longer limit the scope of cross-examination with self-serving declarations about a treatise's lack of reliability and authoritative quality. No longer may experts testify in a vacuum and present theoretical concepts tethered to nothing more than personal opinion.

After it was amended, Rule 706 expanded the use of medical literature on two fronts: a court may now take judicial notice of a treatise as "reliable authority,"¹⁷¹ and "[i]f an opposing expert witness refuses to recognize a treatise as reliable, the judge may permit the impeachment, provided counsel subse-

¹⁶⁸*Id.* at 239 (quoting Samuel S. Wilson, *Medical Treatises as Evidence—Helpful but Strictly Limited*, 29 U. CIN. L. REV. 255, 260 (1960). "The Ohio Supreme Court placed 'a premium on medical illiteracy. The less the witness ha[d] read, the less vulnerable [he was] to effective cross-examination.'" *Id.*

¹⁶⁹In 1980, when the Ohio Rules of Evidence were adopted, Ohio refused to emulate or adopt Federal Rule 803(18). OHIO R. EVID. 706 staff note. Consequently, Ohio does not grant to learned treatises an explicit exception to the hearsay rule. Rule 102 of the Ohio Rules remains the controlling authority. See OHIO R. EVID. 706 staff note. Rule 706 states in relevant part:

Learned Treatises for Impeachment. Statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art are admissible for impeachment if the publication is either of the following:

- (A) relied upon by an expert witness in reaching an opinion;
- (B) established as reliable authority (1) by the testimony or admission of the witness, (2) by other expert testimony, or (3) by judicial notice.

If admitted for impeachment, the statements may be read into evidence but may not be received as exhibits.

OHIO EVID. R. 706. See also OHIO R. EVID. 706 staff note.

¹⁷⁰OHIO EVID. R. 706 staff note. The new amendment to Rule 706 adopts *Hallworth v. Republic Steel Corp.*, 91 N.E.2d 690 (Ohio 1950), which permitted the use of treatises if "recognized as standard authorities," although not relied upon by an expert. *Hallworth*, 91 N.E.2d at 690 (syllabus & 2). The staff note to Rule 706 also points out that Rule 706 leaves undisturbed *Stinson v. England*, 633 N.E.2d 532 (Ohio 1994). *Stinson* held that the substance of a treatise may be employed only to impeach the credibility of an expert who has relied upon the treatise or acknowledged its authoritative nature. *Stinson*, 633 N.E.2d at 560.

¹⁷¹See OHIO EVID. R. 706 (B)(3)

quently lays the foundation through its own expert."¹⁷² Finally, the staff note explicitly states that the trial court determines under Rule 104(A) whether the treatise is a reliable authority.¹⁷³ Thus, Rule 706 is a step in the right direction, as it implicitly accounts for the physician's routine practice of relying on data, information, and expert opinion in the daily management of patients.

Despite its welcome arrival, Rule 706 of the Ohio Rules of Evidence may give Ohio judges cause for concern, because it fails to address a significant problem: expert witnesses in Ohio often rely on medical literature not necessarily established as "reliable authority." Note that Federal Rule 703 permits experts to rely on facts or data not admitted into evidence "if of a type reasonably relied upon by experts in a particular field in forming opinions or inferences upon the subject."¹⁷⁴ Under this "reasonable reliance" test, federal courts have excluded opinions based on information that other experts in the field would not find reliable.¹⁷⁵ The Ohio Rules provide no such test. Consequently a problem emerges: a physician testifying in an Ohio court may rely on literature that has not been established as reliable authority; while, under Rule 706, a lawyer cross-examining that same expert is restricted to impeaching the expert with literature established as "reliable authority."¹⁷⁶ Despite its safeguards,¹⁷⁷ Rule 706 does not empower an Ohio court to prevent an expert from relying on medical or scientific literature of questionable reliability.

B. Medical Literature—Determining the Standard of "Reliable Authority"

In Ohio, there is no clear means of establishing whether medical or scientific literature meets a standard of a reliable authority. This article, however, offers some considerations. First, reliability requires proof of trustworthiness.¹⁷⁸ Prior to *Daubert*, trustworthiness was known by the general acceptance of the piece and/or the absence of personal bias. Federal case law prior to *Daubert* looked to the general acceptance of the treatise as authoritative or the prestige of the author to gauge its admissibility and trustworthiness.¹⁷⁹ In *O'Brien v.*

¹⁷²See OHIO EVID. R. 706 staff note.

¹⁷³See *id.*

¹⁷⁴FED. R. EVID. 703.

¹⁷⁵See *Reference Manual supra* note 2.

¹⁷⁶OHIO R. EVID. 706 (B).

¹⁷⁷See OHIO R. EVID. 706 staff note.

¹⁷⁸See, e.g., *Ward v. United States*, 838 F.2d 182 (6th Cir. 1988).

¹⁷⁹Magill, *supra* note 164, at 58-65. The author catalogs several cases analyzing Dean Wigmore's "mark of trustworthiness," for e.g., *Burgess v. Premier Corp*, 727 F.2d 826 (9th Cir. 1984) (an authoritative text means one generally accepted within the industry); and *Allen v. Safeco Ins. Co.*, 782 F.2d 1517 (11th Cir. 1986) (author's prominence in the field supported by his connection with prestigious forensic science department).

Angley,¹⁸⁰ the Ohio Supreme Court declined to find an editorial from *The Journal of the American Medical Association* authoritative because the article demonstrated personal bias and prejudice toward litigation, thus undermining the logic of the learned treatise exception.¹⁸¹

In the post-*Daubert* review of medical literature, the courts question not only an article's reliability, but the expert's use of literature to support his or her opinions.¹⁸² Consequently, medical or scientific literature ought to exhibit evidence of trustworthiness as demonstrated by the author; or it should at least reflect the academic trappings of an authoritative exposition by a leader in a particular field. In courtrooms where *Daubert* controls admissibility, the use of medical literature to form conclusions not drawn in the literature itself violates the dictates of the scientific method.¹⁸³

C. Factors Establishing the Reliability of Medical or Scientific Literature

Trial judges deciding whether medical or scientific literature meets the test of a "reliable authority" should consider more than the expert's thoughts on the article. Consequently, this article presents five factors which may aid a trial judge in determining the reliability of medical or scientific literature.¹⁸⁴ They are: 1) whether the literature is authored by preeminent experts, raising a strong inference of reliability; 2) whether the literature is a textbook or a single arti-

¹⁸⁰See *O'Brien v. Angley*, 407 N.E.2d 490 (Ohio 1980).

¹⁸¹*Id.* The *O'Brien* court's primary justification for admitting such evidence as a limited exception to the hearsay rule was that learned treatises are inherently more trustworthy than customary forms of hearsay. "A powerful incentive exists to publish a work which will be accepted by the other members of the author's profession as a fundamentally sound and authoritative exposition of the subject." *Id.* at 494.

¹⁸²See, e.g., authorities cited *infra* note 184.

¹⁸³*Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779 (D.N.J. 1996) (asserting that reliance upon medical literature for conclusions not drawn therein departs from accepted scientific methodology).

¹⁸⁴Although these factors are considered by medical and scientific professionals when they review medical and scientific literature, the same factors have also been considered by trial and appellate courts when evaluating the credibility of witness testimony, observations, or conclusions. See, e.g., *Glauser-Nagy v. Medical Mut. of Ohio*, 987 F. Supp. 1002, 1007-09 (N.D. Ohio 1997) (considering the results of randomized controlled clinical studies of breast cancer); *Williams v. Hedican*, 561 N.W.2d 817, 826-28 (Iowa 1997) (recognizing the importance of peer review); *McCrary v. State*, 423 N.E.2d 156, 158 (Ohio 1981) (noting the expert's reputation as a leading expert, an individual published in prestigious medical journals); *McDaniel v. CSX Transp. Inc.*, 955 S.W.2d 257 (Tenn. 1997) (noting that the expert's studies had been reviewed, reconstructed, and published in leading journals in the field; subjected to peer review; and recognized by medical textbooks and journals); *Hand v. Norfolk Southern Ry. Co.*, No. 03A01-9704-CV-00123, 1998 WL 281946 (Tenn. App. 1998) (noting that the doctor's diagnosis was recognized in medical textbooks and journals as well as by several national and world health organizations).

cle;¹⁸⁵ 3) whether the publication or study was produced by a prestigious medical institution, thus imparting credence to the results and conclusions within the article; 4) whether the medical journal itself is granted considerable respect in the medical or scientific community;¹⁸⁶ and 5) whether the publication involves randomized controlled clinical studies with a large population base for both control and test groups.¹⁸⁷ No single factor should decide whether the text or literature is reliable. Rather, the court should balance all of these factors against the testimony and opinion of the witness to determine whether the literature is reliable.

In comparison to Federal Rule 703, Ohio's newly amended Rule 706 only partially enables a jury to compare an expert's conclusions against the state of the art in medicine or science. Although the relevance/reliability standard and Rule 706 together will rarely bar unsound expert testimony from the courtroom, at a minimum, opposing counsel may effectively undermine the expert witness by exposing the lack of reliable medical literature supporting the expert's opinions.

V. CONCLUSION

Long before the Supreme Court decided *Daubert*, *Joiner*, and *Kumho*, lawyers recognized that litigation was driven by expert witnesses. In fact, the availability of and demand for experts has produced a growing industry of professional experts. The abuse of expert witnesses takes an immeasurable toll on the efficiency of the judicial process. Intellectually dishonest experts engaged by the plaintiff and defense bar, taken together, exact an enormous tax on litigation. Experts not only increase the number of cases in the legal system, but they can raise the ante of litigation to a cost-prohibitive level.

The concept of reliable medical and scientific evidence must be applied to both plaintiff and defense experts to achieve any success in curbing the abusive expert. The relevance/reliability approach will admit all medical expert testimony except for the rare physician whose conclusions are based on personal opinion unsupported by clinical methodology, medical literature, or professional experience. Thus, relying on Rule 706 of the Ohio Rules of Evidence, lawyers may introduce reliable literature, to expose antiquated or

¹⁸⁵Textbooks are general in scope, educational in nature, and often replete with generally recognized approaches to diagnosis and treatment. Medical literature however is specific and conveys new and more precise information often supported by statistical analysis.

¹⁸⁶*The New England Journal of Medicine*, for example, is widely known to maintain very high standards of peer review.

¹⁸⁷Randomized controlled clinical studies generate inferences significantly stronger than case-control or cohort studies. "Evidence-based medicine trains [doctors] to search medical databases and journals for randomized controlled trials of treatments that have helped patients with similar conditions to those of their own patients, statistically assuring that a treatment that works for a controlled group is likely to be successful with an individual patient." 15 MED. MALPRACTICE L. & STRATEGY 3, at 10 (Jan. 1998).

discredited medical theories. Clearly the relevance/reliability approach is well-suited to deal with all types of experts; and the freer use of literature in the courtroom depletes the credibility of expert testimony unsupported by good science or the sound practice of clinical medicine.