

**SCANNING THE EVIDENCE:
THE EVIDENTIARY ADMISSIBILITY OF
EXPERT WITNESS TESTIMONY ON MRI
BRAIN SCANS IN CIVIL CASES IN THE
POST-DAUBERT ERA**

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Introduction	480	R
I. Overview of MRI Technology, Evidentiary Requirements, and Evidentiary Challenges Facing Other Developing Scientific Technologies	484	R
A. MRI Technology	484	R
B. Evidentiary Requirements for Expert Witness Testimony	486	R
II. Case Survey of the Evidentiary Admissibility of Expert Testimony on MRI Brain Scans	490	R
A. Research Methodology and Scope	490	R
B. Overview of the Ten Exemplar Cases	492	R
C. Examples of How Civil Courts Evaluate the Qualifications, Relevance, and Reliability of Expert Testimony on MRI Brain Scans	494	R
1. The Qualifications of the Expert Witness	495	R
2. The Relevance of the Expert Testimony	498	R
3. The Reliability of the Expert Testimony	499	R
i. The First Approach: A Factor-Based Analysis of Daubert Reliability	500	R
a. Daubert Factor One: Testability	501	R
b. Daubert Factor Two: Peer Review and Publication	503	R
c. Daubert Factor Three: Known or Potential Error Rate	506	R
d. Daubert Factor Four: General Acceptance	508	R
ii. The Second Approach: A Totality-Based Analysis of Daubert Reliability	511	R

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iii.	The Third Approach: A Rule-702-Based Analysis of Reliability	515	R
a.	First Version: A Rule-702-Based Analysis of Reliability That Applies the Rule 702 Criteria	515	R
b.	Second Version: A Rule-702-Based Analysis of Reliability That Applies the Daubert Principles	516	R
III.	Evaluation of the Court’s Approaches to Assessing the Evidentiary Admissibility of Expert Testimony on MRI Brain Scans	517	R
A.	Observations on How the Case Examples Fared Under the Existing Admissibility Approaches	518	R
1.	The Qualifications of the Expert Witness	518	R
2.	The Relevance of the Expert Testimony	519	R
3.	The Reliability of the Expert Testimony	520	R
i.	The Factors-Based Daubert Approach	521	R
ii.	The Totality-Based Daubert Approach ...	522	R
iii.	The Rule 702 Approach	524	R
B.	Fundamental Problems of Blurring Categorical Analyses Under the Existing Approaches	524	R
C.	Proposal to Reduce Unpredictability Under the Existing Framework: Encourage Courts to Issue Expert Witness Instructions to Guide the Litigating Parties and Expert Witnesses in Advance	528	R
Conclusion	535	R

INTRODUCTION

Neuroscience is in the middle of a revolution, and scientific knowledge of how the human brain develops, functions, and reacts is increasing every day.¹ We know “almost infinitely more” about how the brain works today than we did thirty years ago, and yet we know “almost nothing” in comparison to what the field of neuroscience will likely know in thirty years.² Scientific and technological advances have immeasurably increased our ability to observe the brain’s neurological function and mental processing.³ The domi-

1. Henry T. Greely & Anthony D. Wagner, *Reference Guide on Neuroscience*, in FED. JUDICIAL CTR., REFERENCE MANUAL FOR SCIENTIFIC EVIDENCE 747, 749 (3rd ed. 2011); Henry T. Greely, *Law and the Revolution in Neuroscience: An Early Look at the Field*, 42 AKRON L. REV. 687, 688 (2009).

2. Greely & Wagner, *supra* note 1, at 749; Greely, *supra* note 1, at 687.

3. Greely & Wagner, *supra* note 1, at 749; Greely, *supra* note 1, at 687.

nant type of neuroimaging technology is magnetic resonance imaging (MRI), which is used to produce detailed visualizations of the brain's structure and to compare aspects of brain activity.⁴

In the wake of these neuroscience developments, courtrooms across the country have started seeing neuroimaging evidence in the form of MRI scans of head injuries and brain activity used in all types of criminal⁵ and civil⁶ litigation. The growing use of MRI brain scans in litigation has been widely discussed in the academic literature. Many legal scholars have written extensively about MRI-based neuroimaging and the practical,⁷ constitutional,⁸ and legisla-

4. Greely & Wagner, *supra* note 1, at 766.

5. *See, e.g.*, United States v. Semrau, 693 F.3d 510 (6th Cir. 2012) (lie detection in a healthcare fraud case); *Silvis v. Cal. Dep't of Corr.*, No. 1:07-cv-00332-LJO-GSA-PC, 2011 WL 766130 (E.D. Cal. Feb. 25, 2011) (constitutionally required medical treatment for detainees); *Holland v. State*, 705 So. 2d 307 (Miss. 1997) (death penalty sentencing); *Kelley v. State*, 187 S.W.3d 761 (Tex. App. 2006) (shaken baby syndrome).

6. *See, e.g.*, *Cox v. Standard Ins. Co.*, 585 F.3d 295 (6th Cir. 2009) (disability benefits); *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968 (8th Cir. 1995) (manganese exposure); *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621 (N.D. Ind. June 20, 2011) (automobile accident); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-cv-17000, 2010 WL 7699456 (N.D. Ohio June 4, 2010) (products liability); *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743 (D.N.M. Mar. 23, 2009) (carbon monoxide exposure); *Dunford v. Rolly Marine Serv. Co.*, 233 F.R.D. 635 (S.D. Fla. 2005) (medical conditions that preclude the taking of depositions); *Huber v. JLG Indus., Inc.*, 344 F. Supp. 2d 769 (D. Mass. 2003) (products liability); *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003) (products liability); *Carlen v. Minn. Comp. Epilepsy Program, P.A.*, No. 00-cv-39, 2001 WL 1078633 (D. Minn. Apr. 18, 2001) (medical malpractice); *Lennon v. Norfolk & W. Ry. Co.*, 123 F. Supp. 2d 1143 (N.D. Ind. 2000) (workplace injury); *Jarvis v. Sec'y of the Dep't of Health & Human Servs.*, 99 Fed. Cl. 47 (Fed. Cl. 2011) (vaccine injury compensation); *Lugo v. N.Y.C. Health & Hosps. Corp.*, 929 N.Y.S.2d 264 (App. Div. 2011) (medical malpractice); *Wilson v. Corestaff Servs. L.P.*, 900 N.Y.S.2d 639 (Sup. Ct. 2010) (lie detection in a workplace harassment case); *Crisp v. SouthCo., Inc.*, 738 S.E.2d 835 (S.C. 2013) (workers' compensation); *In re Estate of Leath*, 294 S.W.3d 571 (Tenn. Ct. App. 2008) (mental requirements for revoking wills).

7. *See, e.g.*, Greely, *supra* note 1 (exploring the practical applications of neuroimaging and MRI scans to criminal and civil cases).

8. *See, e.g.*, Nita A. Farahany, *Incriminating Thoughts*, 64 STAN. L. REV. 351 (2012) (Fifth Amendment); Nita A. Farahany, *Searching Secrets*, 160 U. PA. L. REV. 1239 (2012) (Fourth Amendment); Greely, *supra* note 1, at 697 (Sixth Amendment); Aaron J. Hurd, *Reaching Past Fingertips with Forensic Neuroimaging-Non-“Testimonial” Evidence Exceeding the Fifth Amendment’s Grasp*, 58 LOY. L. REV. 213, 215 (2012) (Fifth Amendment); Andrew Taslitz, *Police Are People Too: Cognitive Obstacles to, and Opportunities for, Police Getting the Individualized Suspicion Judgment Right*, 8 OHIO ST. J. CRIM. L. 7 (2010) (Fourth Amendment).

tive policy⁹ implications for litigation and legal practice. In addition several articles have discussed the evidentiary uses of MRI brain scans as interrogation techniques¹⁰ and lie detection tools,¹¹ forensic evidence,¹² evidence of mental state¹³ and culpability,¹⁴ and evidence of mitigating factors during sentencing.¹⁵

9. See, e.g., Henry T. Greely & Judy Illes, *Neuroscience-Based Lie Detection: The Urgent Need for Regulation*, 33 AM. J.L. & MED. 377, 405 (2007) (emphasizing the need to federally regulate fMRI-based lie detection); Francis X. Shen, *Neuroscience, Mental Privacy, and the Law*, 36 HARV. J.L. & PUB. POL'Y 653, 713 (2013) (proposing that law and policy should "certainly be concerned about the government tracking our minds, but [it] should be most concerned about government carrying out that tracking by observing and inferring mental states from our behavior, not our brains").

10. Jonathan H. Marks, *Interrogational Neuroimaging in Counterterrorism: A "No-Brainier" or a Human Rights Hazard?*, 33 AM. J.L. & MED. 483 (2007).

11. E.g., Joseph H. Basking et al., *Is a Picture Worth a Thousand Words? Neuroimaging in the Courtroom*, 33 AM. J.L. & MED. 239, 265–66 (2007); Spencer J. Brooks, *Scanning the Horizon: The Past, Present, and Future of Neuroimaging for Lie Detection in Court*, 51 U. LOUISVILLE L. REV. 353 (2013); Eric K. Gerard, *Waiting in the Wings? The Admissibility of Neuroimaging for Lie Detection*, 27 DEV. MENTAL HEALTH L. 1 (2008); Greely & Illes, *supra* note 9; Leo Kittay, *Admissibility of fMRI Lie Detection: The Cultural Bias Against "Mind Reading" Devices*, 72 BROOK. L. REV. 1351 (2007); John B. Meixner, *Liar, Liar, Jury's the Trier? The Future of Neuroscience-Based Credibility Assessment in the Court*, 106 NW. U. L. REV. 1451 (2012); Joelle Anne Moreno, *The Future of Neuroimaged Lie Detection and the Law*, 42 AKRON L. REV. 717 (2009); Michael S. Pardo, *Neuroscience Evidence, Legal Culture, and Criminal Procedure*, 33 AM. J. CRIM. L. 301 (2006); Lawrence R. Tancredi & Jonathan D. Brodie, *The Brain and Behavior: Limitations in the Legal Use of Functional Magnetic Resonance Imaging*, 33 AM. J.L. & MED. 271 (2007); Kristen Gartman Rogers & Alan DuBois, *The Present and Future Impact of Neuroscience Evidence on Criminal Law*, THE CHAMPION, Apr. 2009, at 19–21.

12. Erin Murphy, *Inferences, Arguments, and Second Generation Forensic Evidence*, 59 HASTINGS L.J. 1047 (2008); Erin Murphy, *The New Forensics: Criminal Justice, False Certainty, and the Second Generation of Scientific Evidence*, 95 CALIF. L. REV. 721 (2007); Adam Teitcher, *Weaving Functional Brain Imaging into the Tapestry of Evidence: A Case for Functional Neuroimaging in Federal Criminal Courts*, 80 FORDHAM L. REV. 355 (2011).

13. Basking et al., *supra* note 11; Teneille Brown & Emily Murphy, *Through a Scanner Darkly: Functional Neuroimaging as Evidence of a Criminal Defendant's Past Mental States*, 62 STAN. L. REV. 1119 (2010); Rogers & DuBois, *supra* note 11, at 21–22.

14. Laura Stephens Khoshbin & Shahram Khoshbin, *Imaging the Mind, Minding the Image: An Historical Introduction to Brain Imaging and the Law*, 33 AM. J.L. & MED. 171 (2007); Deborah W. Denno, *Changing Law's Mind: How Neuroscience Can Help Us Punish Criminals More Fairly and Effectively*, (Fordham Law Legal Studies, Research Paper No. 1909958, 2011), available at <http://ssrn.com/?abstract=1909958>.

15. John H. Blume & Emily C. Paavola, *Life, Death, and Neuroimaging: The Advantages and Disadvantages of the Defense's Use of Neuroimages in Capital Cases—Lessons from the Front*, 62 MERCER L. REV. 909, 924–25 (2011).

MRI brain scans can be difficult for juries to read or understand, so litigants who want to use MRI brain scans at trial frequently use expert witness testimony to help the jury understand and interpret the scans. Expert witness testimony interpreting MRI brain scans must satisfy the same requirements of evidentiary admissibility that apply to all types of expert witness testimony. However, no publication has yet conducted a comprehensive survey and analysis of the case law on brain MRI expert testimony or evaluated whether the traditional framework for evidentiary admissibility sufficiently accommodates expert testimony on this revolutionary neuroimaging technology.¹⁶

This Note has two primary purposes. It reviews the case law in which recent courts have evaluated the evidentiary admissibility of expert witness testimony on MRI brain scans in order to: (1) help litigating parties and presiding courts recognize and navigate commonly disputed admissibility issues facing such evidence; and (2) categorize and evaluate the courts' approaches to these admissibility issues. While the ultimate admissibility of expert testimony on MRI brain scans may—like the admissibility of all evidence—additionally depend on non-evidentiary concerns such as statutory con-

16. A handful of articles from the early 2000s studied how federal and state courts addressed *Daubert* issues arising from criminal or civil litigation challenging expert witness testimony in general. But none of these articles focused specifically on expert witness testimony on MRI brain scans, and none of them examined court decisions issued after 1999. Molly Treadway Johnson, Carol Krafka & Joe S. Cecil, *Expert Testimony in Federal Civil Trials* (Federal Judicial Center, 2000), in *NEW DIRECTIONS IN EXPERT TESTIMONY: SCIENTIFIC, TECHNICAL, AND OTHER SPECIALIZED KNOWLEDGE EVIDENCE IN FEDERAL AND STATE COURTS 1* (ALI-ABA Course of Study Materials, Apr. 26–28, 2001) (questionnaire-based survey of federal district court judges in 1998 regarding their personal experiences with expert testimony in civil cases that progressed to trial); Lloyd Dixon & Brian Gill, *Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision*, 8 *PSYCHOL. PUB. POL'Y & L.* 251 (2002) (case survey that analyzed federal district court opinions issued between 1980 and 1999 in order to examine how litigating parties and presiding judges in civil cases handled expert testimony immediately before and after the 1993 *Daubert* decision); Sophia I. Gatowski et al. *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-Daubert World*, 25 *LAW & HUM. BEHAV.* 433 (2001) (questionnaire-based survey of state court judges in 1998 regarding their opinions about their utility and application of the *Daubert* criteria); Jennifer L. Groscup et al., *The Effects of Daubert on the Admissibility of Expert Testimony in State and Federal Criminal Cases*, 8 *PSYCHOL. PUB. POL'Y & L.* 339 (2002) (case survey that assessed federal and state appellate opinions issued between 1988 and 1998, in order to track changes in how criminal appellate courts used the *Frye* general acceptance criterion, the *Daubert* criteria, and the Federal Rules of Evidence over time).

struction and constitutional interpretation, the scope of this Note is limited to issues raised by the rules of evidence.

Part I provides background information on MRI technology and on the evidentiary requirements that all expert testimony must satisfy in order to be admissible. Part II describes this Note's case survey and research methodology and analyzes ten exemplar cases in light of the evidentiary requirements described in Part I. Part II also identifies the approaches that civil courts have recently used to evaluate the reliability of MRI expert testimony, such as: (1) the factor-based *Daubert* approach, (2) the totality-based *Daubert* approach, and (3) the Rule-702-based approach. Part III discusses the analytical and fundamental challenges to understanding how courts perceive and implement the evidentiary requirements in practice and suggests that the existing framework generates unpredictability in theoretical cohesion and practical application. To address this source of unpredictability, Part III proposes that courts issue "Expert Witness Instructions" to provide guidance to the parties on how they intend to assess the qualifications, relevance, and reliability of the expert testimony. This reform will encourage courts to decide on an admissibility approach before reviewing the case-specific testimony and increase the transparency and predictability of the entire admissibility process—for MRI brain expert witness testimony in particular and for all expert witness testimony in general.

I.

OVERVIEW OF MRI TECHNOLOGY, EVIDENTIARY REQUIREMENTS, AND EVIDENTIARY CHALLENGES FACING OTHER DEVELOPING SCIENTIFIC TECHNOLOGIES

A. *MRI Technology*

Before delving into the legal analysis, it is helpful to first review the MRI technology underlying the expert witness testimony featured in this Note. MRI scans are divided into two categories: structural MRIs, which include traditional MRIs and diffusion tensor imaging (DTI), and functional MRIs (fMRIs).

In structural MRI scanning, an MRI machine creates detailed images of a person's brain anatomy by measuring magnetic changes in the hydrogen protons found in a person's brain tissue.¹⁷ A hydrogen proton is a charged particle in the atomic nucleus that spins on its axis like a small bar magnet.¹⁸ Under normal circumstances,

17. Abi Berger, *How Does It Work? Magnetic Resonance Imaging*, 324 BRIT. MED. J. 35 (2002).

18. *Id.*

these hydrogen protons spin in the body tissue like magnets with randomly aligned axes.¹⁹ An MRI scanner is essentially a very large and very strong magnet.²⁰ When a person lies inside a cylindrical MRI machine, the axes of the hydrogen protons in her brain and body align themselves uniformly along the axis of the MRI scanner.²¹ The machine adds additional energy to the magnetic field by emitting short pulses of harmless radio waves, which disrupt the uniform alignment of the hydrogen protons in the brain tissue.²² When the machine switches off the source of radio wave energy the hydrogen protons return to their resting state and realign into their previous orientations, releasing a small amount of energy in the process.²³ The strength of the energy signal released by the protons depends in part on the relative density of hydrogen protons in the brain tissue, which in turn depends on the relative density of water in the brain tissue.²⁴ The MRI machine detects the released energy and plots the intensity of the signal into high-resolution, cross-sectional images of the brain.²⁵

Structural MRIs are used to examine the brain's anatomical structures, identify any abnormal growth patterns, and track brain development without invasive neurosurgery.²⁶ Structural MRIs can also be used in conjunction with DTI technology to trace the long-distance connections between neuronal cells in different parts of the brain by distinguishing the differential patterns of water diffusion through neuronal gray matter from neuronal white matter.²⁷ Functional MRI scans, by contrast, produce images of brain activity by using MRI technology to detect changes in blood flow.²⁸ When the brain actively performs a task or reacts to a stimulus it activates brain tissue that needs newly oxygenated blood.²⁹ Functional MRI scans measure the blood-oxygen-level dependent (BOLD) response changes in order to generate an image, which can be used to infer

19. *Id.*

20. *Id.*

21. *Id.*; Kittay, *supra* note 11, at 1357.

22. Berger, *supra* note 17, at 35; Kittay, *supra* note 11, at 1357.

23. Berger, *supra* note 17, at 35; Greely & Wagner, *supra* note 1, at 766–68; Kittay, *supra* note 11, at 1357; Tancredi & Brodie, *supra* note 11, at 274.

24. Greely & Wagner, *supra* note 1, at 766–68.

25. Berger, *supra* note 17.

26. Greely & Wagner, *supra* note 1, at 768.

27. *Id.* Gray matter is comprised of signal-processing neuronal bodies, and white matter is comprised of signal-transmitting neuronal axons. *Id.*

28. Kittay, *supra* note 11, at 1358–59.

29. Greely & Wagner, *supra* note 1, at 768.

activity patterns in the brain.³⁰ As a result, parties who want a static image of the brain's anatomical structures should use structural MRI scans, while parties who want a change-over-time visualization of the brain's activity patterns should consider functional MRI scans.

However, despite the fact that MRI technology was developed in the 1970s and used widely in the 1980s, the neuroimaging techniques and body of research are still relatively new and subject to "many questions and controversies."³¹ Litigants who want expert witnesses to interpret MRI evidence at trial must persuade the court that the expert testimony meets all of the requirements for evidentiary admissibility, which are discussed in the next section.

B. Evidentiary Requirements for Expert Witness Testimony

Under the prevailing evidentiary doctrine, in order for expert witness testimony to be admissible, the expert must be qualified to give her opinion on the subject and her testimony must be supported by relevant and reliable theories and techniques.³² The U.S. Supreme Court has charged federal trial courts with the gatekeeper role of excluding unqualified, irrelevant, and unreliable expert testimony before trial.³³ To understand the evidentiary objective behind these requirements, it is helpful to discuss the history and development of the *Frye* test, the *Daubert* factors, and Rule 702 of the Federal Rules of Evidence.

In 1923, the *Frye* test emerged as the predominant standard for evaluating the admissibility of expert testimony.³⁴ In *Frye v. United States*,³⁵ the D.C. Circuit ruled that scientific expert testimony is only admissible if it is based on a method "sufficiently established to have gained general acceptance in the particular field in which it belongs."³⁶ This requirement is often referred to as "the *Frye* test" or the "general acceptance test."³⁷

30. *Id.* at 768–70.

31. *Id.* at 766, 772.

32. David L. Faigman, *Admissibility of Neuroscientific Expert Testimony*, in A PRIMER ON CRIMINAL LAW AND NEUROSCIENCE 89, 92 (Stephen J. Morse & Adina L. Roskies eds. 2013).

33. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

34. Groscup et al., *supra* note 16, at 340.

35. 293 F. 1013 (D.C. Cir. 1923), *superseded by rule*, FED. R. EVID. 702, *as recognized in* *Daubert*, 509 U.S. at 597.

36. *Id.* at 1014.

37. *Daubert*, 509 U.S. at 586; Faigman, *supra* note 32, at 96.

In 1976 the adoption of the Federal Rules of Evidence set forth a new standard for assessing the admissibility of expert testimony.³⁸ At the time, Rule 702 stated that “[i]f scientific, technical, or other specialized knowledge [would] assist the trier of fact to understand the evidence or to determine a fact in issue,” then “a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.”³⁹ Nothing in the text of the rule or Advisory Committee notes specified that Rule 702 should replace the *Frye* test as the standard for expert testimony.⁴⁰

In 1993 the Supreme Court’s decision in the landmark case of *Daubert v. Merrell Dow Pharmaceuticals*⁴¹ completely transformed how courts approached the evidentiary admissibility of expert testimony. In *Daubert*, the Court held that Rule 702 displaced the *Frye* test and required admissible expert testimony to be both “relevant” and “reliable.”⁴² To be “relevant,” expert testimony must be based on “reasoning or methodology” that could be “properly . . . applied to the facts in issue,” and to be “reliable,” testimony must be based on “reasoning or methodology” that was “scientifically valid.”⁴³

The *Daubert* court identified four non-exclusive factors that trial courts could use to guide the reliability analysis.⁴⁴ First, courts could ask whether the theory or technique underlying the expert testimony is testable, falsifiable, or refutable.⁴⁵ Second, courts could assess whether the underlying theory or technique “has been subjected to peer review and publication.”⁴⁶ Publication in a peer-reviewed journal is a relevant but not dispositive consideration because it helps detect any substantive flaws in the underlying methodology but does not inherently correlate with technique reliability.⁴⁷ Third, courts could consider “the known or potential rate of error” and the available standards governing the use of the tech-

38. FED. R. EVID. 702 advisory committee’s note (1976); Groscup et al., *supra* note 16, at 340.

39. Groscup et al., *supra* note 16, at 340.

40. FED. R. EVID. 702 advisory committee’s note (1976); Groscup et al., *supra* note 16, at 340.

41. 509 U.S. at 597.

42. *Id.* at 589, 595.

43. *Id.* at 592–93.

44. *Id.* at 592–94.

45. *Id.* at 593.

46. *Id.*

47. *Daubert*, 509 U.S. at 594.

nique.⁴⁸ Finally, courts could evaluate whether the underlying technique enjoys general or widespread acceptance in the relevant community.⁴⁹ These four *Daubert* factors are often referred to as the “testability (or falsifiability),” “peer review and publication,” “error rate,” and “general acceptance” factors.⁵⁰ However, the *Daubert* court warned that courts should not use the *Daubert* factors to reject or exclude borderline evidence, because “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”⁵¹

The clear purpose of the *Daubert* decision was to relax the traditional and rigid admissibility standards and allow courts greater flexibility in admitting expert testimony,⁵² but there was some skepticism over how the *Daubert* approach would work in practice. Judge Alex Kozinski, the author of the *Daubert* appellate decision that applied the Supreme Court’s new test on remand, wrote that courts faced a “daunting” task because:

[W]e are largely untrained in science and certainly no match for any of the [expert] witnesses whose testimony we are reviewing The task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability. . . . [S]cientists often have vigorous and sincere disagreements as to what research methodology is proper, what should be accepted as sufficient proof for the existence of a “fact,” and whether information derived by a particular method can tell us anything useful about the subject under study. Our responsibility, then, unless we badly misread the Supreme Court’s opinion, is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not “good science,” and occasionally to reject such expert testimony because it was not “derived by the scientific method.”⁵³

48. *Id.* at 594. The Advisory Committee that proposed the 2000 amendments to Rule 702 categorized “the known or potential rate of error” and “the existence and maintenance of standards and controls” as two separate factors. FED. R. EVID. 702 advisory committee’s note to 2000 amendments.

49. *Daubert*, 509 U.S. at 594.

50. Faigman, *supra* note 32, at 102.

51. *Daubert*, 509 U.S. at 596.

52. *Id.* at 588–89.

53. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

Similarly, Justice Stephen Breyer wrote later that *Daubert's* “objective is sometimes difficult to achieve in practice,” because most judges are generalists who “lack the scientific training that might facilitate the evaluation of scientific claims or the evaluation of expert witnesses who make such claims,” while “the decision in a court of law typically (though not always) focuses on a particular event and specific individualized evidence.”⁵⁴

The Supreme Court revisited the *Daubert* factors twice more in the same decade to clarify the appellate review standard, the analytical scope, and the discretionary approach of the new *Daubert* framework. In *General Electric Co. v. Joiner*,⁵⁵ the Court instructed appellate courts to use the “abuse of discretion” standard when reviewing trial court decisions of expert testimony admissibility.⁵⁶ In *Kumho Tire Co. v. Carmichael*,⁵⁷ the Court held that the *Daubert* “gatekeeping” obligation and the Rule 702 inquiry applied to all expert testimony, not just scientific testimony, and that trial courts can discretionarily choose whether to consider some, all, or none of the *Daubert* factors in their reliability analyses.⁵⁸

In 2000, Rule 702 was amended in response to *Daubert*, *Joiner*, and *Kumho Tire*, in order to “affirm[] the trial court’s role as gatekeeper and provide[] some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony.”⁵⁹ Under the current version of Rule 702, “a witness who is qualified as an expert by knowledge, skill, experience, training, or education” can give expert testimony only if it satisfies the following criteria:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.⁶⁰

54. Stephen Breyer, *Introduction to FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 1*, 4 (3rd ed. 2011).

55. 522 U.S. 136 (1997).

56. *Id.* at 139.

57. 526 U.S. 137 (1999).

58. *Id.* at 147–48, 150–51.

59. FED. R. EVID. 702 advisory committee’s note to 2000 amendments.

60. FED. R. EVID. 702(a)–(d).

Although the Rule 702 criteria and the *Daubert* principles bind only federal courts, many states have adopted similar or equivalent approaches through state legislation or case law.⁶¹ A minority of states, including New York and California, still follow traditional or modified versions of the *Frye* approach.⁶²

In sum, courts can only admit expert witness testimony on MRI brain scans if (1) the expert satisfies the qualifications requirement, (2) the testimony fulfills the relevance requirement, and (3) the testimony meets the reliability requirement. The following Part discusses the case survey results and illustrates how civil courts have used the qualifications, relevance, and reliability requirements to assess the evidentiary admissibility of expert testimony on MRI brain scans in the post-*Daubert* era.

II.

CASE SURVEY OF THE EVIDENTIARY ADMISSIBILITY OF EXPERT TESTIMONY ON MRI BRAIN SCANS

A *Research Methodology and Scope*

A survey of the case law indicates that, after the *Daubert* decision in 1993, civil courts have had relatively few opportunities to substantively analyze the admissibility of expert witness testimony on MRI brain scans in written opinions. Specifically, there have only been ten written rulings issued in post-1993 civil cases that substantively address the qualifications, relevance, or reliability requirements of such expert testimony as of early 2015.

These ten exemplar cases were collected and analyzed using the Westlaw and LexisNexis legal research databases.⁶³ The case selection process consisted of searching the Westlaw and LexisNexis databases for key terms such as “neuroscience,” “evidence,” “civil,”

61. For example, the Georgia legislature passed a statute that “applies what in essence is the *Daubert* test in tort cases,” while the Massachusetts Supreme Judicial Court “has adopted *Daubert*, with a twist.” 6 CLIFFORD S. FISHMAN & ANNE T. MCKENNA, *JONES ON EVIDENCE* § 40:15 (7th ed. 2014).

62. *Id.* (suggesting that, as of December 2013, nine states adopted some version of the *Frye* approach and twenty-two states adopted some version of the *Daubert* approach); John W. Parry, *Expert Evidence and Testimony: Daubert Versus Frye*, 28 MENTAL & PHYS. DISABILITY L. REP. 136 (2004) (suggesting that, as of 2004, thirteen states followed some version of the *Frye* approach, twenty states followed some version of the *Daubert* approach, and twelve states followed some version of the Rule 702 approach without formally adopting the *Daubert* standard).

63. There may be other civil cases in which expert testimony on MRI brain scans were at issue, but the scope of the research for this Note only extends to case opinions, court filings, and secondary sources published in these two databases.

“MRI scan,” and “brain scan;”⁶⁴ reviewing each case opinion listed in the search results; and only analyzing the written decisions from civil cases that substantively resolved the admissibility of expert witness testimony on MRI brain scans after 1993. Cases were excluded on the basis of the following criteria: the case was not a civil case, the case did not involve an MRI scan of a person’s head or brain,⁶⁵ the case did not treat evidence of an MRI head scan or MRI brain scan as a central evidentiary issue,⁶⁶ the case failed to mention either the *Daubert* decision or the *Frye* test,⁶⁷ or if the case addressed the admissibility of the MRI brain scans themselves instead of the expert testimony interpreting the MRI brain scans.⁶⁸ The collec-

64. The initial step was to assemble a preliminary list of cases by setting the jurisdiction filters to “all state and federal cases,” setting the date filters to “all dates after 1993,” entering strings of search terms into the search bar, and aggregating all search results into a master list. The first search string was “neuroscience and civil and plaintiff.” The second search string was “‘brain scan’ and civil and plaintiff.” The third search string was “‘MRI scan’ and civil and plaintiff” with results limited to “cases not already viewed.” The fourth search string was “‘MRI scan’ and brain and evidence and civil” with results limited to “cases not already viewed.” The fifth search string was “MRI and head and civil” with results limited to “cases not already viewed.” The sixth and final search string was “MRI and brain and civil” with results limited to “cases not already viewed.” As a last aggregation step, because the “cases not already viewed” search filter only excludes cases viewed within the last thirty days, all search terms were re-processed and all search results were re-compiled again on the last day of compiling the preliminary list to make sure that cases viewed more than thirty days ago were not overlooked.

65. This filter ensured that cases in which the plaintiffs had alleged multiple injuries but had only received MRI scans for the non-head or non-brain injuries were excluded. For example, suppose that a plaintiff had fallen from a forklift, had injured his head and his knee, and had only undergone one set of MRI scans. If the plaintiff had received an MRI scan of his head, then the case remained on the list. If the plaintiff had received an MRI scan of his knee, without receiving an MRI scan of his head, then the case was eliminated in order to restrict the research scope to MRI brain scans.

66. This filter excluded cases that only discussed MRI scans tangentially or in dicta, such as cases in which litigating parties challenged the pricing estimates and medical fees for the MRI scans.

67. The purpose of this filter was to ensure that only case opinions with substantive discussions of expert testimony and evidentiary admissibility remained on the list, because case opinions that disposed of the issue in passing or on non-evidentiary grounds would be less instructive to practicing lawyers. Cases that analyzed the admissibility of expert testimony under the Rule 702 criteria, without expressly acknowledging the *Daubert* factors or the *Frye* test, were eliminated as well.

68. The purpose of this filter was to restrict the research scope to analyzing the expert testimony itself in order to keep the scope of this Note within manageable boundaries.

tion, filtering, and elimination processes ultimately resulted in ten exemplar cases.

B. Overview of the Ten Exemplar Cases

The ten cases discussed in this Note cover a wide variety of legal topics and case law:

*Booth v. KIT, Inc.*⁶⁹ is a carbon monoxide exposure case in which the plaintiffs alleged that a motel's leaking ventilation system exposed them to carbon monoxide and caused them to develop brain injuries.⁷⁰

*Carlen v. Minnesota Comprehensive Epilepsy Program, P.A.*⁷¹ is a medical malpractice wrongful death case in which the decedent's trustee alleged that the defendants provided the decedent with substandard medical care and surgical procedures for a brain tumor that ultimately caused her death.⁷²

*Hose v. Chicago Northwestern Transportation Co.*⁷³ is a manganese exposure case in which a welder filed a Federal Employers Liability Act (FELA) suit against his employer for exposing him to manganese fumes and dust at his workplace.⁷⁴

*Huber v. JLG Industries, Inc.*⁷⁵ is a products liability case, in which the plaintiff sued the manufacturer for head injuries he suffered while operating a "manlift" at his workplace.⁷⁶

69. No. 06-cv-1219, 2009 WL 4544743 (D.N.M. Mar. 23, 2009).

70. *Id.* at *1. This Note focuses on Dr. William Orrison's expert testimony and discusses his qualifications as an expert witness and the reliability of his expert opinion. Specifically the reliability analysis considers the testability, peer review, error rate, and general acceptance of the methodology underlying his expert opinion.

71. No. 00-cv-39, 2001 WL 1078633 (D. Minn. Apr. 18, 2001).

72. *Id.* at *1-3. This Note focuses on Dr. Anthony Hall's expert testimony and discusses the relevance and reliability of his expert opinion. In particular the reliability analysis considers the error rate and general acceptance of the methodology underlying his expert opinion.

73. 70 F.3d 968 (8th Cir. 1995).

74. *Id.* at 971-72. This Note looks at the reliability of Dr. Carol Angle's expert testimony.

75. 344 F. Supp. 2d 769 (D. Mass. 2003).

76. *Id.* at 771. In the construction industry, a "manlift" is "a motorized scaffold characterized by a bucket or platform. Motorized buckets, also known as 'cherry pickers,' can hold up to three people. Motorized platform capacity is limited only by weight." *Manlift*, DICTIONARYOFCONSTRUCTION.COM, <http://www.dictionaryofconstruction.com/?definition/man-lift.html> (last visited Jan. 18, 2014). This Note evaluates the reliability of Dr. Catherine Phillips's testimony.

*Jarvis v. Secretary of the Department of Health & Human Services*⁷⁷ is a vaccine injury case in which the petitioner requested compensation under the National Childhood Vaccine Injury Act, claiming that a hepatitis B vaccination caused her to develop a neurological injury.⁷⁸

*Lennon v. Norfolk & Western Railway Co.*⁷⁹ is an employment injury case in which a railroad worker filed a FELA suit against his employer for injuries that the worker sustained in a workplace accident.⁸⁰

*Lugo v. New York City Health & Hospitals Corp.*⁸¹ is a prenatal medical malpractice case in which the plaintiff claimed that the hospital provided substandard medical care that caused the infant to develop hypoglycemia, brain damage, and cerebral palsy.⁸² *Lugo* is the only state court case discussed in this Note.

*Newman v. Motorola, Inc.*⁸³ is a products liability case in which a cell phone customer alleged that the defendants manufactured and sold him a cell phone that caused him to develop brain cancer.⁸⁴

77. 99 Fed. Cl. 47 (Fed. Cl. 2011).

78. *Id.* at 55. This Note analyzes the reliability of Dr. Carlo Tornatore's expert testimony.

79. 123 F. Supp. 2d 1143 (N.D. Ind. 2000).

80. *Id.* at 1143. This Note assesses the reliability of Dr. David Schreiber's expert testimony.

81. 929 N.Y.S.2d 264 (App. Div. 2011).

82. *Id.* at 44–45. This Note reviews the reliability of Dr. Robert Peyster's expert testimony, specifically with respect to the general acceptance of the methodology underlying his testimony.

83. 218 F. Supp. 2d 769 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003).

84. *Id.* at 769–70. The *Newman* opinion is regarded as the bellwether for how courts address *Daubert* issues in cell phone tort cases. See Douglas Fretty, *Litigating Cell Phone Tort Claims: Science, Preemption, and Causation*, 14 T.M. COOLEY J. PRAC. & CLINICAL L. 151, 186–87 (2012); Allan Kanner & M. Ryan Casey, *Daubert and the Disappearing Jury Trial*, 69 U. PITT. L. REV. 281, 311–12 (2007) (“One of the general features of the mobile-telephone health debate . . . has been the difficulty in achieving standardization of study methodologies and establishing what types of scientific studies should be accorded weight in ascertaining causation . . . [Judge Catherine] Blake's critiques [in *Newman*] of the testing and replication also demonstrate the way post-*Daubert* visions of science, coupled with a tough gatekeeping ethos, can be used to restrict the entry of (novel) scientific claims. . . . Judge Blake, in this case, was engaging in just the sort of amateur scientist antics that [Justice] Rehnquist warned of in his *Daubert* dissent.”); Benjamin J. Wolf, “*Can You Hear Me Now?*”: *Cellular Phones and Mass Tort Litigation After Newman v. Motorola, Inc.*, 14 ALB. L.J. SCI. & TECH. 267, 269 (2003) (“This case gained national headlines because many viewed the decision by the court as a major setback for future plaintiffs who want to bring lawsuits against the cellular phone industry. Specifically, the *Newman* decision is crippling for those plaintiffs who would allege that their cellular phones caused their brain cancer or other health defects.”). This

*Ruppel v. Kucanin*⁸⁵ is an automobile accident case in which the plaintiff claimed that a truck driver drove his trailer rig into the plaintiff's trailer rig and caused him to develop a diffuse axonal brain injury.⁸⁶

*In re Welding Fume Products Liability Litigation*⁸⁷ is a reference document and trial template written by the transferee court presiding over the *Welding Fume* Multi-District Litigation (MDL) for transferor courts that receive subsequent *Welding Fume* cases and that need a summary of the transferee court's pretrial rulings.⁸⁸

C. Examples of How Civil Courts Evaluate the Qualifications, Relevance, and Reliability of Expert Testimony on MRI Brain Scans

The ten exemplar cases collectively provide an instructive guide to the common issues that litigants and judges have faced while challenging and analyzing the evidentiary admissibility of expert witness testimony on MRI brain scans. Part II.(C.)(1) addresses the first stage of the evidentiary admissibility analysis, which asks whether the expert witness is qualified to offer testimony on the contested issue. Part II.(C.)(2) discusses the relevance and "fit" requirement, which is satisfied when the expert testimony is based on methodologies and conclusions that are sufficiently tied to the facts of the case. Part II.(C.)(3) walks through the reliability requirement, which courts faced with MRI brain scans can analyze by using: (1) the *Daubert* framework, through a factors-based approach with express reference to individual *Daubert* factors, (2) the *Daubert* framework, through a totality-based approach without specific reference to individual factors, or (3) the Rule 702 framework, by applying either the Rule 702 statutory criteria or the *Daubert* principles.

Note focuses on Dr. Lennert Hardell's expert testimony and examines his qualifications as an expert witness and the relevance and reliability of his testimony. In particular the reliability analysis considers the testability, peer review, and general acceptance of the methodology underlying his expert opinion.

85. No. 3:08-cv-591, 2011 WL 2470621 (N.D. Ind. June 20, 2011).

86. *Id.* at *1. This Note assesses Dr. Christina Pareigis's and Dr. Randall Benson's expert testimony with respect to the qualifications of the expert witnesses and the reliability of the testimony. In particular the reliability analysis considers the testability, peer review, error rate, and general acceptance of the methodologies underlying the expert opinions. This Note refers to Dr. Pareigis as the first expert and Dr. Benson as the second expert.

87. No. 1:03-cv-17000, 2010 WL 7699456 (N.D. Ohio June 4, 2010).

88. *Id.* at *1. This Note considers the reliability of the methodology underlying Dr. Scott Atlas's testimony.

1. The Qualifications of the Expert Witness

At the outset every expert witness must be qualified to give expert testimony,⁸⁹ which in practice raises two issues. The first is whether the expert has sufficient credentials. The second is whether the credentials are in “the specialty area in which the expert is to testify.”⁹⁰

Proponents of MRI expert testimony have previously emphasized their experts’ board certifications, current positions in the relevant fields, years of experience in the field, estimated number of MRI-based diagnoses and treatments conducted, and references to supporting medical literature.⁹¹ In the *Booth* carbon monoxide case, the court found that the plaintiffs’ expert was a board-certified and practicing neuroradiologist and that he had reviewed 100,000 MRI studies in total and 150 to 200 MRI studies in the carbon monoxide context.⁹² The court also found that he had formed his opinion after personally conducting the plaintiffs’ MRI scans, reviewing their medical histories, and citing “several sources of medical literature in support of his opinions.”⁹³ Likewise, in the *Newman* cell phone case, the court noted approvingly that the expert taught and researched as an oncology professor, had “diagnosed and treated ‘thousands’ of cancer patients and ‘hundreds’ of brain cancer patients since he began work as an oncologist in 1976,” and had “conducted and published numerous studies in the field of cancer epidemiology.”⁹⁴ Both the *Booth* and *Newman* courts ruled that the experts held sufficient credentials and were qualified to give testi-

89. FED. R. EVID. 702.

90. Faigman, *supra* note 32, at 94.

91. *See, e.g.*, *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *2 (D.N.M. Mar. 23, 2009); *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 775 (D. Md. 2002), *aff’d*, 78 F. App’x 292 (4th Cir. 2003); *Ruppel*, 2011 WL 2470621, at *2-4.

92. *Booth*, 2009 WL 4544743, at *2. *See also* Defendants’ Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs’ Expert William W. Orrison, Jr., M.D. at ¶¶ 7-8, *Booth*, 2009 WL 45447431 (No. 1:06-cv-1219) (making the same assertions as to the number of MRI studies reviewed by the expert witness).

93. *Booth*, 2009 WL 4544743, at *2.

94. *Newman*, 218 F. Supp. 2d at 775. (“His education, experience, and training, considered by themselves, establish his qualifications to provide opinion testimony in the fields of oncology and epidemiology, if those opinions otherwise satisfy the *Daubert* standards.”); *see also* Transcript of Hardell *Daubert* Hearing at 622-27, *Newman*, 218 F. Supp. 2d 769 (No. 00-cv-260) (accepting the witness as an expert in oncology and epidemiology after discussing his education, rank, and experience in those fields).

mony on their MRI interpretations.⁹⁵ It is interesting that both courts considered the existence of medical literature in support of the expert's opinion important to the qualifications analysis even though the academic research appears on its face to address the reliability and peer review aspects of the methodology rather than the qualifications of the expert witness herself.

In order to decide whether the expert witness's credentials come from the correct specialty area, courts may be willing to dig into the expert's substantive professional experience instead of taking her formal professional titles at face value. For example, in the *Ruppel* vehicular negligence case, the court held that the plaintiff's first expert witness was qualified to testify on brain MRI diagnoses despite the fact that the expert's formal specialty was in brain rehabilitation instead of in brain injury diagnosis.⁹⁶ The court noted that the expert had "over thirty years of experience in diagnosing brain injuries," which constituted "extensive hands-on experience over a meaningful period of time," and also that the expert was "board certified in physical medicine and rehabilitation," which included "the evaluation, diagnosis, and treatment of brain injury."⁹⁷ The court also focused on the fact that, as a Medical Director of Rehabilitation, the expert "regularly diagnose[d], evaluate[d], and treat[ed] brain injury" and saw "an average of ten new cases a year involving injuries like [the plaintiff's] for a total of about two hundred cases over the course of her career."⁹⁸ As a result, the court found that the plaintiff's expert had sufficient experience upon which to base her diagnostic knowledge and opinion, notwithstanding her formal job position in rehabilitation.⁹⁹

95. *Booth*, 2009 WL 4544743, at *2; *Newman*, 218 F. Supp. 2d at 775.

96. *Ruppel*, 2011 WL 2470621, at *4; see also Defendants' Memorandum in Support of Motion for Partial Summary Judgment and Motion to Exclude Evidence of Diffuse Axonal Injury at 16, *Ruppel*, 2011 WL 2470621 (No. 08-cv-591) ("Dr. Pareigis's curriculum vitae confirms that she is board certified in physical medicine and rehabilitation. According to her deposition testimony, her internship residency and practice were and are in both physical medicine and rehabilitation. . . . Dr. Pareigis is an expert in *rehabilitation*, not in diagnosing brain injuries.") (internal citation omitted).

97. *Ruppel*, 2011 WL 2470621, at *2, *4.

98. *Id.* at *2; see also Affidavit of Christina Pareigis, MD at ¶¶ 2-3, *Ruppel*, 2011 WL 240621 (No. 3:08-cv-591); Plaintiffs' Memorandum in Opposition to Motion for Partial Summary Judgment and Motion to Exclude Evidence of Diffuse Axonal Injury at 6, *Ruppel*, 2011 WL 240621 (No. 3:08-cv-591); Plaintiffs' Memorandum in Response to Defendants' Joint Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D. at 14-15, *Booth*, 2009 WL 4544743 (No. 1:06-cv-1219).

99. *Ruppel*, 2011 WL 2470621, at *4.

A factual finding that the expert made errors or sought external consultation in the past may not automatically preclude the finding that the expert is qualified to testify and interpret MRI brain scans. In *Booth* the court specifically held that the expert was qualified¹⁰⁰ despite his concession that he had previously made mistakes in the past,¹⁰¹ that he had relied on checklists,¹⁰² and that he had changed his opinion after hearing his colleague's MRI interpretations.¹⁰³ Similarly, in the *Ruppel* vehicular negligence case, the court decided that the plaintiff's expert consulting a radiologist before ordering the plaintiff's MRI scans¹⁰⁴ did not defeat the witness's qualification as an expert because such concerns were relevant to the weight of the evidence and not its evidentiary admissibility.¹⁰⁵

In sum the case examples suggest that courts evaluating the qualifications requirement have previously focused their qualifications analyses on the experts' professional certifications, current

100. *Booth*, 2009 WL 4544743, at *2.

101. Defendants' Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 92, at ¶ 25.

102. *Id.* at ¶ 9. In response, the plaintiffs argued that "the checklist is an aid to the clinician because it provides greater assurance that an area of the brain will not be overlooked or a finding will not be omitted . . . Akin to a pilot's checklist, it aids diagnosis rather than detracts from it. It is widely used by physicians and hospitals to enforce focus on areas or symptoms that can be relevant." Plaintiffs' Memorandum in Response to Defendants' Joint Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 98, at 14–15.

103. Defendants' Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 92, at ¶ 25.

104. *Ruppel*, 2011 WL 2470621, at *3 ("Dr. Pareigis testified that she ordered the magnetic resonance imaging ('MRI') with SWY/DTI because she felt that it would give her 'more evidence regarding axonal diffuse injuries.'"); *see also* Defendants' Memorandum in Support of Motion for Partial Summary Judgment and Motion to Exclude Evidence of Diffuse Axonal Injury, *supra* note 96, at 16 (arguing that the plaintiff's expert having consulted a radiologist should defeat her qualification as an expert).

105. *Ruppel*, 2011 WL 2470621, at *3 ("Dr. Pareigis's testimony that she consulted with a radiologist in deciding to order the MRI does not disqualify her as an expert because she can base her conclusion on the opinions of others as long as they are the type of materials reasonably relied upon by experts in her field . . . [T]he Federal Rules of Evidence account for the reality that doctors, like Dr. Pareigis, rely on the opinions of other doctors in reaching their diagnoses. . . . Instead, evidence that Dr. Pareigis consulted a radiologist to order the MRI would go to the weight that the jury may give her testimony.").

employment, quantifiable and qualitative experiences in the relevant fields, and citations to supporting medical studies.

2. The Relevance of the Expert Testimony

In evaluating relevance courts may ask whether “the expert’s opinion logically relates to some specific issue in dispute under the substantive law” or whether “the research basis for the expert’s opinion generalizes to a legal issue in a dispute.”¹⁰⁶

The first question focuses on the substantive law and considers whether “the fact that is the subject of the expert testimony is an issue in the case.”¹⁰⁷ In the *Carlen* medical malpractice case, the plaintiff had argued that the defendants’ negligence caused her tumor growth because the defendants had failed to use “surgical debulking, chemotherapy, and radiation therapy to retard the growth of tumors.”¹⁰⁸ However, the court found that the expert did not identify specific treatment that the defendants should have prescribed, did not address the received treatment’s efficacy in reducing tumor growth, and did not account for the possible complications and risks of the treatment options.¹⁰⁹ These omissions ultimately led the court to find that the expert testimony was too vague, too insufficiently tied to the case-specific facts, and thus irrelevant.¹¹⁰

The second question centers on “the underlying research basis for the expert’s opinion” and focuses on whether the research “can be extrapolated to help resolve a disputed fact that is an issue in the

106. Faigman, *supra* note 32, at 93.

107. *Id.*

108. Plaintiffs’ Brief in Opposition to Defendants’ Motion for Summary Judgment at 26, *Carlen v. Minn. Comprehensive Epilepsy Program, P.A.*, No. 00–cv–39, 2001 WL 1078633 (D. Minn. Apr. 18, 2001).

109. *Carlen v. Minn. Comprehensive Epilepsy Program, P.A.*, No. 00–cv–39, 2001 WL 1078633, at *7 (D. Minn. Apr. 18, 2001). An examination of the filed documents available on Westlaw confirms the court’s conclusion that the plaintiff had not specified a course of treatment in his brief or through his expert’s testimony. Affidavit of Anthony J. Hall at ¶ 6, *Carlen*, 2001 WL 1078633 (No. 00–cv–39) (claiming only that “treatment” would have prolonged the plaintiff’s lifespan); Affidavit of Anthony J. Hall and Charles B. Harris at ¶ 6, *Carlen*, 2001 WL 1078633 (No. 00–cv–39) (arguing that the defendants should have scheduled an enhanced MRI scan for the plaintiff and recommended “some course of treatment” to “reduce or retard the growth of the tumor and the pressure exerted by it”); Plaintiffs’ Brief in Opposition to Defendants’ Motion for Summary Judgment, *supra* note 108, at 26 (generally identifying “surgical debulking, chemotherapy and radiation therapy to retard the growth of tumors” as the proper treatment).

110. *Carlen*, 2001 WL 1078633, at *7.

case.”¹¹¹ The court in *Newman* found that the expert’s testimony that the defendants’ cell phones caused the plaintiff’s malignant tumor was irrelevant for two reasons. First, the underlying research studies did not show “any statistically significant increased risk for the development of malignant brain tumors based on analog cell phone use.” Second, the expert should not have relied on “the increased risk for all brain tumors” given that “the category of benign acoustic neuroma” was not applicable to the plaintiff’s case.¹¹² Initially the *Newman* court’s focus on statistical significance and experimental results in the relevance section might seem odd because quantitative and qualitative defects in the underlying research appear to pertain to the methodology’s reliability more than its relevance. But here is the difference: the relevance requirement works to exclude expert testimony based on research that is unrelated to the disputed issues, regardless of the reliability and scientific validity of the expert’s reasoning and methodology. If there is only research available on both benign and malignant brain tumors *as a group*, then expert testimony based on that research may be irrelevant to and excluded from litigation focused solely on malignant brain tumors. In contrast, the reliability requirement works to exclude expert testimony formed by scientifically invalid methodology or reasoning, regardless of the relevance of the underlying research. Together the relevance and reliability requirements help exclude expert testimony based on substantively unrelated or scientifically invalid research from the courtroom. In sum if the expert uses a scientifically invalid method to extrapolate the cause of a malignant tumor based on research on all tumors, then the expert testimony will be excluded as unreliable, even if the underlying research studies are indeed relevant to the focus of the litigation.

3. The Reliability of the Expert Testimony

In assessing the reliability of contested expert testimony, courts have the discretion to choose their own evaluation criteria based on

111. Faigman, *supra* note 32, at 93.

112. *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 778 (D. Md. 2002), *aff’d*, 78 F. App’x 292 (4th Cir. 2003); *see also* Andrew M. Dansicker, *The Next Big Thing for Litigators*, Md. B.J., July/Aug. 2004, at 12, 16 (“[P]laintiffs’ attorneys [who] have focused on the cell phone industry . . . claim[] that cell phone manufacturers knew but failed to inform the public that substantial cell phone usage causes cancer. The problem with this theory, as the court pointed out in *Newman* . . . is that the science simply does not add up—in other words, the vast majority of medical studies, including one by the National Cancer Institute, have concluded that there is no statistically significant relationship between cell phone usage and cancer.”).

what they think is most appropriate to the case.¹¹³ Specifically in the MRI brain scan context, courts evaluating the admissibility of expert testimony appear to take one of three approaches: (1) analyze reliability under the *Daubert* framework through a factors-based approach with express reference to individual *Daubert* factors,¹¹⁴ (2) analyze reliability under the *Daubert* framework through a total-ity approach without specific reference to any individual factors,¹¹⁵ or (3) analyze reliability under the Rule 702 framework by applying either the Rule 702 statutory criteria¹¹⁶ or the *Daubert* principles.¹¹⁷

i. The First Approach: A Factor-Based Analysis of *Daubert* Reliability

Courts that specifically assess one individual *Daubert* factor can either evaluate the three remaining *Daubert* factors to round out the reliability analysis¹¹⁸ or selectively discuss only the most pertinent factors.¹¹⁹ This section identifies and examines the MRI brain scan rulings that most substantively address each *Daubert* factor in order to explore the issues that might arise when litigating parties assert or challenge the testability, peer review, error rate, or general acceptance of the expert testimony on MRI brain scans.

113. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141–42 (1997).

114. Ruppel v. Kucanin, No. 3:08–cv–591, 2011 WL 2470621, at *6–10 (N.D. Ind. June 20, 2011); Booth v. KIT, Inc., No. 06–cv–1219, 2009 WL 4544743, at *2–4 (D.N.M. Mar. 23, 2009); Carlen, 2001 WL 1078633, at *7; Newman, 218 F. Supp. 2d at 777–83.

115. Hose v. Chi. Nw. Transp. Co., 70 F.3d 968, 974–75 (8th Cir. 1995); Jarvis v. Sec’y of the Dep’t of Health & Human Servs., 99 Fed. Cl. 47, 64–65 (Fed. Cl. 2011); *In re* Welding Fume Prods. Liab. Lit., No. 1:03–cv–17000, 2010 WL 7699456, at *55 (N.D. Ohio June 4, 2010).

116. Huber v. JLG Indus., Inc., 344 F. Supp. 2d 769, 773 (D. Mass. 2003).

117. See, e.g., Lennon v. Norfolk & W. Ry. Co., 123 F. Supp. 2d 1143, 1146 (N.D. Ind. 2000).

118. See, e.g., Ruppel, 2011 WL 2470621, at *6–10; Booth, 2009 WL 4544743, at *2–4.

119. See, e.g., Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999); Newman, 218 F. Supp. 2d at 777–83; Carlen, 2001 WL 1078633, at *7. As a note, many recent cases cite Newman for its proposition that some *Daubert* factors “may be more pertinent than others depending on the nature of the issue, the expert’s particular expertise and the subject of his testimony.” 218 F. Supp. 2d at 773; see, e.g., MCI Commc’ns Servs., Inc. v. Am. Infrastructure-MD, Inc., No. 11–cv–3767, 2013 WL 4086401, at *3 (D. Md. Aug. 12, 2013); Cinaglia v. Benevicz, 290 F.R.D. 465, 468 (D. Md. 2013); Basile Baumann Prost Cole & Assocs., Inc. v. BBP & Assocs. LLC, No. 11–cv–2478, 2012 WL 3115867 (D. Md. July 25, 2012); Goyal v. Thermage, Inc., No. 08–cv–0020, 2011 WL 691185, at *2 (D. Md. Feb. 18, 2011) (quoting Newman v. Motorola, Inc., 218 F.Supp.2d 769, 773); Main St. Am. Grp. v. Sears, Roebuck, & Co., No. 08–cv–3292, 2010 WL 956178 (D. Md. Mar. 11, 2010).

a. *Daubert Factor One: Testability*

The theory or technique underlying the MRI expert testimony should be testable, falsifiable, or refutable in order to satisfy the first *Daubert* factor.¹²⁰ To establish testability, proponents of expert testimony might focus on the “retest reliability” and “reproducibility” of the expert’s methodology or conclusions.¹²¹ In *Ruppel*, for example, the court found that the plaintiff’s expert’s DTI methodology had “high retest reliability” and produced imaging scans of “high reproducibility” based on the expert’s testimony.¹²² The *Ruppel* expert successfully persuaded the court of his methodology’s testability in part by citing to a research study showing that “the scientific methodology of quantitative analysis of FA is reproducible,” that “patients who have been scanned 2 or 3 times with slightly different resolutions have show[n] high reproducibility,” and that a case study on a former football player also exhibited high reproducibility between DTI scans.¹²³

Proponents may preemptively defend against opposing counsel’s allegations that the expert’s methodology was unreliable and lacked external confirmation.¹²⁴ Proponents may also argue that disagreements over the characterization of the methodology speak to the weight of testimony, not its admissibility, and should be litigated at trial, not during pretrial motions.¹²⁵

120. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993).

121. *See, e.g., Ruppel*, 2011 WL 2470621, at *9.

122. *Id.* at *9.

123. Affidavit of Randall Benson, MD at ¶ 34, *Ruppel*, 2010 WL 2470621 (No. 3:08-cv-591) (“Contrary to the statement of Dr. Drnovsek in her written report, the scientific methodology of quantitative analysis of FA is reproducible. In practice, patients who have been scanned 2 or 3 times with slightly different resolutions have show[n] high reproducibility. I have presented DTI data on a former football player who was scanned in both Detroit and New York City with very high reproducibility.”). In other words, the *Ruppel* expert was able to persuade the court of his methodology’s testability simply by asserting that DTI technology had high reproducibility and by citing to one supporting research study. *See Ruppel*, 2011 WL 2470621, at *9 (“However, the Ruppels have presented evidence that the DTI scan and resulting FA quantification analysis can be tested and replicated and that the error rate is not higher than other methods commonly relied upon such as MRIs.” (citations omitted)). At face value, the court’s reasoning might seem naïve and overly trusting of the plaintiff’s bald claims of replicability, but Dr. Benson’s word choice in declaring, “I have presented DTI data,” in his affidavit suggests that the court considered testability arguments and evidence beyond what was available online in the legal databases.

124. *See, e.g., Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *3 (D.N.M. Mar. 23, 2009).

125. *See Ruppel*, 2011 WL 2470621, at *6.

As one example, in *Booth*, the defendants argued that the expert's methodology was unreliable because the expert did not confirm his opinion through external cross-references or verification even though the expert had earlier conceded that MRI interpretations in general are inherently subjective.¹²⁶ The court rejected the defendants' arguments and held the methodology testable; because the defendants had failed to show that the methodology was so suspect as to be "wholly unreliable;" the issue should thus be saved for trial.¹²⁷ It is interesting to note that the court's testability analysis here in the reliability discussion mirrors its analysis in the expert qualifications discussion,¹²⁸ because the court held in both instances that a lack of external confirmation did not make the testimony inadmissible. Arguably the compatible, parallel findings suggest that the court wanted the qualifications and reliability analysis to be consistent in finding that lack of external confirmation would not preclude the testimony's admissibility.

As a second example, the court in *Ruppel* held that disagreements with the expert's characterization of DTI testability and replicability would not exclude the expert evidence during the pretrial stage and should instead be raised during trial.¹²⁹ Oddly the *Ruppel* court appears to resolve the battling experts' contrary characterizations of DTI's testability by siding with the expert who had more expertise in the DTI field.¹³⁰ The court's reliance on the battling experts' qualifications to resolve the testability issue appears to be

126. *Booth*, 2009 WL 4544743, at *3. Defendants argued that, "despite Dr. Orrison's admissions that readings of MRI scans are subjective, that no two human brains are identical, and that there is a range of 'normal' in terms of brain physiology, Dr. Orrison did not attempt to confirm the accuracy of his conclusions either by using a computer program available to verify his readings or by comparing these scans to either healthy patients or patients that were exposed to carbon monoxide." See also Defendants' Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 92, at 4.

127. *Booth*, 2009 WL 4544743, at *3.

128. See *supra* Part II.(C.) (1).

129. *Ruppel*, 2011 WL 2470621, at *10.

130. *Id.* at *9. "While defendants' expert Dr. Drnovsek disagrees with Dr. Benson, she does not have as much experience in [DTI] as Dr. Benson. Dr. Benson is a behavioral neurologist who has been involved in research using advanced MRI methods for eighteen years. He has focused his research on TBI imaging for the past five years and has published a paper on how DTI scans of FA correlate with TBI severity. On the other hand, Dr. Drnovsek, a neuroradiologist, does not do diffusion tensor imaging and before becoming involved in this case her only experience with DTI was a basic familiarity with the literature about DTI and attendance at conferences that 'elaborate[d] on [DTI] application in different pathologies, including traumatic brain injury.' She has not done any personal re-

misguided at best and outcome-oriented at worst given that expert qualifications and testimony reliability should theoretically operate as two separate admissibility requirements.

Opponents might question whether the expert's research has been replicated or validated by other scientists and whether the methodological defects preclude a finding of testability.¹³¹ In the *Newman* case, defense counsel argued that the plaintiff's expert testimony was not testable because the underlying animal epidemiology studies had not "been replicated or otherwise validated by other scientists," and that multiple methodological flaws rendered the expert's conclusions invalid.¹³² During the *Daubert* hearing, defense counsel asked the plaintiff's expert about the methodological problem of recall bias in his research, and the expert replied, "These are standard phrases. As a reviewer, I always talk about recall bias in epidemiological studies. This is standard according to the textbooks."¹³³ The court ultimately excluded the expert testimony in part because of the lack of testability shown by the fact that the expert's "methodology for testing laterality ha[d] not been used by any other scientist proffered to the court" and "ha[d] not been replicated."¹³⁴

b. *Daubert Factor Two: Peer Review and Publication*

Peer review and publication is one way to measure the reliability of the MRI expert's underlying theory or technique because "submission to the scrutiny of the scientific community . . . increases the likelihood that substantive flaws in methodology will be detected."¹³⁵ Litigants might focus on the number and specificity of

search into DTI. Her criticism of Dr. Benson's methods was based on her reading of two articles on the subject." *Id.* (citations omitted).

131. See, e.g., *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 778–79, 783 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003).

132. *Id.* at 783.

133. Hardell Transcript of Daubert Hearing at 705, *Newman*, 218 F. Supp. 2d 769 (No. 00-cv-2609).

134. *Newman*, 218 F. Supp. 2d at 779, 783 (excluding the contested expert testimony in part because of the court's findings that: "Dr. Hardell's methodology for testing laterality has not been used by any other scientist proffered to the court. Nor has it been replicated. The *Inskip* and *Muscat* studies, which tested laterality by other means and admittedly with a smaller number of people, do not show increased risk. Part of the difficulty is that Dr. Hardell, of necessity, assigned a 'phantom' tumor to a particular side of the head in the control group and did so using the same side of the head as the matched case. This procedure appears inconsistent with the epidemiological principle that exposure cannot be defined on the basis of outcome." (citations omitted)).

135. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94 (1993).

the peer-reviewed articles supporting the experts' statements in order to establish or challenge the reliability of the expert's MRI brain testimony.¹³⁶ For example the *Ruppel* court confirmed that the second expert's DTI method had sufficient peer review because there were eighty-three articles discussing DTI in the context of traumatic brain injury, and eleven supporting articles that "specifically address[ed] the effectiveness of DTI in detecting mild [traumatic brain injury]."¹³⁷

Whether an expert's own lack of peer-reviewed publication precludes satisfaction of the peer review requirement remains an open question. The *Booth* court decided that this failure of publication did not hurt the testimony on peer review grounds because the issue went more to the weight of the evidence than to its evidentiary admissibility.¹³⁸ The *Newman* court, however, came to the opposite conclusion.¹³⁹ Specifically the *Booth* court held that opposing counsel's claims that the expert had only co-authored one peer-reviewed publication on carbon monoxide and brain damage¹⁴⁰ should be raised during trial, and not during pretrial arguments challenging evidentiary admissibility.¹⁴¹ In contrast the *Newman* court found it significant that the plaintiff's expert had never been published in

136. See *Newman*, 218 F. Supp. 2d at 783; *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *8 (N.D. Ind. June 20, 2011).

137. *Ruppel*, 2011 WL 2470621, at *8. As an example, the court quoted two articles, the first observing that, "[d]etection of ultrastructural damage by using DT imaging is a major advance in diagnostic imaging. Several studies have supported the capability of FA to help identify white matter abnormalities in patients with traumatic brain injury including [mild TBI]. As confirmed by [one study's] findings, abnormal FA is detected even in the absence of other imaging abnormalities," and the second stating that "[o]ur study shows that DTI can be used to detect differences between patients with cognitive impairment after mild TBI and controls." *Id.* (citations omitted).

138. *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *3 (D.N.M. Mar. 23, 2009).

139. *Newman*, 218 F. Supp. 2d at 777.

140. See Defendants' Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 92, at 4; cf. Plaintiffs' Memorandum in Response to Defendants' Joint Motion in Limine, *supra* note 98, at 10 ("In addition to the fact that such publication is not a requisite of Daubert . . . the statement is false. Dr. Orrison has specific peer reviewed publication on neuroimaging of patients who have been exposed to carbon monoxide . . .").

141. *Booth*, 2009 WL 4544743, at *3 ("Defendants also argue that Dr. Orrison has no peer reviewed publications on the subject of carbon monoxide induced brain damage other than one article that he co-authored that appeared in the *Acta Neurologica Scandinavica*. Again, these perceived weaknesses in Dr. Orrison's opinions can be brought out on cross examination, but are insufficient to exclude the opinions. *Daubert*, 509 U.S. at 596 (stating that vigorous cross-examination, presen-

peer-reviewed journals, specifically singling out the rejecting journal's concerns about the "large confidence intervals" and overly forceful tone of the expert's research papers.¹⁴² The *Booth* court ultimately found that the expert's theories were sufficiently subjected to peer review,¹⁴³ while the *Newman* court found that the expert's testimony was not sufficiently peer-reviewed.¹⁴⁴

If opposing counsel attacks the expert's underlying technique by arguing that the expert did not confirm her conclusions with blind studies or second opinions, then the proponent of the evidence might argue that the admissibility challenge fails because it goes to the weight of the evidence. Such was the outcome in the *Booth* case, after the defendants argued that the expert reached his conclusion without submission "to the peer review process to confirm consistency of his interpretation, and, without any attempt to have the scans reviewed through means of a blind study where several respected neuroradiologists review and interpret the scans without any preconceived idea about what interpretation to reach."¹⁴⁵ The *Booth* court rejected these arguments because they went to the weight of the evidence and were more appropriately raised during cross-examination at trial.¹⁴⁶ Here, again, the *Booth* court showed its consistency: the expert's failure to confirm his opinion by referencing external blind studies or second opinions did not hurt the expert testimony at the peer review stage of the analysis just as it did not hurt the testimony at the expert qualifications or testability stage of the analysis.

tation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking admissible opinion evidence).

142. *Newman*, 218 F. Supp. at 777. Some scholars have criticized the *Newman* court's emphasis on the article rejection process as misguided. See, e.g., Kanner & Casey, *supra* note 84, at 311 ("While limits to peer review have been widely acknowledged, [Judge] Blake's skepticism and forensic investigation of the correspondence between Hardell and various journal editors places her judgment on what might appear to be a scientifically unaccountable basis Sheila Jasanoff explained that: '[s]cientific peer review is likely to differ markedly in its objectives and impact from review carried out by an expert in a litigation context. In legal review, the goal is neither to make good work better nor to retrieve what might be of value from work of lesser significance. It is instead, to seek to aggressively as possible discredit the proffered evidence and to deploy in the process all the skeptical resources that experts specifically engage for this purpose can muster.'" (citations omitted)).

143. *Booth*, 2009 WL 4544743, at *3.

144. *Newman*, 218 F. Supp. 2d at 777.

145. Defendants' Joint Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 92, at 4 (citations omitted).

146. *Booth*, 2009 WL 4544743, at *3.

c. *Daubert Factor Three: Known or Potential Error Rate*

The theory or technique underlying the MRI expert testimony should have a known or potential error rate as well as quality control standards for the operation of the techniques.¹⁴⁷ Proponents of MRI expert testimony may have their experts highlight the error-minimization protocols and the statistical significance of any residual error rates.¹⁴⁸ As an example, the *Ruppel* court looked favorably upon the second expert's interpretation methods after the expert outlined his error rate protocol,¹⁴⁹ "explained the numerous steps he took to minimize the error rates in his DTI analysis,"¹⁵⁰ and asserted that the statistical probability that "clusters of abnormal voxels found in areas of [the plaintiff's] brain were there by chance is next to impossible."¹⁵¹ The *Ruppel* court also noted approvingly that the error rate of the expert's DTI methodology was "not higher than [those of] other methods commonly relied upon

147. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993).

148. See, e.g., *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *6 (N.D. Ind. June 20, 2011). But cf. *Development in the Law—Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1532, 1548 (1995) ("*Daubert* did not set a threshold level of statistical significance either for admissibility or for sufficiency of scientific evidence.").

149. Affidavit of Randall Benson, *supra* note 123, at ¶¶ 29–30 ("[O]nly voxels with [DTI] values reduced by more than 3 standard deviations from the mean were counted as abnormal. Three standard deviations covers [sic] 99.7% of the distribution pattern. That means that the odds of randomly falling three standard deviations below the mean by pure chance is 0.15 out of a hundred and the odds of finding a voxel three standard deviations above the mean is also .15 out of 100 (or 1 out of 660) Since the computer performed 134,733 voxel analyses, statistically speaking, there should be by chance 202 voxels (.0015%) that are at least 3 standard deviations below the mean.").

150. *Ruppel*, 2011 WL 2470621, at *9; see also Affidavit of Randall Benson, *supra* note 123, at ¶ 31 ("To minimize the false positive rate (number of voxels incorrectly called abnormal) a size criterion had to be met for clusters with voxels of reduced [DTI]. Specifically, cluster size had to be at least 1 [sic] standard deviation greater than the mean cluster size for the controls (upper 16%). The probability of having large clusters (contiguous voxels) of reduced 4 [DTI] is determined analytically on the control group in order to further ensure that the patient in question is similar or significantly different from the control group. Since the odds of having a cluster of this size was 1 out of 6, the odds of having voxels of sufficiently reduced [DTI] included in clusters which are 1 standard deviation larger than the mean was 1 in 4,166.").

151. *Ruppel*, 2011 WL 2470621, at *9; see also Affidavit of Randall Benson, *supra* note 123, at ¶ 32. The court also noted, in a separate discussion, that "the possibility of alternative explanations . . . of *Ruppel's* decreased white matter . . . does not bar Dr. Benson's testimony; rather it goes toward the weight to be given to his opinion." *Ruppel*, 2011 WL 4069465, at *11.

such as [non-DTI] MRIs.”¹⁵² As a second example, the *Carlen* court found that the plaintiff’s expert failed to present any error rate evidence to support his novel and extrapolation-based method of assessing cancer causation,¹⁵³ which influenced the court’s ultimate decision to find his testimony unreliable.¹⁵⁴

Opponents can argue that qualitative inconsistencies in the expert’s conclusions render the expert testimony inadmissible on error rate grounds. In response proponents can re-characterize the admissibility challenges as attacks on the weight of the evidence, which are insufficient grounds to exclude testimony before trial. Consider the *Booth* case, in which the defendants argued that the expert opinion was fatally inconsistent because the expert looked at two of the plaintiffs’ MRI brain scans, gave “virtually identical” descriptions for each of the scans, and yet concluded that one plaintiff suffered from “mild” cerebral atrophy while the other suffered from “diffuse” cerebral atrophy.¹⁵⁵ The defendants argued that this

152. *Ruppel*, 2011 WL 2470621, at *9.

153. *Carlen v. Minn. Comprehensive Epilepsy Program, P.A.*, No. 00-cv-39, 2001 WL 1078633, at *8 (D. Minn. Apr. 18, 2001) (noting that the expert’s methodology consisted of “review[ing] several studies relating to the treatment of glioblastoma multiform tumors,” “arriv[ing] at a median life expectancy for a patient with such a tumor,” and “appl[y]ing that median life expectancy to the month in which Ms. Carlen had the enhanced MRI performed”).

154. *Id.* An examination of the court documents available on Westlaw confirms the court’s conclusion. Neither the expert’s affidavits nor the plaintiff’s brief cite to any specific supporting evidence for the expert’s claim that, if the plaintiff had received proper medical treatment in January 1998, then she would have lived beyond June 3, 1998. Affidavit of Anthony J. Hall, *supra* note 109, at ¶ 6 (claiming, without citing any particular studies, that his expert opinion was based on “a number of medical studies which are generally accepted by neurosurgeons as showing a person who has glioblastoma multiforme who is treated has a statistically longer life expectancy than a person who has the same condition who is not treated”); Affidavit of Anthony J. Hall and Charles B. Harris, *supra* note 109, at ¶ 6 (asserting, without any supporting evidence, that if the neurologist or neurosurgeon had “followed the standard of care in the profession would have [sic] explained to Patricia A. Carlen that she would die within approximately three to nine months from January 1998 due to a brain herniation caused by the pressure that would ultimately be exerted on her brain by the tumor if some course of treatment was not undertaken which would reduce or retard the growth of the tumor and the pressure exerted by it”); Plaintiffs’ Brief in Opposition to Defendants’ Motion for Summary Judgment, *supra* note 108, at 26–27 (alleging that “hundreds of articles” and “[n]umerous published medical studies which are generally accepted by neurosurgeons” supported the expert’s opinion of the plaintiff’s life expectancy).

155. *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *3 (D.N.M. Mar. 23, 2009): *see also* Defendants’ Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs’ Expert William W. Orison, Jr., M.D., *supra* note 92, at 4–5. *But see* Plaintiffs’ Memorandum in Response

unexplained inconsistency would confuse the jury and so the expert testimony should be excluded.¹⁵⁶ However, the court rejected this argument and asked defense counsel to raise the inconsistencies during cross-examination at trial instead.¹⁵⁷

d. *Daubert Factor Four: General Acceptance*

To fulfill the general acceptance factor, proponents and their experts should present specific evidence supporting their methodology or conclusions. One way to satisfy the requirement is to show that the experts' MRI methods are regularly used in hospitals,¹⁵⁸ or are supported by medical textbooks and peer-reviewed articles reaching similar qualitative conclusions.¹⁵⁹

As a preliminary matter expert witnesses should actually identify specific studies that support their testimony. In *Carlen* the plaintiff's expert testified that substandard medical care caused the plaintiff's fatal brain tumor based on conclusions that he formed after "review[ing] several studies relating to the treatment of glioblastoma multiform tumors," "arriv[ing] at a median life expectancy for a patient with such a tumor," and "then appl[ying] that median life expectancy to the month in which Ms. Carlen had the enhanced MRI performed."¹⁶⁰ However, the expert failed to cite to any specific studies and could not show that the expert's "methodology ha[d] been generally accepted within the medical community," which influenced the court's ultimate decision to find his testimony inadmissible on reliability grounds.¹⁶¹

to Defendants' Joint Motion in Limine, *supra* note 98, at 10 ("The differences in the reports – a finding of mild cerebral atrophy for Mrs. Booth and diffuse cerebral atrophy for Alexandra – is mentioned, apparently, as a difference that has something to do with error rate. It does not. It, instead, has to do with two separate interpretations of two separate scans.").

156. *Booth*, 2009 WL 4544743, at *3.

157. *Id.* ("Defendants may proffer a qualified expert to point out this alleged inconsistency or develop the inconsistency through cross examination, but the Court will not exclude the opinion on that basis. . . . [N]o court is in a position to declare or even to know with any degree of certainty whether otherwise admissible expert testimony is, in fact, correct." (citing *Goebel v. Denver & Rio Grande W. R.R. Co.*, 346 F.3d 987, 991 (10th Cir. 2003)).

158. *See, e.g., Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *8 (N.D. Ind. June 20, 2011).

159. *See, e.g., Booth*, 2009 WL 4544743, at *4; *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 783 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003); *Lugo v. N.Y.C. Health & Hosps. Corp.*, 929 N.Y.S.2d 264, 278–79 (App. Div. 2011).

160. *Carlen v. Minn. Comprehensive Epilepsy Program, P.A.*, No. 00-cv-39, 2001 WL 1078633, at *7 (D. Minn. Apr. 18, 2001).

161. *Id.*

If no single research study is comprehensive enough to support the entirety of the expert's theory or methodology, proponents of the expert testimony in *Frye* jurisdictions might argue that the court should take an aggregate approach to the medical literature and consider the research studies' collective findings as a whole.¹⁶² In *Lugo*, the prenatal medical malpractice case, the state appellate court admitted the plaintiffs-appellants' causation testimony on general acceptance grounds; although none of the publications individually "provide[d] conclusive support for the theory of causation espoused by the plaintiffs' expert," the court noted that, "when considered in the aggregate for the limited purpose of applying the *Frye* test, and against the backdrop of the undisputed generally accepted principles concerning hypoglycemia set forth at the hearing, those articles establish that this theory was properly based upon far more than theoretical speculation or a scientific 'hunch.'"¹⁶³ The *Lugo* court found it sufficient that, when "[s]ynthesized, the [plaintiffs-appellants'] materials provided an objective basis for their opinion that a period of severe hypoglycemia of relatively short duration can cause neurologic injury as reflected as [periventricular leukomalacia] on a MRI brain scan," and instructed that "[t]he absence of medical literature directly on point with the circumstances at bar pertains to the weight to be given to this opinion testimony, but does not preclude its admissibility."¹⁶⁴ Other sources have cited *Lugo* for its aggregate approach to assessing expert testimony on general causation.¹⁶⁵

162. See, e.g., *Lugo*, 929 N.Y.S.2d at 279. Although courts adhering to the *Daubert* framework "rarely discuss this issue explicitly," one scholar noted that some of these courts "appear to look at each study separately and give no consideration to those studies that cannot alone prove causation." Margaret A. Berger, *The Admissibility of Expert Testimony*, in FED. JUDICIAL CTR., REFERENCE MANUAL FOR SCIENTIFIC EVIDENCE 11, 19 (3rd ed. 2011). The resistance against using the aggregate approach in evaluating expert testimony is peculiar given the observation "that many of the most well-respected and prestigious scientific bodies consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence." *Id.* at 20.

163. *Lugo*, 929 N.Y.S.2d at 279.

164. *Id.* at 279. The court elaborated, "Both the plaintiffs' experts and the defendants' experts agree that an episode of severe glucose deprivation in a newborn can cause neurologic damage; the principal dispute between them, which was emphasized by the testimony at the *Frye* hearing, is over how long such an episode must last before neurological damage results. This factual disagreement should not have been resolved as a matter of law by the [state] Supreme Court in the course of its *Frye* inquiry." *Id.*

165. See, e.g., *Rosati v. Brigham Park Co-operative Apartments, SEC No.2, Inc.*, No. 15229/08, 2012 WL 2899030, at *2 (N.Y. Sup. Ct. July 17, 2012) (citing *Lugo*

In addition to arguing that the expert's method is well-regarded in specific peer-reviewed journals, proponents of the expert testimony might emphasize that the expert's method is regularly used in at least some hospitals' practices. In *Ruppel*, the court concluded that the expert's DTI method of diagnosing the plaintiff's brain injury qualified as a generally accepted method of determining mild traumatic brain injury ("TBI") despite being a new technology.¹⁶⁶ The court noted that DTI is "regularly used at some hospitals even though it is not the regular standard of care at the average hospital" and that there were many peer-reviewed articles vouching for "the effectiveness of DTI in detecting mild TBI," which indicated that DTI was "well on its way to gaining general acceptance in the scientific community as a tool for identifying mild TBI."¹⁶⁷

External research studies offering quantitatively or qualitatively different conclusions that contradict the expert's own conclusions can also play an important role in the general acceptance analysis. In *Newman*, the court excluded the testimony of both plaintiffs' experts in part because other studies had reached qualitatively different results.¹⁶⁸ The *Newman* court found that neither of the plaintiffs' experts met the general acceptance requirement because "numerous national and international scientific and governmental published reports" had qualitatively contradicted the experts' causation conclusions by "finding no sufficient proof that use of handheld cellular phones causes human brain cancer."¹⁶⁹ Compare the *Newman* case with the *Booth* case, in which the court found that the expert's statements satisfied the general acceptance require-

for the proposition that, "[w]here a 'synthesis' of the medical literature produced by the plaintiff's expert at a *Frye* hearing 'considered in the aggregate . . . establish[es] that [the expert's] theory [is] properly based upon far more than theoretical speculation or a scientific hunch,' the expert's opinion will pass the *Frye* test" of general acceptance (citations omitted)); Mark C. Surprenant & Diana Cole Surprenant, *The Emerging Battlefield: Should the Use of a Nonmonotonic, Non-Threshold Dose-Response Curve for Alleged Endocrine-Disrupting Chemicals Survive a Daubert/Frye Challenge?*, 80 DEF. COUNS. J. 45, 57 n.84 (2013) (noting that, although *Frye* courts subscribe to a "weight-of-the-evidence" methodology, some courts, such as the *Lugo* court, "have declined to examine each study selected by the expert so long as the methodology has been generally accepted in the relevant scientific community" even if "none of the studies in isolation supports the experts' causation theory").

166. *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *7 (N.D. Ind. June 20, 2011).

167. *Id.* at *8.

168. *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 783 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003).

169. *Id.*

ment even though other studies had reached quantitatively different conclusions.¹⁷⁰ Specifically, after the plaintiffs' expert in *Booth* concluded that all of the plaintiffs had abnormal MRI brain scans, the defendants challenged the expert's testimony as "statistically suspect" by comparing the expert's finding of a 100% MRI abnormality rate to the 12% MRI abnormality rate featured in an external study examining seventy-three patients exposed to carbon monoxide.¹⁷¹ The plaintiffs had countered that their expert's 100% abnormality rate was "not surprising" in light of the plaintiffs' particularly large exposure to carbon monoxide.¹⁷² The *Booth* court ultimately decided that the expert's testimony satisfied the general acceptance requirement because the defendants' challenge had merely identified "perceived weaknesses" in the expert's conclusions and were thus arguments addressing the weight of the evidence rather than its admissibility.¹⁷³ The challenge for litigating parties in this situation arises from not knowing how the court will treat qualitatively or quantitatively contradictory research studies.¹⁷⁴

ii. The Second Approach: A Totality-Based Analysis of *Daubert* Reliability

As an alternative to analyzing the reliability of expert testimony by specifically considering some¹⁷⁵ or all¹⁷⁶ of the *Daubert* factors,

170. *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *4 (D.N.M. Mar. 23, 2009).

171. *Id.*

172. *Id.*; see also Plaintiffs' Memorandum in Response to Defendants' Joint Motion in Limine, *supra* note 98, at 11 ("Because the exposure at the motel was massive and the measurement of carbon monoxide levels in victims' blood profoundly abnormal (more than 15 to 20 times normal for some individuals even though blood readings were taken after prolonged administration of oxygen), it would not be surprising for all of the individuals to have suffered brain damage.").

173. *Booth*, 2009 WL 4544743, at *4. The plaintiffs in the *Ruppel* case later cited *Booth* for this particular proposition in their expert witness motions. Plaintiffs' Memorandum in Opposition to Motion for Partial Summary Judgment and Motion to Exclude Evidence of Diffuse Axonal Injury, *supra* note 98, at 21; see also Plaintiffs' Memorandum in Response to Defendants' Joint Motion, *supra* note 98, at 6 (arguing that the defendants' motion did not implicate *Daubert* or Rule 702).

174. This type of unpredictability is not unique to the MRI brain scan context. Many scientific and technical questions have more than one legitimate answer. Nevertheless, "[c]ourts handling *Daubert* motions sometimes sound as though only one possible answer is legitimate. If scientists seeking to testify for opposing sides disagree, some courts conclude that one side must be wrong. The possibility that both sides are offering valid scientific inferences is rarely recognized, even though this happens often in the world of science." Berger, *supra* note 162, at 24.

175. See, e.g., *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 777-83 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003); *Carlen v. Minn. Comprehensive Epi-*

some courts may instead assess *Daubert* reliability without expressly referring to any of the *Daubert* factors, as if they were conducting a totality test.¹⁷⁷ Courts can use this freeform approach to directly examine the strengths and weaknesses of the contested testimony and holistically determine whether the testimony satisfies *Daubert* as a whole. This section reviews the exemplar cases in which the court used the freeform approach of evaluating *Daubert* reliability without referring to specific *Daubert* factors.

In the *In re Welding Fume Products Liability Litigation* case the expert witness opined that “a patient with a normal MRI has never had enough manganese exposure over his working career to suffer brain damage yielding clinical manifestations.”¹⁷⁸ The court held that this expert testimony could not satisfy any of the *Daubert* criteria because “there were simply too many analytical gaps between the opinions Dr. Atlas sought to offer and the data upon which he relied (or did not rely) to derive them.”¹⁷⁹ In particular, the court was concerned that:

Dr. Atlas stated that he did not know – and did not need to know, before reaching his opinions – the following information: (1) when the patient’s clinical symptoms began to manifest; (2) the span of time during which the patient suffered manganese exposures; (3) the details or extent of the patient’s daily and weekly manganese exposures, such as whether his exposures ever exceeded the [threshold limit value] (which, as defendants admit, does carry risk of neuro-injury); (4) how the patient’s exposures during the six-month period before his MRI compared with his exposures during the rest of his career; (5) the amount of manganese exposure necessary to result in an abnormal MRI; (6) the amount of manganese exposure necessary to cause clinical symptoms; (7) the rate at which manganese clears from the brain; and (8) whether manganese

lepsy Program, P.A., No. 00–cv–39, 2001 WL 1078633, at *7 (D. Minn. Apr. 18, 2001).

176. See, e.g., *Ruppel v. Kucanin*, No. 3:08–cv–591, 2011 WL 2470621, at *6–10 (N.D. Ind. June 20, 2011); *Booth*, 2009 WL 4544743, at *2–4.

177. See, e.g., *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974–75 (8th Cir. 1995); *Jarvis v. Sec’y of the Dep’t of Health & Human Servs.*, 99 Fed. Cl. 47, 64–65 (Fed. Cl. 2011); *In re Welding Fume Prods. Liab. Lit.*, No. 1:03–cv–17000, 2010 WL 7699456, at *55 (N.D. Ohio June 4, 2010).

178. *Welding Fume*, 2010 WL 7699456, at *55.

179. *Id.*

clears from the brain even if exposure to manganese continues.¹⁸⁰

The court found that these “analytical gaps” were sufficient to exclude the testimony under *Daubert*, but it did not provide further explanation.¹⁸¹

Similarly, in the *Hose* manganese exposure case, the circuit court concluded that the expert testimony was reliable without identifying or mentioning any of the individual *Daubert* factors because there was indeed a “sufficient factual basis” underlying the expert’s opinion.¹⁸² The court interpreted the *Daubert* reliability principle as requiring that “the evidence must be based upon scientific knowledge, i.e., ground[ed] in the methods and procedures of science, and must represent more than [a] subjective belief or [an] unsupported speculation.”¹⁸³ The court found that the expert testimony “clearly had sufficient factual basis” and specifically referenced the expert’s reliance on the plaintiff’s medical history; laboratory studies showing the plaintiff’s manganese levels; the expert’s clinical examinations of the plaintiff-appellee; “a series of [MRIs] suggesting the presence of manganese in [the plaintiff’s] brain; and reports from other doctors.”¹⁸⁴

180. *Id.*; see also Deposition of Scott Atlas at 42, 45–46, 63–64, 100, 101, *Welding Flume*, 2010 WL 7699456 (No. 1:03-cv-17000) (transcribing the expert’s deposition statements describing the information that he did not know).

181. *Welding Flume*, 2010 WL 7699456, at *55. However, the court held that the expert could testify “(1) about his own experience and literature review, which showed that some patients with enough manganese accumulation to yield an abnormal MRI have no clinical symptoms; (2) about his literature review, which indicated that patients who have abnormal MRIs due to manganese accumulation seem to maintain these abnormal MRIs for at least three months; (3) that, because he has never seen a report in the literature of a faster clearance rate than three months, he infers that faster clearance rates are unlikely; and (4) he infers from these facts that it takes less manganese accumulation in the brain to cause an abnormal MRI than to cause sufficient brain damage to result in clinical symptoms.” *Id.*

182. *Hose*, 70 F.3d at 972–75.

183. *Id.* at 972 (internal quotation marks omitted). The *Hose* opinion was written in 1995, before *Kumho Tire* held in 1999 that the *Daubert* principles applied to non-scientific testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). The *Hose* court’s outdated interpretation of *Daubert* is only relevant here to the extent it gives context to the *Hose* court’s analysis.

184. *Hose*, 70 F.3d at 974–75 (“Dr. Angle’s opinion testimony clearly had sufficient factual basis. In addition to patient history, Dr. Angle relied on laboratory studies showing elevated levels of manganese in Hose’s body and on his work clothes, her own clinical examinations of Hose showing physical impairment, a series of magnetic resonance images [] suggesting the presence of manganese in

Lastly, in the *Jarvis* vaccine injury compensation case, the Court of Federal Claims held that the plaintiff-petitioner's expert testimony failed the *Daubert* reliability requirement¹⁸⁵ because there was no objective evidence that the plaintiff-petitioner actually suffered the injury upon which her claim was based.¹⁸⁶ The court held that expert testimony in vaccine injury compensation cases needs to be "connected to the existing data or methodology" by more than "the *ipse dixit* of the expert" because the Special Master will otherwise reject any expert testimony with "too great an analytical gap between the data and the opinion proffered."¹⁸⁷ In this case the expert offered his "opinion that petitioner had suffered an inflammatory brain lesion that was too small or too short-lived to be detected by diagnostic imaging," but the expert failed to cite to any publications or policy statements in support of his statement, thus leaving the court with an "evidentiary record devoid of any objective indicia" and "nothing but [the expert's] *ipse dixit* that the hypothesized injury ever occurred."¹⁸⁸ The court found that the

Hose's brain, and reports from other doctors showing memory loss, sensory loss, slow cognition, and other ailments.").

185. *Jarvis v. Sec'y of the Dep't of Health & Human Servs.*, 99 Fed. Cl. 47, 60 (2011) (asserting that, for Vaccine Act cases, "[t]he Federal Circuit has held that this reliability inquiry may be appropriately guided by the general principles set forth in *Daubert*"); *see also Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338–39 (Fed. Cir. 2010) ("We have previously held that Special Masters may look to the *Daubert* standards in evaluating expert testimony. . . . By inclusion of the terms 'relevant and reliable,' Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters."); *Terran v. Sec'y of Dep't of Health & Human Servs.*, 41 Fed. Cl. 330, 336 (1998) ("Although the Federal Rules of Evidence do not apply in vaccine cases, the [Court of Federal Claims] believes *Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence. . . . While the Supreme Court designed the test to determine whether evidence is relevant and reliable in the context of the Federal Rules of Evidence, [the *Daubert* test] is equally capable of being used to determine whether information is relevant and reliable in the context of the Vaccine Act."), *aff'd sub nom. Terran ex rel. Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302 (Fed. Cir. 1999); *cf. Estep v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 664, 667 n.2 (1993) (rejecting the *Daubert* approach for Vaccine Act cases because the *Daubert* analysis applied only to cases governed by the Federal Rules of Evidence).

186. *Jarvis*, 99 Fed. Cl. at 51.

187. *Id.* at 61.

188. *Id.* at 64. Subsequent cases have also cited *Jarvis* for this proposition. *See, e.g., Roberts v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698, at *5 (Fed. Cl. Aug. 29, 2013); *Dingle v. Sec'y of Health & Human Servs.*, No. 08-579V, 2013 WL 4083220, at *12 (Fed. Cl. July 23, 2013); *Isaac v. Sec'y of the Dep't of Health & Human Servs.*, 108 Fed. Cl. 743, 768 (2013), *aff'd sub nom. Isaac v. Sec'y of Health & Human Servs.*, 540 F. App'x 999 (Fed. Cir. 2013).

expert testimony was therefore properly excluded on *Daubert* reliability grounds without conducting further analysis into the individual *Daubert* factors.¹⁸⁹

The *Welding Fume, Hose*, and *Jarvis* cases illustrate how a court might conduct a *Daubert* reliability analysis without specifically referencing any of the individual *Daubert* factors. The case law suggests that parties should consider whether the expert testimony is based upon sufficient facts and objective evidence and whether there are analytical gaps in the expert's methodology or conclusions.

iii. The Third Approach: A Rule-702-Based Analysis of Reliability

a. First Version: A Rule-702-Based Analysis of Reliability That Applies the Rule 702 Criteria

As yet another alternative to evaluating reliability, courts might choose to analyze the expert testimony without using the *Daubert* framework at all.¹⁹⁰ One approach is to assess the expert testimony directly under the requirements of Rule 702, as illustrated by the *Huber* manlift case.¹⁹¹ In *Huber* the district court expressly rejected a *Daubert* analysis and analyzed reliability directly under the amended Rule 702 criteria, explaining that “the *Daubert* factors are not talismanic” and “do not have to be ‘met’ before expert testimony can be found reliable.”¹⁹² The court structured its reliability analysis based on “all three of the Rule 702 criteria,” which it described as requiring that “(1) expert testimony be based upon sufficient facts or data, (2) expert testimony be the product of reliable principles and methods, and (3) those principles and methods be applied reliably to the facts of the case.”¹⁹³ First the court found that the expert's causation testimony was indeed based on sufficient facts and data such as the patient's encephalography (EEG) brain scans, the

189. *Jarvis*, 99 Fed. Cl. at 65 (“Given the lack of any objective basis for Dr. Tornatore's opinion testimony, the Chief Special Master correctly applied basic principles of evidentiary reliability when she discounted this expert's bare assertions.”).

190. *See, e.g.*, *Huber v. JLG Indus., Inc.*, 344 F. Supp. 2d 769, 773 (D. Mass. 2003).

191. *Id.*

192. *Id.*; *see also* *Carlucci v. CNH Am. LLC*, No. 10-12205-DPW, 2012 WL 4094347, at *3 (D. Mass. Sept. 14, 2012) (citing *Huber* for the proposition that the four *Daubert* factors “are not the end of the inquiry; rather, they are merely helpful guidelines for a judge to consider in weighing the overall question of admissibility”).

193. *Huber*, 344 F. Supp. 2d at 773.

patient's medical history,¹⁹⁴ and the patient's injury diagnosis.¹⁹⁵ Second, the court determined that the testimony was indeed the result of reliable principles and methods after the expert testified that (1) "her specialty and training is in epilepsy and seizure disorder," (2) "she was Huber's treating physician for his seizure disorder and had seen him after the accident but before litigation ensued," and (3) "she relied on brain images from EEG and MRI scans."¹⁹⁶ Third, the court stated without further explanation that the expert "reliably applied the principles and methods to the facts of this case."¹⁹⁷ The court concluded that the causation testimony satisfied all three of the Rule 702 requirements and was thus admissible on reliability grounds.¹⁹⁸

b. Second Version: A Rule-702-Based Analysis of Reliability That Applies the Daubert Principles

Finally, courts might conduct the Rule 702 analysis through an application of the *Daubert* principles in a hybrid approach that essentially evaluates reliability under both the *Daubert* framework and the Rule 702 framework.¹⁹⁹ Consider the expert witness's causation testimony in the *Lennon* employment injury case.²⁰⁰ In *Lennon* the expert testified that the plaintiff's accident caused white matter lesions, demyelination, and processing deficits in the plaintiff's brain.²⁰¹ The expert based his conclusions on his own experience as a board certified neurologist, his understanding of peer-reviewed

194. It is interesting to note that, in deciding whether the expert testimony was based on sufficient facts and data, the court specifically singled out the expert's reliance on the plaintiff's medical history despite the fact that the expert had never personally seen the plaintiff's medical records and instead relied on the patient's self-reporting. Partial Testimony of Dr. Catherine Phillips, *Huber*, 344 F. Supp. 2d 769 (No. 00-cv-40079) ("Q[uestion:] So your reasoning is more or less that he suffered a closed head injury in the accident and that he had no seizures before the accident. And there is nothing else in his medical history that is capable of causing a seizure disorder, therefore, his accident caused his seizure disorder; is that about it? A[nsWER:] As far as we know—I don't have access to his medical records, but I have no reason to disbelieve this young man that he has never had seizures beforehand or if he—there is a question of him in one of my notes as to whether he has had something, but certainly he had never had epilepsy or recurrent seizure disorder. And this injury was very significant.").

195. *Huber*, 344 F. Supp. 2d at 773.

196. *Id.*

197. *Id.*

198. *Id.*

199. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589, 595 (1993).

200. *See Lennon v. Norfolk & W. Ry. Co.*, 123 F. Supp. 2d 1143, 1146 (N.D. Ind. 2000).

201. *Id.* at 1155–56.

neurological articles on head trauma and white matter lesions, and his comparison of the plaintiff's MRI scan with textbook examples of MRI scans showing white matter lesions.²⁰² In response the defense argued that the expert's conclusion was invalid because there was "no reliable scientific evidence" supporting his claim that trauma can cause the plaques appearing in the MRI scans of the plaintiff's brain and because there was no specific study suggesting that the type of fall that the plaintiff experienced could cause such an injury.²⁰³ The court first noted that "[t]he present motions raise the issue of whether . . . Dr. Schreiber's testimony should be admitted pursuant to [Rule] 702," which "in turn necessitates application of the United States Supreme Court's decision in *Daubert*."²⁰⁴ The court then rejected the defendant's argument and ruled in the plaintiff's favor, explaining that to otherwise "require a physician to point to so specific a test would be to defeat the general purpose behind *Daubert* which is to prevent the jury from being persuaded by something which can only be deemed to be junk science."²⁰⁵ Instead, the court continued, shaky but admissible evidence has traditionally been tested by cross-examination, the presentation of contrary evidence, and jury instructions on the burden of proof because it is the jury's responsibility to decide whether the expert's opinion is believable; it is not the court's responsibility to decide whether the expert's opinion is correct.²⁰⁶ Thus, the *Lennon* court found the plaintiff's expert testimony sufficiently reliable under the *Daubert* principles as cloaked inside a Rule 702 analysis.²⁰⁷

III.

EVALUATION OF THE COURT'S APPROACHES TO ASSESSING THE EVIDENTIARY ADMISSIBILITY OF EXPERT TESTIMONY ON MRI BRAIN SCANS

Expert testimony on MRI brain scans faces many analytical and fundamental challenges under the existing evidentiary admissibility framework. Although the analysis in Part II that led to the identification of the admissibility framework was drawn specifically from the MRI brain scan context, the problems facing the *Daubert* and Rule 702 approaches in accommodating MRI brain scan technology reflect the generalized problems facing the approaches in accom-

202. *Id.*

203. *Id.* at 1146, 1158.

204. *Id.* at 1146.

205. *Id.* at 1158.

206. *Lennon*, 123 F. Supp. 2d at 1159.

207. *Id.* at 1146, 1158–59.

modating any new and innovative technology. These problems generate unpredictability in how courts might choose and conceptualize their approaches to admissibility and how they might implement the requirements of expert qualification, testimony relevance, and testimony reliability during the admissibility analysis. Courts can reduce this theoretical and practical unpredictability by providing the parties with Expert Witness Instructions that preview the court's planned or preferred approach to expert witness admissibility.

A. *Observations on How the Case Examples Fared Under the Existing Admissibility Approaches*

This section uses the case-specific analysis from Part II.(C.) (2) to assemble a big-picture view of how well the existing framework functions in evaluating each of the qualifications, relevance, and reliability requirements. The process of drawing general observations across myriad case opinions and court approaches reveals itself to be a challenging (and perhaps impossible) endeavor, which this Note attributes to two problems. First the sample size of case examples is simply too small for statistically significant findings, which is an unresolvable consequence of the dearth of published, substantive case opinions on this particular topic. Second there is a troubling lack of transparency in how courts identify and implement their admissibility analyses. There remains substantial unpredictability in how courts understand and apply the existing admissibility framework.

1. The Qualifications of the Expert Witness

Three of the ten MRI brain scan cases focused on expert qualifications as a key evidentiary issue, suggesting that expert qualifications went unchallenged in the seven other featured cases. In all three cases the courts held that the expert witness possessed sufficient credentials and work experience to testify about the MRI brain scans.²⁰⁸ The small sample size of cases and the diversity of

208. As a reminder, in the *Booth* carbon monoxide case, the court focused on the expert's board certification, his current occupation as a practicing neurologist; his experience in reviewing 100,000 MRI scans in total and at least 150 MRI scans in the carbon monoxide context; his personal evaluation of the plaintiff's MRI scans; and the medical literature he cited in support of his opinion. *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *2 (D.N.M. Mar. 23, 2009); see also Defendants' Memorandum of Law in Support of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orrison, Jr., M.D., *supra* note 92, at ¶¶ 7-8. In the *Newman* cell phone case, the court discussed the expert's

case outcomes make it impossible to draw any statistically significant conclusions about how courts evaluate the expert qualifications requirement in the MRI brain scan context.

So what observations *can* one draw from these case results? Perhaps these case outcomes suggest that the qualifications requirement could be easy to satisfy because the MRI brain experts need only professional certification, current occupational research or practice, both general and brain-specific experience in the field, and supporting medical research. This may be because the requirement is straightforward; proponents can accurately anticipate how the court will assess the MRI brain expert's qualification, which allows them to be selective in choosing experts and strategic in emphasizing the expert's credentials and work experience to the court. Courts may have high levels of tolerance in evaluating whether the MRI brain expert satisfies the preliminary evidentiary requirement of expert qualification. Or perhaps the qualifications requirement is difficult for opponents to contest, which discourages them from challenging an expert's qualifications at all.

The most realistic interpretation of how courts evaluate MRI brain expert testimony, however, is that evaluating expert qualifications is an inherently subjective, discretionary, and case-specific process, which makes it impossible to draw any useful observations from the case law. Further transparency on how civil courts conceptualize, understand, and enforce the expert qualifications requirement in the MRI brain scan context would shed light on the whole process.

2. The Relevance of the Expert Testimony

Only two of the ten MRI brain scan cases highlighted testimony relevance as a key evidentiary issue, suggesting that satisfaction of the relevance requirement went unchallenged in the eight other cases. In both of the two cases that did discuss relevance, the courts found the expert testimony inadmissible because it was either too vague or too unsupported to be related to the issue in dispute in

current occupation as an oncology professor, thirty years of experience, experience in diagnosing and treating thousands of cancer cases and hundreds of brain cancer cases, and his own published research studies. *Newman v. Motorola*, 218 F. Supp. 2d. 769, 775 (D. Md. 2002); *see also* Hardell Transcript of *Daubert* Hearing at 705, *Newman*, 218 F. Supp. 2d. 769 (No. 00-cv-2609). In the *Ruppel* vehicular negligence case the court held that the expert was qualified despite the fact that she had consulted with her colleagues before forming her opinion. *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *3 (N.D. Ind. Jun. 20, 2011).

the case.²⁰⁹ Again the small sample size and diversity of results precludes this Note from drawing any statistically robust conclusions about how courts in the MRI brain scan context evaluate the relevance of expert testimony. Perhaps the relevance requirement is straightforward because proponents of expert testimony know to emphasize that the testimony contains enough detail and enough supporting research, while opponents know to argue that the expert testimony is too vague and unsupported for the court to find relevance. Or perhaps the relevance requirement is not straightforward, but litigating parties find it easy enough to predict how the court will assess the testimony's relevance. Again the most realistic interpretation is likely that evaluating testimony relevance is an inherently subjective, discretionary, complicated, and contextual process, which makes it impossible to draw any useful observations from the case law. Additional guidance on how civil courts evaluate relevance would be helpful in understanding the admissibility approaches.

3. The Reliability of the Expert Testimony

The courts' approaches to the admissibility of MRI brain expert testimony diverged the most during the reliability analyses, as seen in Part II.(C.) (3). Again the varied case results and small sample sizes made it impossible to distill unified themes or generalized guidance from the case results. The three different approaches to testimony reliability constitute, at least in the MRI brain scan context, the greatest source of unpredictability for parties preparing pretrial motions and case strategy in case involving expert testimony on MRI brain scans. Will the court be more amenable to a factors-based *Daubert* approach, a totality-based *Daubert* approach, a statute-based Rule 702 approach, or a hybrid *Daubert*-based Rule 702 approach? Should parties plan to present evidence on the *Daubert* factors and specifically address the testability, peer review,

209. As a reminder, in the *Carlen* medical malpractice case, the court excluded the expert's causation testimony as irrelevant because the testimony did not identify alternative medical treatments or address their efficacy in slowing the plaintiff's tumor growth, which meant that the expert's causation testimony did not logically relate to the contested legal issue in the case. *Carlen v. Minn. Comprehensive Epilepsy Program, P.A.*, No. 00-cv-39, 2001 WL 1078633, at *7 (D. Minn. Apr. 18, 2001). In the *Newman* cell phone case the court excluded the expert testimony as irrelevant because the expert used quantitatively and qualitatively discrepant research to form his opinion, which meant that the expert could not extend the research basis of his opinion into generalized statements on the contested legal issue. *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 778 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003).

error rate, and general acceptance of the expert testimony? Should they prepare their experts to present testimony that helps the jury understand the brain MRI evidence, is based on sufficient facts and data, is the product of reliable principles and methods, and reliably applies those principles and methods to the facts of the case? Should they take a hybrid approach and incorporate both the *Daubert* principles and the statutory criteria into their presentation of the expert testimony? Or should they eschew formal criteria and requirements altogether and opt for a free-form presentation that is more conducive to a case-specific totality review? It is clear that there remains substantial unpredictability in how courts understand and apply the existing admissibility framework.

i. The Factors-Based *Daubert* Approach

Four case opinions used the factors-based *Daubert* approach²¹⁰ to evaluate the expert testimony's reliability. Two of these courts found the contested testimony reliable²¹¹ and two courts found the

210. Although the factors-based *Daubert* section in Part II.(C.) (3.) (i) discussed a total of five cases, only the *Booth*, *Carlen*, *Newman*, and *Ruppel* courts adopted the *Daubert* approach to evaluating reliability. *Lugo* evaluated reliability under the *Frye* approach and ultimately found that the expert testimony was generally accepted and thus admissible. *Lugo v. N.Y.C. Health & Hosps. Corp.*, 929 N.Y.S.2d 264, 278–80 (N.Y. App. Div. 2011).

211. In the *Booth* carbon monoxide case the court concluded that the expert's MRI testimony satisfied all four *Daubert* factors and ultimately held that the evidence was reliable. Specifically the court found that: (1) the expert's failure to confirm his opinion with external sources did not disqualify his testimony on testability grounds, (2) neither the expert's own lack of published articles nor his failure to externally confirm his opinion precluded satisfaction of the peer review requirement because both concerns addressed the weight of the evidence rather than its admissibility, (3) the expert's contrary interpretations of similar MRI brain scans did not preclude satisfaction of the error rate requirement because such inconsistencies went to the weight of the evidence, and (4) research studies reaching quantitatively different conclusions from the expert's own conclusions did not preclude the court from finding general acceptance because the quantitative discrepancy went to the weight of the evidence. *Booth*, 2009 WL 4544743, at *3–4. Similarly, in the *Ruppel* medical malpractice case, the court considered all four of the *Daubert* factors and decided that the expert testimony satisfied each of them, which led the court to conclude that the testimony was reliable. Specifically the court found that: (1) the underlying DTI methodology had high levels of testability based on the expert's declarations of retest reliability and on the reproducibility results of a single case study, (2) eighty-three articles generally discussing DTI in the brain injury context and eleven articles specifically discussing DTI's efficacy in detecting mild traumatic brain injury constituted sufficient peer review, (3) the methodology fulfilled the error rate requirement because the expert took procedural steps to minimize errors and statistical measures to confirm the low error rate, and (4) DTI was generally accepted as a diagnostic tool for brain inju-

contested testimony unreliable.²¹² These results may suggest that the greater the number of *Daubert* factors considered, the greater the likelihood of the court finding the testimony reliable. However, the more likely interpretation of these results is that the court considers as many *Daubert* factors as the parties choose to dispute, and its analysis is highly contextual and driven by case-specific facts. Either way it is clear that the case law can provide examples of how courts have used the *Daubert* criteria to resolve reliability disputes, but it cannot provide a magic formula, a bright-line rule, or any predictive power for how courts evaluate the admissibility of expert testimony on MRI brain scans.

ii. The Totality-Based *Daubert* Approach

Three case opinions used the totality-based *Daubert* approach to evaluate the expert testimony's reliability.²¹³ These decisions demonstrate that the challenges of interpreting the case outcomes under the factor-based *Daubert* approach are magnified with regards to trying to characterize or explain the case outcomes under the totality-based *Daubert* approach. The totality approach gives

ries because it was regularly used in some hospitals and because there were many research articles vouching for its diagnostic abilities. *Ruppel*, 2011 WL 2470621, at *6–10.

212. In the *Carlen* medical malpractice case the court only considered two of the *Daubert* factors, found that the expert testimony failed both of them, and ultimately declared that the testimony was unreliable. Specifically the court found that: (1) the expert's methodology did not meet the error rate requirement because the expert failed to present any evidence of his error rate and (2) the method was not generally accepted because the expert could not cite to any research studies that supported its validity. *Carlen*, 2001 WL 1078633, at *7. And in the *Newman* cell phone case the court only discussed two of the *Daubert* factors, determined that the expert testimony failed both of them, and concluded that the testimony was unreliable. Specifically the court held that: (1) the expert's method for testing laterality had not been used or tested by anyone else and (2) the expert's conclusions were not generally accepted because the majority of published reports had reached the qualitatively opposite conclusion. *Newman*, 218 F. Supp. 2d at 783.

213. In the *Hose* manganese exposure case the court determined that the expert testimony was reliable because the expert considered multiple sources (such as the plaintiff's medical history, available laboratory studies, the expert's clinical examination, and reports from other doctors) in addition to the MRI brain scans before forming his opinion. *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 972–75 (8th Cir. 1995). In contrast the courts in both the *Jarvis* vaccine injury case and the *Welding Fume* manganese exposure case found the contested expert testimony unreliable because there were too many "analytical gaps" between the expert's conclusion and the available data upon which it was based. *Jarvis v. Sec'y of the Dep't of Health & Human Servs.*, 99 Fed. Cl. 47, 65 (2011); *In re Welding Fume Prods. Liab. Lit.*, No. 1:03-cv-17000, 2010 WL 7699456, at *55 (N.D. Ohio June 4, 2010).

courts the freedom to structure the reliability analysis entirely around the case-specific facts without forcing their concerns and discussions within the confines of the four established *Daubert* factors. This tailored approach may be desirable to the extent that it provides the litigants with a personalized evaluation of the contested expert testimony, but it risks the court's reliability analysis becoming a completely unpredictable and discretionary process. This makes it harder for proponents of expert testimony to anticipate how the testimony will fare in the pretrial admissibility hearing because so much depends on how opposing counsel mounts the challenge and what the court decides to emphasize as an indicator of reliability and so little depends on how courts have handled the reliability question in previous cases. The opacity of the process and decreasing relevance of previous cases may encourage opposing counsel to present as many reliability challenges as possible hoping something sticks, regardless of whether similar challenges succeeded in the past, because they have nothing to lose. It is also possible that the risk of multiple reliability challenges and of inconsistent treatment across courtrooms discourages plaintiffs from presenting expert testimony on MRI brain scans at all. This would pervert the *Daubert* framework's goal of making sure that only unqualified, irrelevant, and unreliable testimony is excluded from the courtroom.

In light of the totality approach's unpredictability, why do civil courts still opt for the totality-based *Daubert* approach to evaluate testimony reliability? Perhaps judges find it too difficult to understand the *Daubert* criteria and scientific reliability generally, so their opinions acknowledge the utility of the *Daubert* criteria but purposely do not apply the actual *Daubert* factors in the reliability analysis.²¹⁴ Or perhaps judges understand the *Daubert* criteria perfectly well but affirmatively choose not to apply the factors because an unconstrained and individually-tailored analysis produces a better measure of scientific reliability than a set of one-size-fits-all factors.²¹⁵ It is clear that courts apply the totality-based *Daubert* ap-

214. This was the explanation suggested in a 2002 case survey of criminal appellate opinions in an effort to discern why case opinions in the wake of the *Daubert* decision increased their general discussions of *Daubert* but gave only cursory mention to the four *Daubert* factors. Groscup et al., *supra* note 16, at 367.

215. See COMM. ON IDENTIFYING THE NEEDS OF THE FORENSIC SCI. CMTY., NAT'L RESEARCH COUNCIL, STRENGTHENING FORENSIC SCIENCE IN THE UNITED STATES: A PATH FORWARD 27 (2009) ("[A]ny checklist for the admissibility of scientific or technical testimony is imperfect. Conformance with items on a checklist can suggest that testimony is reliable, but it does not guarantee it.").

proach in a black box. Parties would benefit from more predictability and guidance.

iii. The Rule 702 Approach

Two of the ten exemplar cases adopted the Rule 702 approach to evaluating expert testimony reliability.²¹⁶ Although the small sample size precludes statistically robust conclusions, the observation that only two cases used Rule 702 as the primary framework for evaluating reliability, and that one of these cases essentially applied the *Daubert* approach, suggests that courts evaluating testimony reliability will base their analyses primarily around the *Daubert* principles instead of the statutory criteria from Rule 702.

B. Fundamental Problems of Blurring Categorical Analyses Under the Existing Approaches

The difficulty of organizing the case examples from Part II into unified themes or generalized guidance stems from the deeper, fundamental problems of courts blurring categorical distinctions in the course of using and applying the existing admissibility framework. Some courts blurred the distinction between the expert qualifications and testimony reliability analyses, which creates uncertainty around what the admissibility requirements demand. Some courts blurred the distinction between evaluating the expert's methodology and reasoning and evaluating the expert's ultimate conclusions, which unpredictably expands the scope of the established framework. In addition some courts appeared to blur the distinction between issues of evidentiary admissibility and issues of evidentiary weight, which undercuts the purpose of the admissibility requirements and unpredictably shrinks their scope. The three instances of categorical blurring may not appear individually in every case, but collectively they suggest that the existing framework for analyzing expert qualifications, testimony relevance, and testimony reliability generates considerable unpredictability in theoretical cohesion and practical application.

First, when the qualifications, relevance, and reliability analyses in the case law blend together, it is hard to tell what the require-

216. The court in the *Huber* products liability case directly applied the statutory criteria listed in the text of Rule 702 and found the contested testimony reliable. *Huber v. JLG Indus., Inc.*, 344 F. Supp. 2d 769, 733 (D. Mass. 2003). In contrast the *Lennon* court in an employment injury case applied the hybrid approach by invoking the *Daubert* principles and ultimately found the expert testimony reliable. *Lennon v. Norfolk & W. Ry. Co.*, 123 F. Supp. 2d 1143, 1146, 1158–59 (N.D. Ind. 2000).

ments of the expert testimony are. This problem arises when courts use the same line of reasoning to prove that the testimony satisfies two distinct requirements. As discussed, the *Carlen* court looked at whether the expert could cite to specific research studies, an issue that seems more relevant to the peer review analysis, during its discussion of general acceptance.²¹⁷ The *Booth* and *Newman* courts considered the supporting medical literature during their analyses of both peer review and expert qualifications.²¹⁸ Finally, the *Ruppel* court relied on the expert's comparative expertise, an issue seemingly confined to the expert qualifications requirement, during its reliability assessment of testability.²¹⁹ The observation that the admissibility discussions sometimes blend into each other would be less surprising if it only happened with the *Daubert* factors, as seen in the *Carlen* case, since the four factors do share the common goal of enabling the court to assess reliability.²²⁰ However, the *Booth*, *Newman*, and *Ruppel* courts took the blurring even further by muddling the distinction between the expert qualifications and reliability analyses, which is peculiar because the requirements serve completely different functions. The qualifications inquiry focuses on the expert witness and ensures that she is qualified to give expert testimony on the particular subject, while the reliability analysis focuses on the testimony itself and ensures that it is based on reliable principles. Conflating the qualifications and reliability analyses makes it difficult to understand the nature, scope, and effect of each requirement in theory and in practice.

A second problem arises when courts blur the distinction between the expert's methodology and conclusions. In Part II.(C) the blurring occurred during the relevance analysis, as seen in the *Newman* case, and during the reliability analysis, as seen in the *Welding Fume* case. In *Newman*, the court determined that research address-

217. *Carlen*, 2001 WL 1078633, at *7.

218. *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *1-3 (D.N.M. Mar. 23, 2009); *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 775, 777 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (4th Cir. 2003).

219. *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *9 (N.D. Ind. June 20, 2011).

220. See Paul C. Gianelli et al., *Reference Guide on Forensic Identification Expertise*, in FED. JUDICIAL CTR., REFERENCE MANUAL FOR SCIENTIFIC EVIDENCE 55, 64 (3rd ed. 2011) ("The [*Daubert*] factors listed by the Court are generally complementary. For example, the second factor, peer review and publication, is a means to verify the results of the testing mentioned in the first factor; and in turn, verification can lead to general acceptance of the technique within the broader scientific community. These factors serve as circumstantial evidence that other experts have examined the underlying research and found it to be sound. Similarly, another factor, an error rate, is derived from testing.")

ing both benign and malignant tumors as a group could not be generalized to support conclusions about only malignant tumors and thus found the expert testimony irrelevant to the plaintiff's claim alleging an increased risk of malignant tumors.²²¹ This can be interpreted as a decision on the integrity of the expert's methodology since the court frowned upon the expert's manner of using research on tumors in general to generate conclusions on a specific type of tumor. At the same time it can also be interpreted as a decision on the integrity of the expert's conclusions since the court disapproved of the expert's intermediate conclusion that research on tumors in general could support a final conclusion on a specific type of tumor. Similarly, in *Welding Fume*, the court held that the expert's causation testimony was unreliable because he based his conclusion on research that failed to address the patient's timeline of symptoms, the patient's manganese exposure, the manganese exposure necessary for causation, or the manganese's rate of dissipation.²²² This can be interpreted as an evaluation of the expert's methodology, since the court rejected the expert's method as generating conclusions beyond what his research could support, and also as an assessment of the expert's conclusions, since the court rejected the expert's conclusion that his research could in fact support an opinion on causation. The problem with the courts blurring the distinction between methodology and conclusion is that, as gatekeepers, the courts should focus "solely on principles and methodology, not on the conclusions that they generate."²²³ *Daubert* instructed courts not to exclude expert testimony merely because they disagree with the expert's conclusions, and so courts should not stretch the existing admissibility framework beyond what *Daubert* originally authorized them to do.²²⁴ The method may be reliable and scientifically valid even if the court disagrees with the expert's conclusions.

To be fair to the *Newman* and *Welding Fume* courts, the challenge of evaluating the expert's methodology and reasoning without passing judgment on the expert's conclusion is not new, and it

221. *Newman*, 218 F. Supp. 2d at 778.

222. *In re Welding Fume Prods. Liab. Lit.*, No. 1:03-cv-17000, 2010 WL 7699456, at *55 (N.D. Ohio June 4, 2010).

223. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-95 (1993) ("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.").

224. *Id.*

is not specific to the MRI brain scan context. Four years after *Daubert*, the *Joiner* court excused its own failure to maintain the distinction by proclaiming that:

conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.²²⁵

The *Joiner* decision did not clearly define the extent to which evaluations of the expert's methodology can tread into the previously forbidden realm of evaluating the expert's conclusions. The ambiguity of when courts find it acceptable to blur the distinction between methodology and conclusions introduces yet another unpredictable complication in understanding the framework in theory and applying it in practice.

A third problem is that courts sometimes conflate the issues of evidentiary admissibility and evidentiary weight, which runs the risk of the courts unpredictably shrinking the scope of the admissibility requirements by reframing admissibility issues as weight of the evidence issues. The court is tasked with the pretrial responsibility to evaluate the admissibility of the expert's testimony and to decide whether the testimony is qualified, relevant, and reliable enough to be used at trial. The court's job is to police the line between issues of admissibility, which the court should resolve, and issues of evidentiary weight, which the jury should resolve. The problem arises when courts decline to exclude otherwise inadmissible evidence by rejecting defense counsel's admissibility challenges and reframing them as sufficiency arguments that should instead be raised during trial. For example, as previously noted in Part II.(C.) (1), both the *Booth* and *Ruppel* courts held that the experts' qualifications were sufficient for admissibility purposes despite opposing counsel's challenges that the experts had made errors or sought external consultation in the past.²²⁶ The effect of these decisions was to undercut the scope, purpose, and ability of the qualifications requirement to ensure that the jury would only hear expert testimony from

225. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

226. *Ruppel v. Kucanin*, No. 3:08-cv-591, 2011 WL 2470621, at *3 (N.D. Ind. June 20, 2011); *Booth v. KIT, Inc.*, No. 06-cv-1219, 2009 WL 4544743, at *2 (D.N.M. Mar. 23, 2009); Defendants' Memorandum of Law in Supp. of Motion in Limine to Exclude the Opinion Testimony of Plaintiffs' Expert William W. Orison, Jr., M.D., *supra* note 92, at ¶ 9.

sufficiently qualified expert witnesses. The *Booth* and *Ruppel* courts also rejected opposing counsel's admissibility challenges on weight of the evidence grounds during the testability, error rate, and general acceptance discussions under the factor-based *Daubert* approach to reliability.²²⁷ Shrinking the scope of the qualifications requirement, or of any other admissibility requirement, generates unpredictability in how the courts will use the existing framework to evaluate the admissibility of expert testimony both in theory and in practice.

C. *Proposal to Reduce Unpredictability Under the Existing Framework:
Encourage Courts to Issue Expert Witness Instructions to
Guide the Litigating Parties and Expert Witnesses
in Advance*

The analytical and fundamental challenges facing MRI brain testimony under the existing admissibility framework make it very challenging for parties to anticipate how courts will conceptualize the requirements in theory and implement them in practice. One way to increase transparency is to have courts issue expert witness instructions identifying their planned or preferred approaches to evaluating the admissibility of expert witness testimony on MRI brain scans. This will increase the transparency of the admissibility process and guard against any temptation for the court to prematurely form an opinion on the expert testimony challenges and to later select a particular analytical approach in order to produce the desired admissibility result. The transparency and bias reduction effects on the admissibility process are especially relevant to expert testimony on MRI brain scans because of the rapidly developing nature of the underlying MRI technology and the growing presence of MRI brain scans in civil litigation. The same transparency and bias considerations also apply to all expert witness testimony because of its inherently technical characteristics and pervasive use in the courtroom. This section will discuss the logistics, benefits, and concerns associated with expert witness instructions in the broader context of all expert witness testimony, as the considerations raised are not theoretically or practically confined to the MRI brain scan context.

The court's process for formulating expert witness instructions would adapt the process for formulating jury instructions in order to notify the litigants of the proposed evaluation approach for the expert witness testimony. First the parties would disclose the iden-

227. *Ruppel*, 2011 WL 2470621, at *6–10; *Booth*, 2009 WL 4544743, at *3–4.

tivity of the expert witnesses they plan to call at trial. Second the court would allow each party to submit proposed expert witness instructions for the court's consideration. Third the court would read the proposed instructions, decide whether to accept any of the proposed language, and publish its own official version of the expert witness instructions through court order. In sum the expert witness instructions would increase transparency and predictability by encouraging the court to settle on a particular admissibility approach before hearing the expert witness challenges and by notifying the parties in advance of how the court planned to evaluate the expert testimony's admissibility.

The court would retain the discretion to choose the admissibility framework for evaluating the qualifications, relevance, and reliability, but the advance notice would reduce the unpredictability that often accompanies this discretion. For example the court might notify the parties that factual findings that the expert previously erred or sought external consultation would indeed be an admissibility issue, not a weight of the evidence issue, and would therefore disqualify an expert witness. This would reduce the likelihood of the court later conflating issues of evidentiary weight and admissibility in its analysis and would send an early signal to opposing counsel to save this argument for trial. In addition the court might decide to draw a bright line between assessing the expert's process of arriving at her conclusion as distinct from assessing the conclusion itself. This would greatly reduce the ambiguity seen in the *Newman* and *Welding Fume* decisions and would assure the parties that the court planned to abide by *Daubert's* mandate to focus on the expert's methodology rather than on her conclusions. Most importantly the court could tell the parties its reliability approach ahead of time, which would eliminate considerable unpredictability and anxiety because the parties would know whether to expect a factors-based *Daubert* approach, the totality-based *Daubert* approach, the Rule-702-based approach, or the hybrid approach to reliability.²²⁸

Consider the court's instructions to the expert witnesses in *Soldo v. Sandoz Pharmaceuticals Corp.*,²²⁹ which provide an illuminating example of how a court might formulate the expert witness instructions proposed in this Note. *Soldo* was a product liability case in which the plaintiff claimed that the defendant's lactation-related

228. Another option is the *Frye* general acceptance approach, at least for jurisdictions that still follow *Frye*.

229. 244 F. Supp. 2d 434 (W.D. Pa. 2003).

drug caused her to suffer a stroke.²³⁰ The court appointed its own expert witnesses to advise it on “whether the methodology or technique employed by plaintiff’s medical witnesses . . . in formulating their opinions, is scientifically reliable and whether the methodology or technology properly can be applied to the facts in issue.”²³¹

The *Soldo* court’s instructions to the expert witnesses were quite comprehensive. The court gave a causation-specific instruction that a “medical expert witness does not have to rely on definitive published studies before concluding that exposure to a particular object or chemical was the most likely cause of the plaintiff’s illness,”²³² as well as a clarifying instruction that “[t]he grounds for the expert opinion merely have to be good; they do not have to be perfect.”²³³ The court instructed the expert witnesses that “[i]n reaching your conclusion, your focus must solely be on principle and methodology and not on the conclusions they generate,” but also that “[c]onclusions and methodology are not entirely distinct from one another. Thus, the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable.”²³⁴ However, the court warned, “When an expert’s testimony relies in part on his own *ipse dixit* . . . it is open to attack” because “an expert’s self-serving assertion that his conclusions were derived by the scientific method [cannot] be deemed to be conclusive.”²³⁵ In evaluating reliability, the *Soldo* court instructed, the experts could consider the following non-exhaustive list of factors:

- (1) whether the expert’s hypothesis and methodology [have] been tested or are capable of being tested;
- (2) whether the expert’s hypothesis and methodology [have] been subjected to peer review and publication;
- (3) whether there is a known and potential error rate of the technique;

230. *Id.* at 441, 443.

231. Order of Court, Exhibit 1, Mar. 26, 2001, *Saldo*, 244 F. Supp. 2d 434 (No. CIV.A.98-1712), ECF No. 296, at 1. The case docket indicates that the court later revised its instructions to the expert witness in later court orders, but the revised instructions were not available online during the writing of this Note. *See, e.g.*, Order of Court, May 15, 2001, *Saldo*, 244 F. Supp. 2d 434 (No. CIV.A.98-1712), ECF No. 312; Order of Court, July 30, 2001, *Saldo*, 244 F. Supp. 2d 434 (No. CIV.A.98-1712), ECF No. 330.

232. Order of Court, Exhibit 1, Mar. 26, 2001, *supra* note 231, at 2.

233. *Id.* at 3.

234. *Id.* at 1, 3.

235. *Id.* at 4.

- (4) whether the hypothesis or technique has been generally accepted in the proper scientific community;
- (5) the existence and maintenance of standards controlling the methodology's operation;
- (6) the relationship of the technique to methods that have been established to be reliable;
- (7) the expert's qualifications; and
- (8) the nonjudicial uses to which the method has been put.²³⁶

The reliability factors suggested by the *Soldo* court appear to be an expanded version of the *Daubert* factors.²³⁷ The *Soldo* court's reliability factors also appear to merge the expert qualifications analysis into the reliability analysis, perhaps in acknowledgment of the tendency of the courts to blur the distinction between the two admissibility requirements as discussed in Part III.(B).

In addition to evaluating reliability the *Soldo* court also provided guidance on relevance or "fit." The court said that the experts must check for relevance or "fit" between the expert's conclusion and the facts while keeping in mind that "[t]here is no 'fit' where there is simply too great an analytical gap between the data and the opinion offered, as when an expert offers animal studies showing one type of cancer in laboratory mice to support causation of another type of cancer in humans."²³⁸ The court instructed that if the appointed experts were to conclude that the contested expert testimony was irrelevant or unreliable, then the appointed experts should "indicate if [the] opinion by the party's expert might represent a 'legitimate and reasonable' minority view within the profession."²³⁹

Thus the *Soldo* court issued instructions to the expert witnesses for the primary purpose of helping court-appointed expert witnesses evaluate the evidentiary admissibility of the plaintiff's expert witness testimony. The instructions in *Soldo* are one model of how courts can use similar instructions to help litigant-appointed expert witnesses and litigants prepare for the court's admissibility determination as proposed in this Note.

Advance notice of the court's intended admissibility approach, like the *Soldo* court's instructions to the expert, would reduce much of the unpredictability plaguing the existing admissibility frame-

236. *Id.* at 1–2.

237. See Joe S. Cecil, *Ten Years of Judicial Gatekeeping Under Daubert*, 2005 AM. J. PUB. HEALTH 74, 77 (Supp. 1 2005).

238. Order of Court, Exhibit 1, Mar. 26, 2001, *supra* note 231, at 3.

239. Cecil, *supra* note 237, at 77 (citing Order of Court, Exhibit 1, Mar. 26, 2001, *supra* note 231, at 4).

work. Expert witness instructions would allow all parties to operate from the same starting point, obviate court inclinations towards bias by encouraging the court to select its approach before reviewing the case-specific testimony, and reduce the risk of the court unexpectedly blurring categorical distinctions in the qualifications, relevance, and reliability analyses later. Transparency would benefit all parties: counsel could better anticipate the court's admissibility standards and prepare their experts accordingly; courts would see more targeted *Daubert* motions, more effective *Daubert* arguments, and more efficient *Daubert* hearings; and litigants could enjoy the strategic and financial benefits associated with the time, effort, and money saved by the advance notice.

There are, however, some conceptual drawbacks to the expert witness instructions proposal. These potential issues fall into two categories: those based on the relative utility of the expert witness instructions themselves and those that arise in the event that a court adopts an approach different from the one it identified in the expert witness instructions.

The utility-based set of drawbacks is easier to address because the benefits of increased transparency and predictability outweigh any theoretical limits on the expert witness instructions' utility, especially in comparison to the status quo. The first potential, utility-based drawback is that the admissibility analysis should be tailored to the case-specific facts and legal issues, so it is better for a court to adapt its legal approach to the parties' evidence and arguments rather than stubbornly sticking with a pre-announced approach that the court now knows is inappropriate for the case. This concern over poor tailoring is in practice less troubling than it seems because litigants who expect the court to take a particular approach to admissibility will be incentivized to structure their expert evidence and arguments around the court's selected approach. The court has already notified the parties of the evidentiary considerations it considers most important to the admissibility analysis, so parties have little to gain if they attempt to admit evidence or pursue lines of questioning that fall outside the scope of the approach. It is also important to remember that all of the different approaches under the existing admissibility framework pursue the same qualifications, relevance, and reliability goals, and so any harmful effects flowing from a bad fit between the selected admissi-

bility approach and the actual issues in the case will likely be insignificant.²⁴⁰

Second, while instructions perfectly tailored to the case-specific issues might in theory be ideal, expert witnesses and litigants would only enjoy the benefits of transparency if the court formulated the instructions before the parties submitted their expert disclosures and before the expert witnesses wrote their expert reports. The need for the court to issue the instructions before reading the expert disclosures and expert reports means that the court's admissibility approach will necessarily be more generalized instead of completely tailored to the individual case. However, even a generalized form of supplementary guidance would be an improvement on the current system—for both the parties and the court system as a whole—by providing greater transparency and certainty. Generalized advance notice would also make it harder for courts to give in to the temptation of analyzing admissibility with an eye for a particular evidentiary outcome.

Third, advance notice might provide little to no benefit in cases where the court adopts a totality-based approach because multi-factor balancing tests inherently carry some degree of unpredictability. But even if this is true advance notice will still provide transparency benefits in cases where the court does not choose a totality-based approach, which means expert witness instructions would still be an overall improvement over the status quo of keeping the parties in the dark.

Fourth, advance notice might disproportionately benefit litigants who have the time, money, and energy to strategically shape the expert testimony around the court's expectations for admissible evidence, putting resource-strapped parties at a comparative disadvantage. However, advance notice would still be an improvement over the status quo because resource-endowed parties would otherwise have in the current system an even larger advantage over resource-strapped parties when it comes to reading between the lines of contradicting case opinions, guessing at how the court will implement the admissibility requirements and comprehensively prepar-

240. Indeed, if taken to its logical conclusion, this argument suggests that courts could choose to agree on a single set of expert witness instructions and incorporate them into their local rules. This would accomplish the dual purposes of reducing the likelihood of a particular court straying from the pre-announced approach while still providing the litigating parties with advance notice. However, for this local rules proposal to work, courts as well as legislatures would first need to overcome any reluctance they might have with the idea of courts promulgating new evidentiary rules.

ing for every possible admissibility approach. All four of these potential drawbacks are outweighed by the increased transparency and predictability effects of the proposed expert witness instructions.

More troubling concerns arise if a court identifies one approach in its expert witness instructions and, after seeing the expert witness disclosures and hearing the evidentiary challenges, ultimately adopts a different approach in its admissibility analysis.²⁴¹ Whatever the justification, a court's decision to switch admissibility approaches midstream clearly and completely defeats the purpose of Expert Witness Instructions and advance notice. The problem of the court dashing the parties' expectations creates a host of interesting but hard questions. Would the court's departure from its pre-selected admissibility approach turn its forward-looking expert witness instructions into a non-binding and thus prohibited advisory opinion, or would it merely be superfluous as harmless dicta? Would the court's decision to switch approaches mid-case be reviewable on appeal? And if so, on what grounds and subject to which standard of review? For example, could the parties' frustrated expectations serve as the basis for a due process challenge? These issues should indeed be addressed before the legal system can implement the expert witness instructions proposal, but the resolution of these issues is beyond the scope of this Note and could perhaps serve as topics for future articles.

In sum courts should issue expert witness instructions in advance of any expert witness disclosures and admissibility challenges in order to provide the parties with a clearer view of the courts' planned or preferred approaches, standards, and expectations. Such expert witness instructions would increase transparency and predictability, reduce outcome-oriented bias, and substantially im-

241. This might occur if the court decides that a particular expert witness's testimony is more amenable to, say, the totality-based *Daubert* approach than to the factors-based *Daubert* approach because the specific type of MRI technology underlying the expert's methodology and reasoning is too novel to have garnered any peer review or general acceptance. The court might reason that expert testimony using this type of MRI scanning will likely never be admissible in court, regardless of its probative value, because it automatically fails two of the four *Daubert* factors. Under these circumstances the court might want to open-mindedly embrace all the insights offered by the latest MRI technology, and so it may justify its decision to switch approaches midstream by claiming that the benefits of retroactively tailoring the admissibility approach to the case-specific issues outweigh the harms of frustrating the parties' established expectations of a certain approach. The more cynical version of this argument is that the court, after considering the expert witness disclosures and challenges, selects a new approach in order to produce and justify a particular admissibility result.

prove the status quo of how courts currently evaluate the evidentiary admissibility of expert testimony on MRI brain scans in particular and of expert testimony in general.

CONCLUSION

Expert witness testimony interpreting MRI brain scans is appearing in courtrooms throughout the country, but the process of how civil courts conceptualize and implement the admissibility requirements for this type of expert testimony is poorly understood. Evidentiary doctrine requires courts to be gatekeepers and to exclude any expert testimony that fails to satisfy the expert qualifications, testimony relevance, or testimony reliability requirements, but how courts actually implement these admissibility principles in practice is unclear. A comprehensive survey of recent civil case law in the post-*Daubert* era provides examples of how courts have recently approached the qualifications, relevance, or reliability analyses. Court approaches to reliability fall into three main categories: a factors-based *Daubert* approach, a totality-based *Daubert* approach, and a Rule-702-based approach. The results of the case survey suggest that expert testimony on MRI brain scans faces considerable challenges under the existing admissibility framework. The diversity of evaluation approaches, varied case outcomes, and small sample size of analyzed cases make it too challenging to identify unified themes or generalized guidance for future cases. In addition the opinions blur categorical distinctions and present further obstacles to understanding how courts perceive and apply the admissibility requirements, making it difficult for litigants and courts in future cases to know which admissibility approach to apply. The analytical and fundamental challenges beleaguering the existing admissibility framework generate considerable unpredictability for litigating parties challenging and defending the admissibility of expert witness testimony of MRI brain scans in particular and of expert witness testimony in general. One way to reduce the unpredictability is by supplementing the existing framework with expert witness instructions. This type of advance notice from the court would provide many transparency-related benefits and be a substantial improvement over the established approaches to evaluating the admissibility of expert witness testimony on MRI brain scans.

