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DAUBERT'S BACKWASH: LITIGATION-GENERATED SCIENCE

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In the 1993 landmark case Daubert v. Merrell Dow Pharmaceuticals, *the United States Supreme Court articulated its position on the admissibility of scientific evidence. The Court reasoned that federal judges should rely on the processes scientists use to identify unreliable research, including the process of peer review, to determine when scientific evidence should be inadmissible. In response, lawyers and their clients, seeking to rely on such evidence, have begun funding and publishing their own research with the primary intention of providing support to cases they are litigating. This Article examines the phenomenon of litigation-generated science, how it potentially undermines the* Daubert *review process, and how such evidence should be handled by the scientific community and by courts under* Daubert.

Through the familiar concepts of *peer review* and *general acceptance*, as expressed in *Frye*[1] and *Daubert*[2] jurisprudence, our legal system

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In keeping with the spirit of this Article, the attorney authors acknowledge that we practice in products liability and toxic tort litigation and frequently represent defendants in lawsuits alleging health effects and other injuries and exposure to chemical products. We fully expect and hope that the principles and proposed approaches discussed in this Article would be applied even-handedly to all parties in science-based litigation.

1. Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). Almost eighty years ago, the District of Columbia Circuit Court, in a remarkably short and simple opinion, established in *Frye* the now-familiar standard of "general acceptance" as the test for determining the admissibility of novel scientific evidence. *Id. See* Daubert v. Merrell Dow Pharms., 509 U.S. 579, 585–86 (1993). The test has been widely used, even after the adoption of the Federal Rules of Evidence, to determine whether scientific testimony would be permitted in federal, and many state, courts. *See* ERIC D. GREEN AND CHARLES R. NESSON, PROBLEMS, CASES, AND MATERIALS ON EVIDENCE 649 (1983).

2. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). In *Daubert*, the Supreme Court, addressing the growing dissatisfaction with the *Frye* test, determined that *Frye's* "general acceptance" standard had been superseded by the adoption of the Federal Rules of Evidence. *Id.* at 587. *Daubert's* multi-factor and two-prong test of reliability and fit (discussed in detail

relies heavily on the activities of scientists to help keep meritless scientific ideas and methodologies out of the courtroom. Given sufficient time and resources, the processes scientists use to identify unreliable research work reasonably well. Improperly performed or fraudulent studies may have a moment in the sun, but they ordinarily cannot survive the intense scientific scrutiny that follows. Recognizing this, the Supreme Court in *Daubert* explicitly encouraged federal court litigants to rely on the scientific community, initially and primarily, to protect the courts from unreliable, novel[3] science.

But what if the novel science under review is actually not the work of independent researchers, but of lawyers intent on creating evidence to survive a *Daubert* review? Since its issuance in 1993, *Daubert* has escalated the rejection of expert testimony which relies on unaccepted scientific methodologies[4] to support novel litigation opinions.[5] Those experts' opinions often have little or no support in the scientific literature and are instead derived from anecdotal evidence, claims of injury, alleged "clusters," or strained reinterpretations of existing research.[6] Lawyers who seek to support novel litigation theories are discovering that unless they have original, peer-reviewed, published literature supporting their theories, a *Daubert* hearing may be the end of their case. Plaintiffs' law firms and their consortiums, specializing in novel toxic tort lawsuits and funded by massive settlements in asbestos, tobacco, and other litigation, can now fund the scientific research needed for their cases and arrange for publication of that research in one of the thousands of scientific and medical journals in the U.S. and elsewhere.

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in Section III.A) is now the law in all federal courts and has been adopted by many state courts. *See* Connecticut v. Porter, 241 Conn. 57, 698 A.2d 739 (1997) (surveying state court adoption of *Daubert* standard).

3. The word *novel* is used to refer to litigation theories based on scientific causation arguments that have not received previous serious attention or review by the scientific community. *See, e.g.*, Valentine v. Pioneer Chlor Alkali Co., 921 F. Supp. 666, 674 (D. Nev. 1996) ("The assertions of plaintiffs' experts that exposure to chlorine damages the brain and nervous system are novel, and, as noted above, unsupported by scientific research extraneous to this litigation.").

4. Peter Huber apparently coined the term "junk science" in 1991 to refer to such evidence. *See* PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 209 (1991). The term has come to represent the realm of opinion and conjecture often used to support litigation, but having no basis or support in legitimate scientific methodology. *See* Gen. Elec. v. Joiner, 522 U.S. 136, 153 (1997) ("[T]his is not the sort of 'junk science' with which *Daubert* was concerned.").

5. *See* Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335 (1999) (arguing that the threshold for admissibility of scientific expertise has risen significantly as a result of *Daubert*).

6. *See infra* Sections III & IV.

Original research on the plaintiffs' side, in turn, may drive defendants to respond with litigation-focused research of their own.

Both the courts and the medical/scientific professions are thus likely to face, and in fact are already facing,[7] a growing and potentially troubling phenomenon—the creation of a body of scientific studies generated for and funded by litigation. To be sure, litigation science[8] is not inherently bad science. In fact, the entities that bring and defend toxic tort-related lawsuits may someday provide a source of funding for important public health research. Nonetheless, the reliability and accuracy of litigation-based research is likely to be viewed with suspicion because of the potential bias arising from the source of funding for the research and the relationship between the researchers and the lawyers. Pressures resulting from the need to obtain the "right" outcome may result in manipulated procedures, distorted data, selective reporting of results, or even falsified outcomes.

Unless it is recognized as a special problem, litigation science threatens to upset the notions upon which *Daubert* is built. By relying on the processes of peer review,[9] publication, and "general acceptance" in the scientific community, the *Daubert* Court placed its trust in large part on the objectivity and thoroughness of scientists as the vehicle for preventing improper methodologies from entering the scientific realm, and thereby the legal realm. The Court's reliance is based on the concept of the scientific and medical communities as principled, independent seekers of factual reality, largely unaffected by the blatant advocacy on which our litigation process is based. To the extent this concept is accurate to begin with,[10] it begins to fall apart if lawyers and litigation experts invade the realm of scientific research and manipulate the medical and scientific publication system to achieve their litigation ends. Is the scientific journal community equipped to detect and reject biased and invalid litigation-based studies? Is the broader scientific community capable of recognizing the potential flaws in such studies and, if necessary, refusing to accord them "general acceptance?"

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7. *See infra* Section I.

8. The phrase "litigation science" (or "litigation-generated science"), as used in this Article, refers to studies conducted for expected use in litigation. In many instances, the research will have been funded by lawyers or litigants and/or controlled in some manner by the lawyers or their testifying experts.

9. Unless otherwise noted, our use of the phrase "peer review" is akin to what is also known as "journal peer review." Journal peer review is distinguished from other forms of peer review that are typically referred to as regulatory peer review or funding peer review.

10. As discussed in Section II.B.4, *infra*, even researchers performing scientific studies unrelated to any litigation face pressures that can affect the validity of test results and reporting.

Will any scientists even be interested enough to respond to an obscure publication that might support admissibility under *Daubert*? If the answer to these questions is no, then courts must find a way to perform the screening that would ordinarily be the province of the scientific world.

In this Article, we analyze the peculiar risks involved in litigation-generated science and propose that *both* scientists and courts must develop a more rigorous frame of reference for identifying litigation science in the first instance and determining whether such science is reliable. Part I of this Article offers some examples of litigation science in recent cases to give the reader perspective on how litigants are creating scientific research and using journal publication to pass *Daubert* muster. Part II then provides background on the falsification process[11] by which the scientific community evaluates the reliability of its own science and on which *Daubert* would have courts rely. We offer a brief primer on publication peer review, a key part of that process, because publication is likely the doorway through which lawyers will attempt to legitimize litigation science. Part III briefly reviews some of the approaches courts have taken under *Daubert*'s peer review requirement and how courts have handled litigation science to date. Part IV analyzes the peculiar risks of litigation-generated science and suggests a methodology for both scientists and the court system to examine litigation-generated studies, focusing in particular on the importance of disclosure of the litigation connection and obtaining independent verification of the research. To provide structure to portions of that methodology and to give courts and litigants an unbiased resource for validating litigation-based studies, it may be necessary to either utilize an existing source of independent experts, such as Duke University's Registry,[12] or to create a special institute for litigation research.

Litigation-driven science may ultimately provide a useful contribution to the scientific literature, but not until there are processes in place to ensure its scientific reliability. The scientific and legal communities need to recognize the peculiar risks posed by litigation science, ensure disclosure of its source, and require thorough

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11. The "falsification process" is the methodology by which scientists reduce hypotheses to more reliable conclusions. *See infra* notes 77–102 and accompanying text.

12. The Registry is a list of independent scientific and technical experts who are willing to advise courts in the resolution of cases involving scientific and technical issues. Private Adjudication Center, *About the Registry*, *in* THE REGISTRY OF INDEPENDENT SCIENTIFIC AND TECHNICAL ADVISORS, *available at* http://www.law.duke.edu/pac/registry/about.html (last visited Nov. 3, 2001).

peer review and independent guarantees of its reliability before letting it into either the scientific realm or the courtroom.

I. THE GROWING USE OF LITIGATION SCIENCE

The use of litigation science in courts is not a mere theoretical concern. While not yet a tidal wave, examples of studies performed by testifying experts for use in litigation, often accompanied by publication in supposedly peer-reviewed journals, appear in a number of recent published opinions. It is likely that other instances exist but have not found their way into the published literature of court opinions. As background, we briefly provide descriptions of published examples here. Section III discusses the courts' handling of these proffered tests in more detail.

Ruffin v. Shaw Industries, Inc.[13]: Plaintiffs alleging toxic injury from carpet emissions retained an expert, Dr. Anderson, to perform testing on a carpet sample in an air chamber and claimed to have achieved toxic effects on mice as a result. She did not publish her findings. Dr. Anderson's testing prompted not only a Congressional hearing,[14] but also attempts to replicate the result by the United States Environmental Protection Agency, a University of Pittsburgh researcher, and two carpet manufacturers, Dow Chemical Company and Monsanto Company.[15] None of the attempted replications obtained any relevant toxic effects, much less the fatal effects achieved by Dr. Anderson.[16]

Black v. Rhone-Poulenc, Inc.[17]: Plaintiffs' expert psychologist, Dr. Scotti, performed a form of an epidemiological study to demonstrate the effects of fire and release of toluene from a plant in West Virginia on persons living near the plant. He presented his findings at two symposia, but did not reveal the litigation connection of his study at those symposia and did not otherwise publish the study.[18] Dr. Scotti's firm, Survey Associates, was formed as a result of work for the plaintiffs' law firm and had never done any work

13. 149 F.3d 294, 297–98 (4th Cir. 1998).

14. *See Potential Health Risks from Carpets and Carpeting Material: Hearing Before the House Subcomm. on Environment, Energy, and Natural Resources*, 103d Cong. 1 (1993) (opening statement of Rep. Synar, Chairman, House Subcomm. on Environment, Energy, and Natural Resources).

15. 149 F.3d at 297–98.

16. *Id.*

17. 19 F. Supp. 2d 592, 594 (S.D. W. Va. 1998).

18. *Id.* at 600.

other than for that law firm.[19] The law firm helped identify participants in the study; placed its phone number on flyers recruiting participants; provided personnel to conduct study interviews; and otherwise injected itself into the process of the study.[20]

Bourne v. E.I. DuPont de Nemours & Co.[21]: In a series of cases alleging birth defects from exposure to a fungicide, defended in part by the attorney authors of this Article, plaintiffs' counsel, through its chief testifying expert, commissioned a number of studies in repeated efforts to demonstrate in utero effects at levels commensurate with the plaintiff mothers' exposures.[22] The plaintiff's law firm funded a series of research projects,[23] at considerable expense,[24] to support the experts' assertions of human dermal absorption of the fungicide and their extrapolation of human teratogenic effect levels from isolated cell *in vitro* studies.[25] Plaintiffs' expert discussed two of the tests with the lead researcher (his colleague at the same university), provided samples of the fungicide, and assisted in the design and interpretation of the studies.[26] The authors of these studies submitted them for publication in the

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19. *Id.* at 601.

20. *Id.* at 601–02.

21. No. 2:97-0090 (S.D. W. Va., filed Dec. 31, 1996). The *Bourne* case was one of four filed in West Virginia alleging that exposures by mothers in England to a home garden version of DuPont's fungicide Benlate caused the children to be born without eyes and with various other conditions. Plaintiffs voluntarily dismissed three of the cases at the time their experts reports were due. The fourth case, *Bourne*, proceeded through expert discovery. The federal court recently ruled in *Bourne* that plaintiff's experts' causation testimony should be excluded because their unsound methodologies did not satisfy Daubert's criteria for reliability and relevance. *See* Memorandum Order, Bourne v. DuPont, Civ. Action No. 2:97-0090, filed Jan. 29, 2002 [hereinafter Bourne Opinion] (on file with the *University of Michigan Journal of Law Reform*).

In a previous Florida case, *Castillo v. DuPont*, the plaintiff had obtained a jury verdict in 1996 using one of the same experts as in *Bourne* but that verdict was reversed on appeal on *Frye* grounds based on the improper methodology used by the plaintiff's chief expert. 748 So. 2d 1108 (Fla. Ct. App. 2000), *reh'g granted*, 2000 Fla. LEXIS 1812 (Aug. 31, 2000). As of this publication, the Florida Supreme Court had not yet rendered its decision in the *Castillo* matter.

22. Deposition of W.G. McLean, *Slight v. E.I. DuPont de Nemours & Co.*, at 19–26, 42–49 (Sept. 29, 1998) [hereinafter Dep. of W.G. McLean] (on file with the *University of Michigan Journal of Law Reform*) (*in vitro* studies resulted from discussions with plaintiffs' expert and were partly funded by plaintiffs's law firm); Deposition of Dr. Paul Sibbons, *Bourne*, at 31–35 (Oct. 22, 1999) (on file with the *University of Michigan Journal of Law Reform*) (describing whole embryo rat studies commissioned by plaintiffs' expert); Court Order, *Bourne* (Oct. 12, 1999) (on file with the *University of Michigan Journal of Law Reform*) (granting extension for plaintiffs to perform requested dermal absorption study).

23. *See, e.g.*, Dep. of W.G. McLean, *supra* note 22, at 48–49.

24. One of these studies alone cost Plaintiff's firm over $200,000. *See* Letter from Ana Rivero-Alexander to Honorable Judge John T. Copenhaver (March 3, 2000) (on file with the *University of Michigan Journal of Law Reform*).

25. Bourne Opinion, *supra* note 21, at 4–19.

26. *See* Dep. of W.G. McLean, *supra* note 22, at 93–101.

journal *Neurotoxicology*[27] but the journal did not require any conflicts disclosure, and the authors did not inform the journal that the studies were funded by a law firm and conducted on behalf of a testifying expert.[28] The other studies were not peer reviewed or published.

Valentine v. Pioneer Chlor Alkali Co.[29]: In a litigation alleging neurological damage from escaped chlorine, plaintiffs' expert Dr. Kilburn conducted a variant of an epidemiological study of allegedly exposed individuals to demonstrate causation. All of the exposed participants in his study, however, were current plaintiffs or were otherwise involved in the litigation.[30] Dr. Kilburn published his study in a journal, but the court noted that the journal was not among the more than 3000 journals listed in the National Library of Medicine's database or on the shelves of Johns Hopkins School of Medicine.[31]

Nelson v. American Home Prods. Corp.[32]: Plaintiff retained several experts that the court found to be highly qualified, but only two of the experts formed their causation opinions before the case was filed.[33] These opinions, however, were largely on anecdotal case reports.[34] A third expert, Dr. Hoyt, made similar causation diagnoses prior to the case before the court, but all three of his previous diagnoses were in the context of litigation against the same defendant.[35] He also developed a new theory that had not been published or tested.[36] Another expert, Dr. Rhodes, published an article addressing alleged causation while he was a paid expert in another litigation.[37] A fifth expert, Dr. Wurster, based his opinion solely on materials received from plaintiff's lawyers—he did no independent research.[38]

Daubert v. Merrell Dow Pharmaceuticals, Inc. (Daubert II)[39]: In the underlying *Daubert* case, plaintiffs' epidemiologists performed a "reanalysis" of existing epidemiological studies to generate their

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27. W.G. McLean et al., *The Effect of Benomyl on Neurite Outgrowth in Mouse NB2A Human SH-SY5Y Neuroblastoma Cells in Vitro*, 19 NEUROTOXICOLOGY 629 (1998).
28. *See* Dep. of W.G. McLean, *supra* note 22, at 127.
29. 921 F. Supp. 666 (D. Nev. 1996).
30. *Id.* at 676.
31. *Id.* at 670 n.3.
32. 92 F. Supp 2d 954 (W.D. Mo. 2000)
33. *Id.* at 968–69.
34. *Id.*
35. *Id.* at 959.
36. *Id.* at 959–60.
37. *Id.* at 958, 968.
38. *Id.* at 961, 968.
39. 43 F.3d 1311 (9th Cir. 1995) (on remand from the U.S. Supreme Court following *Daubert* decision).

opinion that Bendectin causes birth defects. The reanalysis concluded, contrary to the finding of each of the underlying, independently-performed studies, that Bendectin is a human teratogen.[40] The reanalysis was never published in a journal.[41] One of the plaintiffs' experts also apparently performed laboratory studies of Bendectin but did not include enough information on the studies in his affidavit to make them an issue in the case.[42]

Worthington City Schools v. Abco Insulation[43]: In this asbestos case, defendants' expert utilized data collected from defendant companies in a number of litigations to publish an article showing that the level of asbestos in the air in school buildings was no higher than in ambient outside air.[44] The study was published in a scientific journal, *Regulatory Toxicology and Pharmacology*.[45] Plaintiffs attempted to have the article and testimony excluded because of its litigation taint.[46]

Lust v. Merrell Dow Pharmaceuticals, Inc.[47]: In a case alleging birth defects from a fertility drug, plaintiffs' expert relied on an article he had published several years before the instant litigation setting forth his theory of causation.[48] He apparently had not performed any independent research but relied on his interpretation of existing animal studies.[49] During a deposition, however, the expert admitted that the article was not peer reviewed and was based on research for a different litigation when he was already a "professional plaintiff's witness."[50]

National Bank of Commerce v. Dow Chemical Co.[51]: To support her litigation opinion, plaintiffs' expert, Dr. Sherman, published two articles in purportedly peer reviewed journals.[52] The articles addressed "case reports" of alleged birth defects from exposure to a Dow insecticide.[53] Dr. Sherman's role in the litigation was not reported in the published articles, and her opinion in court

40. *Id.* at 1314.
41. *Id.* at 1318.
42. *Id.* at 1317 n.4.
43. 616 N.E.2d 550 (Ohio Ct. App. 1992).
44. *Id.* at 553.
45. *Id.* at 552–53.
46. *Id.* at 553.
47. 89 F.3d 594 (9th Cir. 1996).
48. *Id.* at 596.
49. *Id.*
50. *Id.* at 597.
51. 965 F. Supp. 1490 (E.D. Ark. 1996).
52. *Id.* at 1499. The plaintiffs' expert had published articles in the *International Journal of Occupational Medicine & Toxicology and Archives Environmental Health. Id.*
53. *Id.* at 1498.

extended beyond the conclusions expressed in the published articles.[54]

These examples are likely not exhaustive, but they are enough to illustrate that law firms and experts supporting novel litigation theories are becoming increasingly willing to conduct and publish their own studies to support those theories. All but two of the examples described occurred *after* the publication of the Supreme Court's *Daubert* opinion.[55] This is not a coincidence. *Daubert* has placed a premium on verified, peer-reviewed research to support a causation opinion, and some plaintiffs attorneys are advising their colleagues to generate peer-reviewed testing and research to support their cases.[56] If that research does not exist, litigants can now be expected to create it.

II. ENSURING RELIABILITY IN THE SCIENTIFIC COMMUNITY

To deal with litigation science under *Daubert* or otherwise, it is imperative that the legal system understand how scientists would address the potential unreliability of such research. To a large extent, the legal profession depends upon scientists, at least in the first instance, to ferret out unreliable science, including unreliable litigation science. The lawyer's critical eye can sometimes uncover scientific fallacies and errors, but lawyer scrutiny is no substitute for the far more knowledgeable evaluation by scientists possessing the proper expertise.[57] The methodologies by which scientists ensure reliability, however, are by no means foolproof. Courts and litigants must initially have some understanding of those methodologies to ascertain the degree and exactitude of the scientific review of a study or theory, and in particular to determine whether claimed peer review is nothing more than a cover for an improperly conducted study.

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54. *Id.* at 1517.

55. *Worthington* and much of the research in *Ruffin* preceded *Daubert.*

56. Robert M.N. Palmer, *Opening the Gates,* TRIAL 86, 90 (June 2000) (recommending that plaintiff experts conduct their own testing and "publish extensively in peer-reviewed journals" to avoid a *Daubert* dismissal).

57. *See* Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985) ("[T]he examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine.").

A. The Methodologies Used by Scientists to Ensure Validity

The approach taken by the Supreme Court in *Daubert* assumes that the scientific community itself takes measures to ensure scientific reliability and validity and that the legal system can rely in part on those measures. Thus, when the Court identifies "peer review and publication" as a "relevant, though not dispositive, consideration in assessing the scientific validity" of a methodology, and "general acceptance" as an "important factor,"[58] the Court is implicitly referencing the processes that scientists use to assess themselves and their scientific products. The Court encourages federal litigants to rely on those processes.

In some circumstances, the Court's reliance is reasonably well placed. Certainly as to the bulk of scientific inquiry, in which researchers incrementally add to or modify well-established principles, there is little risk of error. Even in the case of new and important theories that are on the cutting edge, given time and enough reason to invest their energies and resources, scientists and medical professionals can and do develop reasonably accurate assessments of health risks and reject erroneous and baseless theories. This process, however, is often time-consuming, haphazard, and cumbersome.[59] There is no court of science to judge the validity of any given research. Instead, the verdict often arrives in pieces and varying stages of uncertainty as further studies, criticisms, and hypotheses come into play, until most (though rarely all) professionals feel sufficiently comfortable with the conclusions to lay the issue to rest and move to the next crisis. As described by one scientist-author,[60] science is not built on stone as much as on pilings in a swamp—the pilings are never driven to bedrock, but scientists quit pounding when they feel the principle is secure enough to build on.[61] In the interim, a large number of published studies actually

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

59. In her book on the breast implant litigation, Dr. Marcia Angell of the *New England Journal of Medicine* describes the resulting patchwork of studies on a given subject as a "mosaic of information that taken together yields the answer to a scientific question." MARCIA ANGELL, SCIENCE ON TRIAL 109 (1996).

60. *See* KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE 138 (1997) (citing KARL POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY 111 (1972)).

61. An excellent example is the story of prions. Several years ago, Dr. Stanley Prusiner of the University of California San Francisco theorized that certain rare brain diseases (scrapie in sheep, kuru in cannibals in New Guinea, mad cow disease in cattle, and others) were caused by the genetic transmission of non-genetic, non-DNA material he termed *prions*. His theory attracted the attention, a good deal of it negative and even hostile, of some of the top scientists in the world. It also provoked a wealth of new research, much of it undertaken in an effort to disprove the theory, that ended up supporting it. Dr. Prusiner won

turn out to be wrong. Indeed, the scientific literature is full of "peer-reviewed" but inaccurate articles and theories.[62] The falsification process ultimately produces a reliable conclusion, but the debris left behind is considerable and—in isolation—far from reliable.

Within this process, scientists have developed methods of reducing error and approximating reliability, *i.e.*, driving the piling deep enough. Chief among these methods, of course, is the scientific method itself, the basic foundation for the validity of any scientific inquiry.[63] A researcher using the scientific method must first set forth a hypothesis, then design an experiment to test the hypothesis, collect and analyze the results, and publish the results.[64] It is imperative that the test results can be replicated and verified by others.[65] The quality of any study will be determined in the first instance by the extent to which it follows or deviates from the scientific method.

Scientists have also developed external methods of ensuring that unreliability is minimized. These methods taken together are sometimes referred to as the broader version of "peer review,"[66] to be distinguished from the more limited form of publication peer review performed by journals in accepting an article. When a theory attracts enough attention, scientists engage in repeated episodes of testing and criticism until most of the flaws are removed from the espoused theory.[67] This is the process of

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the Nobel Prize three years ago, but it has taken many years for his revolutionary idea to be accepted. *See* Press Release, The Nobel Assembly at the Karolinska Institute, The 1997 Nobel Prize in Physiology or Medicine (Oct. 6, 1997), *at* http://www.nobel.se/medicine/laureates/1997/press.html; Stanley B. Prusiner—Autobiography (1997) *at* http://www.nobel.se/medicine/laureates/1997/prusiner-autobio.html.

62. *See* FOSTER & HUBER, *supra* note 60, at 100, 157. One author estimated that ninety percent of the primary literature in physics is wrong. *See* HENRY H. BAUER, SCIENTIFIC LITERACY AND THE MYTH OF THE SCIENTIFIC METHOD 48 (1992) (citing opinion of John Ziman).

63. The rudiments of the scientific method derive from the works of Bacon, Galileo, and Newton. *See* Ernan McMullin, *The Development of Philosophy of Science 1600–1900, in* COMPANION TO THE HISTORY OF MODERN SCIENCE 816–28 (R.C. Olby et al. eds., 1990).

64. *See* MARTIN GOLDSTEIN & INGE F. GOLDSTEIN, HOW WE KNOW: AN EXPLORATION OF THE SCIENTIFIC PROCESS 19 (1978); JOHN M. ZIMAN, RELIABLE KNOWLEDGE: AN EXPLORATION OF THE GROUNDS FOR BELIEF IN SCIENCE 6 (1978); Francisco J. Ayala & Bert Black, *Science and the Courts*, 81 AM. SCIENTIST 230, 234 (1993).

65. *See* KARL F. POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY 44–45, 53–54 (1972).

66. *See, e.g.*, SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 95 (1995); Lars Noah, *Sanctifying Scientific Peer Review: Publication as a Proxy for Regulatory Decisionmaking*, 59 U. PITT. L. REV. 677, 692 (1998).

67. *See* Bert Black et al., *The Law of Expert Testimony—A Post Daubert Analysis, in* EXPERT EVIDENCE: A PRACTITIONER'S GUIDE TO LAW, SCIENCE AND THE FJC MANUAL 37 (Bert Black & Patrick Lee eds., 1997).

"falsification," described by Karl Popper in an article cited by Justice Blackmun in *Daubert*,[68] as the driving force that pushes science away from the erroneous to something closer to the truth. In science, the final answer is merely the latest one not yet proven false.

The ability of scientists to establish the reliability of a particular theory depends on many factors, including presumably the degree of public and scientific interest in the subject matter, the funding available for studies, the level of interest generated among experts in the field, the quality and completeness of the original data made available, and the novelty of the new concept. In the best scenario, all of the above factors will come together to generate a large body of replicated studies confirming or refuting a range of health-related conclusions that ultimately achieve widespread publication and a general scientific consensus. Far more common, however, are the many obscure theories/studies that are published in second- or third-tier journals and never receive any significant attention or criticism.[69]

Litigation-related science, because it is typically novel, tends to fall into the latter category.[70] If a litigation-based methodology or theory is sufficiently provocative and important from a public health standpoint, it can generate significant review, commentary, and critical examination by the scientific community.[71] Ultimately, the processes referenced by the *Daubert* Court work relatively well *after* the issue has received sufficient attention to generate otherwise disinterested university or privately-sponsored research.[72] Early

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68. *Daubert*, 509 U.S. at 593 (citing KARL R. POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989)). Popper espouses a theory of "critical rationalism" that requires scientific propositions to be formulated to permit other scientists tot attempt to falsify them. By surviving such scrutiny, the propositions gain credibility. *See* FOSTER & HUBER, *supra* note 60, at 19–20.

69. *See* FOSTER & HUBER, *supra* note 60, at 162 & n.32.

70. As examples, note the published epidemiological work in *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 666 (1996), *supra* text accompanying note 29, attempting to establish undocumented toxic effects of toluene, and the *in vitro* studies published to support novel birth defect theories in *Bourne v. E.I. DuPont de Nemours & Co.*, *supra* text accompanying notes 27–28. In these cases, there was no existing literature (outside the litigation context) to support these novel theories, and the published articles attracted little scientific attention.

71. The experiments performed by Dr. Anderson in *Ruffin v. Shaw Industries, Inc.*, 149 F.3d 294 (4th Cir. 1998), attracted the attention of Congress, EPA, and other researchers. *See supra* text accompanying notes 14–15. Likewise, the breast implant cases, after lengthy litigation, finally generated enough concern for researchers at the Mayo Clinic to conduct a comprehensive epidemiological study in 1994. *See* ANGELL, *supra* note 59, at 100; S.E. Gabriel, *Risk of Connective-Tissue Diseases and Other Disorders after Breast Implantation*, 330 NEW ENG. J. MED. 1697–1702 (1994).

72. For example, at least three reported breast implant cases were dismissed on *Daubert* standards after a scientific panel convened to examine the issue released a report

in any health-related litigation, however, neither the scientific interest nor widespread public scrutiny will have taken place.[73] Instead, the early lawsuits in any health case are often based on unproven conjecture derived from a limited base of regulatory or other studies, or perhaps merely from case reports or alleged associations of exposures and conditions.[74] More to the point of this Article, novel lawsuits may also draw from a new expert study or theory developed and funded by the litigants.[75] Until the cases expand into a national health issue, the scientific scrutiny referenced by the Supreme Court will likely be very limited. By the time the national interest is captured, it is often too late and the consequences of mushrooming litigation may have already compelled massive settlements and bankruptcies before the scientific verdict is even rendered.[76]

In the interim, courts faced with the initial cases must decide what to do with novel science. It is at this point that courts and litigants must understand something of the processes used by scientists to conduct "falsification." The degree to which the novel theory has been subjected to one or more of these processes will determine the comfort level of the court in admitting or excluding the evidence under *Daubert*. The more important processes are described below.

Informal collaboration: Researchers often run their theories by their colleagues or work in collaboration to ensure errors are

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showing that there was no association between silicone breast implants and connective tissue or autoimmune disease. *See* Allison v. McGhan Med. Corp., 184 F.3d 1300, 1311 n.9 (11th Cir. 1999); Grant v. Bristol-Myers Squibb, 97 F. Supp. 2d 986, 989–90 (D. Ariz. 2000); Bushore v. Dow Corning-Wright Corp., No. 92-344-CIV-T-26C, 1999 WL 1116920, at *5 (M.D. Fla. Nov. 15, 1999).

73. *See* POPPER, *supra* note 68.

74. The Benlate eye defect cases discussed above, *supra* note 21, are good examples. Plaintiffs initiated those cases after the United Kingdom news media in 1993 reported that Benlate was associated with alleged "clusters" of children born with no eyes in farming regions of England and Scotland. Based on these allegations and well-known rat studies showing eye defects through high-dose gavage exposure, plaintiffs began legal proceedings against DuPont. The government of the United Kingdom commissioned a study, published in the *British Medical Journal*, that ultimately found no evidence of "clusters" in any region of England. H. Dolk, et. al., *Geographical Variation in Anophthalmia and Microphthalmia in England 1988–1994*, 317 BRIT. MED. J. 905–09 (1998).

75. All of the cases discussed in Section I involved a novel allegation of injury (*e.g.*, birth defects from use of fertility drug in *Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594 (9th Cir. 1996), or the toxic carpet effects in *Ruffin*, 149 F.3d at 294).

76. In the breast implant litigation, thousands of lawsuits had been filed, verdicts of up to $25 million rendered, and the biggest class action settlement in history reached, all before the first epidemiological study dealing with breast implants was published in 1994. *See* ANGELL, *supra* note 59, at 10. The study found no relationship with the alleged injuries. *Id.*

eliminated.[77] To the extent a researcher acts alone, or collaborates with colleagues who are not suitably disinterested, the risk of error and potential bias increases. Legitimate collaboration, on the other hand, will often flag problems in the study or in the application of the scientific method to the author's work.

Professional workshops: Many professional groups conduct conferences and workshops at which researchers can present their findings early in the process, ordinarily even before publication takes place. Plenary presentations receive the most attention, abstracts and poster presentations far less. Sometimes a professional society will publish the plenary presentations through a related journal. In some instances, a novel theory may receive considerable discussion and generate either widespread disagreement or a consensus among the society members. This form of "peer review" has been going on since the 1700s, when the Royal Society in London and other scientific societies regularly debated new papers and scientific ideas.[78] If a novel theory is a sufficiently dramatic departure from the existing body of knowledge, the proponent's failure to submit it to the relevant society for consideration may be considered a major weakness in a *Daubert* analysis.[79]

Good laboratory practice (GLP): Laboratories performing work for regulatory purposes (especially those for Food and Drug Administration or Environmental Protection Agency review) are required to conform to strict laboratory protocols that help ensure a lack of error and trustworthy results.[80] The regulators will reject studies that do not meet these criteria, and the result may well be the disapproval of the drug or other product.[81] Because of the financial

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77. *See* Black et al., *supra* note 67, at 41 (referencing collaboration as a form of "informal" peer review).

78. *See* David A. Kronick, *Peer Review in 18th Century Scientific Journalism*, 263 JAMA 1321–22 (1990).

79. *See Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) [*Daubert II*] (criticizing plaintiffs' expert for failing to "publish[] his work on Bendectin in a scientific journal or solicit[] formal review by his colleagues" despite ten years of litigation). On the other hand, the majority of papers presented at conferences are not thoroughly vetted at the conference and never end up in publication. *See* Roberta Scherer et al., *Full Publication of Results Initially Presented in Abstracts*, 272 JAMA 158, 161 (1994) (only one-half of ophthalmology abstracts ultimately published); Dan B. Murrey et al., *Publication Rates of Abstracts Presented at the 1993 Annual Academy Meeting*, 359 CLINICAL ORTHPAEDICS & RELATED RESEARCH 247, 248–49 (1999). For this reason, the mere presentation of a paper at a conference, by any means, should not be viewed as a thorough form of peer review. *See* Black v. Rhone-Poulenc, Inc., 19 F. Supp. 2d 592, 600 (S.D. W. Va. 1998) (presentation at two symposia rejected as sufficient peer review for *Daubert* admissibility).

80. *See, e.g.*, 21 C.F.R. Part 58 (good laboratory practices for drug applications); 40 C.F.R. § 158.70, 158.80 (referencing protocols for pesticide application testing).

81. FOSTER & HUBER, *supra* note 60, at 100–01.

implications of poorly documented studies, company laboratories are generally careful about the GLP quality of their work.[82]

GLP standards are more rigorous than those used by university laboratories. GLP standards, however, are not necessarily a *sine qua non* of acceptable research.[83] Many laboratories conduct valid studies without strict application of GLP.[84] Nonetheless, research undertaken outside the contours of GLP or other rigorous standards may require closer scrutiny in litigation to ensure that researchers have utilized proper processes, quality control, and documentation.[85]

Grant funding requirements: If grant money is required, the applicant must meet the standards of the funding organization to obtain the grant.[86] Those standards generally include measures to ensure that the research will be properly conducted and free of obvious flaws.[87] Approval of a rigorously reviewed grant is helpful in establishing the reliability of the study.[88] Denial of grant funding, however, must be interpreted carefully since promising

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82. *See id.* at 174–75.

83. Although FDA requires GLP, *see generally* 21 C.F.R. Pt. 58, it implicitly acknowledges that good scientific studies may be conducted without adherence to GLP by allowing for the submission of petitions not conducted according to GLP if the petitioner can explain why GLP was not used. *See e.g.*, 21 C.F.R. § 71.1(g); 21 C.F.R. § 101.7(c); 21 C.F.R. § 170.35(c)(1)(iv).

84. *See* Allan S. Felsot, *Numbers, Numbers Everywhere—And Not a Drop of Meaning*, 13 J. ENVTL. L. & LITIG. 91, 110 (1998) ("While data derived from GLPs and CLPs may be tracked by an independent third party (e.g., an auditor), they do not guarantee that the best available technology is used, nor that the design of experiments is optimal. Thus, the data may be auditable, but its quality may still be open to question.") (citing Maureen S. Barge, *Good Laboratory Practices and the Myth of Quality*, in GOOD LABORATORY PRACTICES: AN AGROCHEMICAL PERSPECTIVE 41, 41–46 (Maureen S. Barge & Willa Y. Gardner eds. 1988)).

85. *Id.* at 109 (explaining that the genesis for good laboratory practices "grew out of fraudulent data collection cases"); FOSTER & HUBER, *supra* note 60, at 101 (noting that because GLP standards "enforce standardized experimental methods and standardized methods of collecting and reporting data, they are effective in reducing 'data dredging,' 'data torturing,' 'cargo cult science,' 'pathological science,' and other abuses").

86. *See generally* NIH Grants Policy Statement (Revised March 2001), *available at* http://grants.nih.gov/grants/policy

87. *See, e.g.*, 42 U.S.C. § 289(a) (requiring peer review of NIH grant applications); Exec. Order No. 12,372, 3 C.F.R. § 197 (1982) (providing external review requirements of applications for federal scientific research funding); U.S. Public Health Service, Grants Policy Statement, http://www.grants.nih.gov/grants/policy/nihgps/ (advocating the use of peer review as a means of choosing grant allocation requests).

88. NIH, for example, requires organizations applying for grants to disclose and address any potential conflicts of financial interests. *Id.* at 51. Like other government agencies, NIH has a number of civil and criminal penalties at its disposal to use against researchers who falsify information or engage in research misconduct. *Id.* at 32–34, 55–56. Finally, NIH conducts its dual peer review of grants applications thus ensuring that some peer review takes place. *Id.* at 34–37.

projects may be denied funding for reasons separate and apart from the merits of the proposal.

Publication peer review. After a study is completed, the researcher may elect to submit the results in a written article to a relevant journal. Ideally, the article will undergo peer review by external experts in the field, whose comments will require changes or further demonstration of validity and will ultimately determine whether the article is published or not.[89] There are thousands of scientific and medical journals in the world, however, and many cannot fill their pages.[90] The resulting seller's market means that a researcher can publish even an inadequate article somewhere.[91] Serious and adequate publication peer review remains relatively rare. Even adequate publication peer review is sometimes limited in that the review may involve only one or two peer reviewers, and even the best reviewers can only identify gross errors in methodology or conclusions.[92] Because of its inherent limits, publication peer review should be considered essentially a screening mechanism useful (if properly performed) for weeding out some forms of truly bad science but generally insufficient to test thoroughly the methodologies used and theories set forth.[93]

The publication peer review process is critical to the evaluation of novel litigation science because it is likely to be the primary means by which the proponents of the research claim scientific acceptance of their methodologies and theories. Because the publication process is vital for litigation-generated science, we discuss it in more detail in the following section.

Post-publication analysis and comment. If the subject of the article is important enough, a published article will generate letters to the editor, commentary, criticism, and replication attempts by others. This is "peer review" in the broader and more comprehensive sense—the process by which ideas are exposed to other scientists

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89. *See* ANGELL, *supra* note 59, at 95 (noting that publication peer review is necessary to weed out errors caused by the natural biases and subjectiveness of even the best-intentioned author); Ayala & Black, *supra* note 64, at 234–39.

90. *See, e.g.*, Noah, *supra* note 66, at 699 (identifying 25,000 journals in the biomedical field alone) (citations omitted).

91. *See* STEPHEN LOCK, A DIFFICULT BALANCE: EDITORIAL PEER REVIEW IN MEDICINE 39–41, 85 (1985).

92. *See* Noah, *supra* note 66, at 696 & n.89.

93. Publication peer review is incapable, for instance, of identifying fraud, manipulation, or statistical or methodological errors not identified in the article itself because the peer reviewers do not have access to the underlying research data. *See* FOSTER & HUBER, *supra* note 60, at 100 (discussing inability of peer reviewers to catch data manipulation). *See generally id.* at 70–109 (discussing types of scientific errors found in reported and published studies).

and subjected to falsification efforts. True "peer review" and "general acceptance," in the *Daubert* sense, has not occurred until this process takes place and the broader scientific community has had the opportunity to scrutinize and test the theory first put forth through publication peer review.[94]

Regulatory review. A large group of studies are never submitted for publication at all because they are conducted by researchers on behalf of companies attempting to obtain regulatory approval of their products. The lack of publication, however, does not mean these studies are unusable for *Daubert* purposes. In fact, the converse is true, because the review these studies receive at the hands of the regulatory agencies is often more intense than that offered by journal publication.[95] As one example, the underlying data and test documentation for a regulatory study must be available and transparent because the agencies can request to see the data if necessary, whereas journal peer reviewers rarely see any underlying data for submitted articles.[96] Indeed, there is a growing overlap between regulatory approval and peer review. Federal regulators are placing increased reliance upon peer-reviewed articles when making regulatory decisions.[97] Advisory panels and other forms of peer review are also entering into the regulatory approval process.[98] In

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94. *See* Black et al., *supra* note 67, at 41–42. As the Court in *Daubert* stated: "Publication . . . is but one element of peer review . . . . [S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593 (1993) (citations omitted). Even when there has been sufficient time for post-publication analysis and comment, courts must pay attention to whether the audience that receives the journal is sufficiently qualified to allow their review of the publication to be considered "scientific review" for purposes of *Daubert*. *See* United States v. Plaza, 179 F. Supp. 2d 492, 508–09 (E.D. Pa. 2002) (in a case challenging finger printing analysis, the court expressed concern that, even though there have been numerous writings discussing fingerprint identification techniques, those at the top of the field are skilled professionals but they do not have any "advanced academic training" to be considered a " 'scientific community' in the *Daubert* sense.").

95. *See* FOSTER & HUBER, *supra* note 60, at 174.

96. *See* Suzanne R. Hill, et al., *Problems with the Interpretation of Pharmacoeconomic Analysis*, 283 JAMA 2116–2121 (2000); Drummond Rennie & Harold S. Luft, *Pharmaco-Economic Analyses: Making them Transparent, Making them Credible*, 283 JAMA 2158–2160 (2000).

97. *See* SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 33–36 (1990); Noah, *supra* note 66, at 679; Thomas S. Burack, Note, *Of Reliable Science: Scientific Peer Review, Federal Regulatory Agencies, and the Courts*, 7 VA. J. NAT. RESOURCES L. 27, 35 (1987); *see also* Nancy S. Bryson & Richard J. Mannix, *Good Science, Junk Science, and Regulatory Science: Is There a Role for the* Daubert *Guidelines in Administrative Rulemaking?*, 8 ENVIRONMENTAL QUALITY MANAGEMENT 89, 89–92 (1998).

98. *See* 7 U.S.C. § 136w(d)–(e) (Supp. V 1999) (peer review of pesticide studies); 21 U.S.C. § 360c(b) (Supp. V 1999) (FDA medical device classification panels); 21 U.S.C. § 379e(b)(5)(C) (Supp. V 1999) (FDA's color additive advisory committee); 42 U.S.C. § 9604(i)(13) (Supp. V 1999) (peer review for research conducted under Superfund); 42

addition, Congress has begun to recognize the importance of and establish standards for regulatory peer review.[99]

In addition to the GLP requirements discussed above, regulatory studies must meet detailed standards in terms of design and reporting. Regulatory studies are also evaluated through the skeptical eye of regulators whose job it is to ensure public safety.[100] Shortcomings in the research will cause the studies to be rejected, and the product would ordinarily not be approved as a result.[101] Moreover, unlike publication review, companies and individuals are subject to debarment from future projects, civil penalties, and, in severe cases, criminal prosecution if they falsify data or commit fraud on government agencies.[102]

While scientists can rely on any or all of the above to pursue falsification, there is no standard path through these processes or any particular point at which the novel theory or methodology is declared valid. At some point, assuming the novel approach merits attention at all, the cumulative weight of various approvals, coupled with decreasingly successful falsification efforts, erodes the need for or interest in further challenges. Courts should assess the degree to which a novel litigation-driven approach has been tested under the above processes and the degree of the scientific community's confidence in the resulting theory or methodology.

B. Publication Peer Review

Publication peer review is the most likely venue for testing the reliability of novel litigation science. It is a readily accessible means for litigation experts to obtain some measure of "general acceptance" and peer review in a short time frame. In the scientific publishing world, however, publication peer review is an amor-

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U.S.C. § 289(a) (1994) (peer review of NIH grant applications); 21 C.F.R. § 14.100 (2001) (listing FDA's standing advisory committees).

99. *See, e.g.*, Science Integrity Act, H.R. 574, 106th Cong. (1999); Regulatory Improvement Act of 1999, S. 746, 106th Cong. (1999).

100. *Regulatory Improvement Act of 1999: Hearing on S. 746 Before the Senate Comm. on Governmental Affairs*, 106th Cong. 174–75 (1999) (statement of D. Lynn Johnson, Vice-President, Eastman Chemical Co.).

101. *Id.*

102. *See, e.g.*, 21 C.F.R. § 312.70 (2001) (FDA disqualification procedures for submitting false drug data); 21 C.F.R. § 812.30 (2001) (FDA disqualification procedures for submitting false medical device data); 42 C.F.R. § 50.101 (2001) (HHS standards for misconduct in science); 45 C.F.R. § 689.1 (2001) (National Science Foundation standards for misconduct in science and engineering).

phous beast that is currently undergoing a great deal of scrutiny. Neither courts nor scientists should blithely assume that publication in a purportedly "peer-reviewed" journal is a seal of approval for a particular methodology or theory.[103]

1. The Growth and Use of Peer Review in Journal Publication—In 1989, two authors published the first historical surveys of peer review, largely in response to an extended effort by one of the authors of this Article to generate research on peer review practices.[104] Those histories trace the beginnings of journal peer review to the early 1700s, when scientific and professional societies foreshadowed journal peer review by requiring review of memoirs for publication in the records of their proceedings.[105] In the intervening two centuries, the development of peer review has been sporadic and disorganized.[106] In fact, up until World War II, few journals referred articles to outside specialists for review, relying instead on staff editors and officers of specialized journals, or on the editors' sometimes hard-headed notions of their own expertise.[107] Journals had difficulty finding enough articles, and the scientific and medical professions were still experiencing a general opposition to the specialization that later spurred the growth of peer review.[108]

The pressures that led to "modern" peer review—referral of articles to outside specialists for review—grew primarily from the need for greater expertise as scientific and medical knowledge and processes expanded. The luxury of separating the wheat from the chaff through external peer review was not an option, however, until after World War II,[109] when the quantity of available articles increased to the point that at least the better journals could afford to reject a large proportion of submissions.[110] Even then, the practice tended to be a realistic option only for those journals—typically the better ones—that did not have to scramble to fill their

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103. A full dissection of the status of scientific peer review is beyond the scope of this Article. For additional surveys of the publication peer review, see Noah, *supra* note 66.

104. *See* John C. Burnham, *The Evolution of Editorial Peer Review*, 263 JAMA 1323, 1323 (1990); Kronick, *supra* note 78.

105. *See* Burnham, *supra* note 104, at 1323–24.

106. *See* Kronick, *supra* note 78, at 1321–22.

107. *See* Burnham, *supra* note 104, at 1324–25 (recounting the story of one editor, the owner of the *Journal of Nervous and Mental Disease* through the first half of the 20th century, who refused to accept any authority other than his own even in the subfields of neurology and psychiatry).

108. *Id.* at 1325.

109. *See* Ann C. Weller, *Editorial Peer Review in U.S. Medical Journals*, 263 JAMA 1344 (1990) (citing D.J. PRICE, LITTLE SCIENCE, BIG SCIENCE . . . AND BEYOND (1986)).

110. Burnham, *supra* note 104, at 1325, 1327.

publications. Nor did peer review reforms spread evenly or generally across journals, as might be expected. Instead, each journal tended to find its own way independently, with little regard to the practices of other journals.[111]

2. Publication Peer Review Practices and Limitations—In the last decade, the scientific publishing community has begun to evaluate peer review and publication practices for consistency and validity.[112] These efforts have disclosed the variety of peer review practices in use and highlighted the limitations of peer review in identifying flawed research. The limitations in the institution of publication peer review are severe enough that some commentators now talk about the "game" of peer review that journals play and the bureaucratic process that has grown up around it.[113] While no one has recommended doing away with publication peer review altogether, institutional reform is needed.[114]

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111. The initial investigations into peer review resulted from events that called into question the ability of journals to keep flawed science out of their publications. *See, e.g.*, Arnold S. Relman & Marcia Angell, *How Good Is Peer Review?*, 321 NEW ENG. J. MED. 827, 828 (1989); Drummond Rennie, *More Peering into Editorial Peer Review*, 270 JAMA 2856(1993). From time to time, as would be expected in any human endeavor, the pressures to publish lead to unethical or questionable publishing practices and the publication of erroneous or even fraudulent work. Some of these incidents have been highly publicized.

112. Since 1986, one of the authors of this Article has written extensively to encourage scientific inquiry into the validity and quality of peer review. *See* Drummond Rennie, *Problems in Peer Review and Fraud: Cleave Ever to the Sunnier Side of Doubt, in* 'BALANCING ACT' ESSAYS TO HONOR STEPHEN LOCK 9–19 (1991); Mildred K. Cho et al., *Masking Author Identity In Peer Review: What Factors Influence Masking Success?*, 280 JAMA 243 (1998); Amy C. Justice et al., *Does Masking Author Identity Improve Peer Review Quality? A Randomized Controlled Trial*, 280 JAMA 240 (1998); Drummond Rennie & Annette Flanagin, *Congress on Biomedical Peer Review: History, Ethics, and Plans for the Future*, 280 JAMA 213 (1998); Drummond Rennie, *Editorial Peer Review in Biomedical Publication: The First International Congress*, 263 JAMA 1317 (1990); Drummond Rennie, *Editorial Peer Review: Let Us Put It on Trial*, 13 CONTROLLED CLINICAL TRIALS 443 (1992); Drummond Rennie et al., *Fourth International Congress on Peer Review in Biomedical Publication: Call for Research*, 282 JAMA 1085 (1999); Drummond Rennie, *Freedom And Responsibility in Medical Publication: Setting the Balance Right*, 280 JAMA 300 (1998); Drummond Rennie, *Guarding the Guardians: A Conference on Editorial Peer Review*, 256 JAMA 2391 (1986); Drummond Rennie & Elizabeth Knoll, *Investigating Peer Review.*, 109 ANNALS OF INTERNAL MEDICINE 181 (1988); Drummond Rennie, *More Peering into Editorial Peer Review*, 270 JAMA 2856 (1993); Drummond Rennie et al., *Peer Review in Prague*, 280 JAMA 214 (1998); Drummond Rennie & Annette Flanagin, *Peer Review in Prague: The International Congress on Peer Review and Global Communications, 1994*, 274 JAMA 986 (1995); Drummond Rennie et al., *The International Congress on Peer Review in Biomedical Publication*, 261 JAMA 749 (1989); Drummond Rennie & Annette Flanagin, *The Second International Congress on Peer Review in Biomedical Publication*, 272 JAMA 91 (1994); Richard Smith & Drummond Rennie, *And Now, Evidence Based Editing*, 311 BRIT. MED. J. 826 (1995).

113. Elizabeth Knoll, *The Communities of Scientists and Journal Peer Review*, 263 JAMA 1330, 1331 (1990).

114. *See, e.g.*, Noah, *supra* note 66, 703 & n.108 (1998). One particular author published at least twelve fraudulent papers, including one in the prestigious *New England Journal of Medicine*, before being exposed. *See* W. Whiteley et al., *The Scientific Community's Response to*

Some of the problems with peer review's screening capacity are inherent in the process. Peer reviewers, for instance, are wholly dependent on the veracity of the researcher in the conduct of the underlying research. Reviewers often do not see anything other than what the researcher includes in the article and therefore cannot confirm any of the findings.[115] Underreporting of data may be relatively prevalent, but it is difficult to ascertain during peer review. Studies *finding* a result are far more likely to be published than those in which nothing happens, even though the latter can be of equal or even greater scientific value.[116] In addition, authors can "slice and dice" the results, selectively report data (intentionally or not) to emphasize certain outcomes, or leave out populations whose study results are less interesting.[117]

The flaws inherent in one set of humans reviewing another's work are also of concern. Authors often fear that the reviewers, intentionally or not, may be biased against them, their institutions, or their theories. Reviewers, in turn, have to worry about backlash against their criticisms if the reviews are unblinded. If the reviews are blinded, reviewers' criticisms may be unchecked and insufficiently critiqued. Even apart from bias and the like, peer review is a subjective process that can result in considerable variation across reviewers.[118] One study found that reviewers showed only a modest ability to detect intentional flaws consistently in test manuscripts and in fact identified only a minority of such flaws.[119]

In addition to the weaknesses inherent in publication peer review, the history of peer review development has left a patchwork of highly variant practices. The term *peer-reviewed publication* is frequently used as if it described a monolithic process, applied by all

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Evidence of Fraudulent Publication, 272 JAMA 170 (1994); *see also* Philip M. Boffey, *U.S. Study Finds Fraud in Top Researcher's Work on Mentally Retarded*, N.Y. TIMES, May 24, 1987, at A16; Eugene Garfield & Alfred Welljams-Dorof, *The Impact of Fraudulent Research on the Scientific Literature*, 263 JAMA 1424 (1990).

115. *See* Relman & Angell, *supra* note 111, at 828.

116. Iain Chalmers, *Underreporting Research Is Scientific Misconduct*, 263 JAMA 1405, 1407 (1990) (citing Kay Dickersin, *The Existence of Publication Bias and Risk Factors for Its Occurrence*, 263 JAMA 1385, 1385–89 (1990) and R.J. Simes, *Confronting Publication Bias: A Cohort Design for Meta-Analysis*, 6 STAT. MED. 11, 11–29 (1987)). Underreporting of data is believed to be very prevalent. *See* Drummond Rennie & Annette Flanagin, *Publication Bias: The Triumph of Hope Over Experience*, 267 JAMA 411, 411–22 (1992).

117. *See* Chalmers, *supra* note 116, at 1407.

118. *See* Michael L. Callaham et al., *Reliability of Editors' Subjective Quality Ratings of Peer Reviews of Manuscripts*, 280 JAMA 229, 230 (1998) (twenty percent of variance in reports attributable to reviewers).

119. *Id.*

respectable journals.[120] To the contrary, peer review practices can differ in a number of respects, any one of which can affect the quality of the review. A sampling of important but highly variant practices includes:

External vs. internal review: Three-fourths of the journals reviewed in one study use their own editorial board members as reviewers.[121] This approach is potentially inconsistent with the *sine qua non* of modern peer review, i.e., review by specialized experts external to the author and publication's own editors and board.[122]

Selection of reviewers: Outside reviewers, if used, can be selected from a journal database (large or small), from personal acquaintances or meeting contacts, or even from recommendations by the authors themselves.[123] Some journals will even change referees when requested by the author.[124]

Blinding: The reviews can be "double-blind," meaning neither the reviewers nor the authors know each others' identities,[125] or they can be single-blind (the reviewers are told the authors' names)[126] or not blinded at all (the authors also learn the reviewers' names).[127] The degree of blinding might affect the objectivity of the review, but the research on this point is not yet clear.[128]

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120. Laypersons who assume uniformity would not be alone, because many medical journal editors themselves also assumed uniformity of practice until the last decade. *See* Weller, *supra* note 109, at 1344 (citing LOCK, *supra* note 91).

121. Cynthia D. Good et al., *A Worldwide Assessment of Medical Journal Editors' Practices and Needs—Results of a Survey by the World Association of Medical Editors*, 89 S. AFR. MED. J. 397, 400 (1999).

122. *See id.* at 400; Lois A. Colaianni, *Peer Review in Journals Indexed in Index Medicus*, 272 JAMA 156, 157 (1994). The *British Medical Journal*, in contrast, maintains a file of 2000 outside reviewers that it calls upon for specialized topics. *See* Stephen Lock, *What Do Peer Reviewers Do?*, 262 JAMA 1341, 1341 (1990). Further, only forty-four percent of journals reported that they consistently obtained external epidemiological and statistical reviews of published research, leaving open the possibility of inadequate review in these areas as to the other journals. Good, *supra* note 121, at 400.

123. *See* Weller, *supra* note 109, at 1345 and Table 1.

124. *See* Lowell L. Hargens, *Variation in Journal Peer Review Systems*, 263 JAMA 1348, 1349 (1990).

125. *See id.* (the *Astrophysical Journal* uses double-blind reviewing); Weller, *supra* note 109, at 1345 (thirty-two percent of a group of interdisciplinary and specialized journals remove the author's name before submission to the reviewers).

126. Single-blind reviews are used exclusively, for instance, among the sixteen top clinically-oriented journals. *See* Weller, *supra* note 109, at 1345 (referred to as "anonymous" review).

127. Only a small percentage of journals studied by Weller used fully non-blinded reviews (both authors' and reviewers' names revealed). *Id.*

128. The cited articles and others have to date explored the degree and types of blinding used but have not generated data as to the effects of blinding practices on the quality of the review.

Intensity of the review process: The number of "referee cycles" (transmittals between reviewer/editor and author to make changes) that a manuscript undergoes also varies, not just for individual articles, which could be explained by the quality of the initial drafts, but also across journals.[129] The variation could indicate differences in editing rigor.[130]

Available resources: The resources devoted to peer review can vary greatly. Smaller journals cannot match the resources of journals like the *New England Journal of Medicine*, which has seven full-time physician editors, six part-time physician specialists, three statistical consultants, and thousands of outside peer reviewers at its disposal.[131]

Decision-making: The outside reviewers can participate in a consensus publication decision with the journal's editors, and many journals solicit the external reviewers' opinions on publication. Most reviewers, however, do not directly participate in the publication decision, which is the province of the journal editors alone.[132]

Rejection rates: The rejection rate of articles also varies dramatically.[133] As some have argued, the rejection rate of a journal may well be a direct measure of the quality of the journal's peer review practices.[134]

Journals vary widely in how they communicate their peer review practices to their readers. Two recent surveys, for instance, found that of the 94 percent of journals claiming to be peer reviewed,[135] actual evidence of such peer review existed in only 38 to 55

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129. *See* Hargens, *supra* note 124, at 1348–49.

130. *Id.* at 1349.

131. *See* ANGELL, *supra* note 59, at 95–96 (1996).

132. Hargens, *supra* note 124, at 1349; Weller, *supra* note 109, at 1345, 1346 tbl. 5.

133. Chemistry and physics journals rejected a mere fifteen percent and thirty percent, respectively, of submitted articles, while the behavioral science journals rejected seventy to ninety percent. *See* Hargens, *supra* note 123, at 1348. A 1990 study found similarly large discrepancies among a reputable astronomy journal (eighteen percent rejection), a zoology publication (forty-one percent), and a sociology journal (eighty-seven percent). *Id.* Weller also found a statistically significant difference in rejection rates between her two categories of journals. Weller, *supra* note 109, at 1346 & tbl 5. The rejection discrepancies would be more palatable if they were related to the number of submissions received. Instead, they appear consistent for individual journals regardless of fluctuations in submission rates. Hargens, *supra* note 123, at 1348.

134. *See* Drummond Rennie, *The Present State of Medical Journals*, 352 THE LANCET SII 18, SII 19 (1998). In some instances a low rejection rate may indicate a more passive-aggressive form of ensuring quality by requiring repeated revisions until an author simply gives up. One highly respected astronomy journal, for instance, almost never officially rejects articles that receive a negative review, but instead continues to require revisions until the article passes muster or the author gives up. Hargens, *supra* note 123, at 1351.

135. Good et al., *supra* note 121, at 400.

percent of the sampled journals.[136] Investigators also found that among the "peer-reviewed" journals, less than half of their published articles actually included a statement implying that the article had been peer reviewed.[137] Even then, the descriptions of the process were so vague and uninformative that no court or litigant could possibly determine on the face of the journal exactly what the notion of "peer review" for that particular article might mean.[138] If journals are not fully or adequately describing whether and how an article has been peer reviewed, the legal profession will find itself considerably adrift in attempting to match publishing practices with the dictates of *Daubert.*

The historical patchwork of peer review practices across journals is no mere annoyance for those who rely on *Daubert.* What might have been a clean, bright-line rule disintegrates at best into another area requiring time-consuming discovery, court inquiry, balancing tests and, at worse, into a false notion of reliability.

3. The Vancouver Group and the Uniform Requirements—The investigations into the quality of peer review have led to the growth of a movement to ensure consistent peer review and disclosure practices across journals, primarily through the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals ("Uniform Requirements").* The meetings of journal editors that eventually led to the *Uniform Requirements* began rather quietly in 1978 as a means of establishing a consistent format for journal submissions. Called the "Vancouver Group" after its initial meeting place, the journal editors published their first formatting requirements in 1979.[139]

Subsequently, the Vancouver Group expanded and changed its name to the International Committee of Medical Journal Editors ("ICMJE").[140] The ICMJE gradually took on a broader mandate than mere publication form, ultimately establishing uniform criteria regarding acceptability, confidentiality, identification of authors, and most importantly, peer review and conflicts of interest.[141] The ICMJE has published seven versions of the *Uniform Requirements* since 1979, the latest in 2001.[142] The authors of the

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136. Colaianni, *supra* note 122, at 157.

137. *Id.*

138. *Id.* The author found such descriptions as "subject to peer review," "sent to two specialists," "to aid referring," and "are reviewed."

139. INT'L COMM. MED. J. EDS., UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS, *at* http://www.icmje.org (last modified Oct. 2001) [hereinafter UNIFORM REQUIREMENTS].

140. *Id.*

141. *Id.*

142. *Id.*

Uniform Requirements claim that over 500 journals currently subscribe to the *Uniform Requirements*,[143] but it is uncertain in fact how many journals actually follow the practices and how faithful their adherence is.[144]

The *Uniform Requirements* are primarily a functional set of directions to obtain consistency in manuscript format and submissions across journals. To date, the *Uniform Requirements* have addressed peer review by including a definition of a "peer-reviewed journal" and a requirement that the journal disclose its peer review practices:

> A peer-reviewed journal is one that has submitted most of its published articles for review by experts who are not part of the editorial staff. The number and kind of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers' opinions may vary, and therefore each journal should publicly disclose its policies in its instructions to authors for the benefit of readers and potential authors.[145]

This provision addresses two of the peer review concerns discussed above. First, the authors of the *Uniform Requirements* dealt with inconsistency in the use of outside reviewers by establishing *external* review, i.e., by editors not part of the journal staff, as the basic requirement of a peer-reviewed journal. This in itself was a major step, and many journals still do not require external review for all articles. Second, the *Uniform Requirements* chose to address the vast array of peer review practices utilized across journals, not by requiring consistency, but by recognizing the inconsistency and requiring disclosure of those practices in the journal. Thus, apart from external review, journals adhering to the *Uniform Requirements* may still engage in widely varying peer review practices, but they will presumably disclose those practices in some form available to the reading public.

A number of leading journal editors have convened three international congresses on peer review practices since 1989 to encourage research into peer review and the identification of

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143. *Id.*

144. Studies on author conformity with the *Uniform Requirements* show a great divergence of recognition and practice. *See* Drummond Rennie et al., *The Contributions of Authors*, 284 JAMA 89, 89–91 (2000); Drummond Rennie et al., *When Authorship Fails: A Proposal to Make Contributors Accountable*, 278 JAMA 579, 579–585 (1997).

145. UNIFORM REQUIREMENTS, *supra* note 139.

practices that are effective at screening out invalid research.[146] These efforts may allow the profession to add more specificity to the *Uniform Requirements* regarding peer review. Until then, the value of the *Uniform Requirements* in promoting consistency among journal practices will remain fairly limited.

Litigants dealing with articles published in journals that subscribe to the *Uniform Requirements* can at least be assured of some external review, although the quality of review and number of reviewers is still an issue. Moreover, at least in theory, litigants dealing with a journal that conforms to the *Uniform Requirements* can identify the scope of the review from the journal's disclosure of its practices. Most articles likely to be the subject of novel science litigation, however, will not find their way into the more prestigious journals, but will be published among the many journals that do not subscribe to the *Uniform Requirements.* Until more journals use the *Uniform Requirements*, and perhaps until the *Uniform Requirements* contain more detailed prescriptions, the *Requirements* will serve primarily as a minimal benchmark for external review and disclosure of practices.

4. The Role of Bias and Disclosure in Publication Peer Review—The role of potential bias and nondisclosure of conflicts by article authors has become a focal point of the recent turmoil in the publishing world regarding peer review. Potential bias among authors is inherent in the world of research, because studies cost money and must be funded by someone. When that funding comes from any source with an interest in the outcome, a potential conflict or bias arises. The recent concerns over peer review have encompassed numerous articles on the nature of author conflicts, the impact of conflicts on article validity and acceptability, and the need for disclosure.[147]

Some of the heightened scrutiny of potential conflicts is the result of several highly publicized incidents resulting from the

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146. *See* Drummond Rennie & Annette Flanagin, *Congress on Biomedical Peer Review: History, Ethics, and Plans for the Future*, 280 JAMA 213 (1998); Drummond Rennie, *Editorial Peer Review in Biomedical Publication: The First International Congress*, 263 JAMA 1317 (1990); Drummond Rennie, *The Second International Congress on Peer Review in Biomedical Publication*, 272 JAMA 91 (1994). Each of these volumes of *JAMA* contains a number of research articles regarding peer review that were presented at the respective conferences.

147. *See, e.g.*, Erdem I. Cantekin et al., *Biomedical Information, Peer Review, and Conflict of Interest as They Influence Public Health*, 263 JAMA 1427 (1990); Sheldon Krimsky & L.S. Rothenberg, *Financial Interest and Its Disclosure in Scientific Publications*, 280 JAMA 225 (1998); Sheldon Krimsky et al., *Scientific Journals and Their Authors' Financial Interests: A Pilot Study*, 67 PSYCHOTHERAPY & PSYCHOSOMATICS 194 (1998); John C. Morris, *Conflicts of Interest: Research and Clinical Care*, 8 ALZHEIMER DISEASE & ASSOCIATED DISORDERS 49 (1994); Michael S. Pritchard, *Conflicts of Interest: Conceptual and Normative Issues*, 71 ACAD. MED. 1305 (1996).

publication of articles without disclosure of conflicts. For example, the *Los Angeles Times* recently disclosed that the prestigious *New England Journal of Medicine* had published a key drug survey article without disclosing that the author was a consultant to the drug company.[148] Following the media exposure, the *Journal*'s editors conducted a self-audit and learned that the *Journal* had published nineteen other articles by authors with ties to pharmaceutical companies and without disclosing the potential conflict.[149] Although no issues were raised regarding the articles' contents or findings, the credibility of both the articles and the *Journal* was questioned because of the apparent conflict and its nondisclosure. Similarly, in 1990 a Boston newspaper excoriated the *Journal of the American Medical Association* for publishing an editorial in 1990 on post-pertussis vaccination encephalitis without disclosing the author's role as a paid consultant and testifying expert for the drug company. As it turned out, the author himself failed to disclose that relationship on his signed disclosure forms.[150]

Journals are taking steps to avoid the credibility backlash of undisclosed conflicts. The *Uniform Requirements*, for instance, declare that "[p]ublic trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is

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148. *See* Terrence Monmaney, *Medical Journal's Article Raises Conflict Concerns; Research: Positive assessment of anti-balding drugs was written by a professor who has worked for makers*, L.A. TIMES, Sept. 28, 1999, at A1 (criticizing V.H. Price, *Treatment of Hair Loss*, 341 NEW ENG. J. MED. 964, 964–73 (1999)).

149. *See* Marcia Angell & Alastair J.J. Wood, *Authors' Conflicts of Interest: A Disclosure and Editors' Reply*, 341 NEW ENG. J. MED. 1618–19 (1999); Marcia Angell et al., *Disclosure of Authors' Conflicts of Interest: A Follow-up*, 342 NEW ENG. J. MED. 586 (2000); Kelly M. McMasters, *Disclosure of Authors' Conflicts of Interest—A Follow-up*, 343 NEW ENG. J. MED. 146 (2000); Vera H. Price, *Authors' Conflicts of Interest: A Disclosure and Editors' Reply*, 341 NEW ENG. J. MED. 1618 (1999); Terrence Monmaney, *Top Medical Journal Admits 19 Lapses of Ethics Policy*, L.A. TIMES, Feb. 24, 2000, at A1.

150. *See* Vincent Garbitelli, *Pertussis Vaccine Encephalopathy*, 264 JAMA 2385 (1990) (letter to the editor/comment criticizing James D. Cherry, *Pertussis Vaccine Encephalopathy: It Is Time to Recognize It As the Myth That It Is*, 263 JAMA 1679–80 (1990)); Marie R. Griffin et al., *Pertussis Vaccine Encephalopathy*, 264 JAMA 2385–86 (1990) (letter to the editor/comment); James E. Lewis, *Pertussis Vaccine Encephalopathy*, 264 JAMA 2383–84 (1990) (letter to the editor/comment); John H. Menkes, *Pertussis Vaccine Encephalopathy*, 264 JAMA 2384–85 (1990) (letter to the editor/comment); John A. Tilelli & Robert L. Manniello, *Pertussis Vaccine Encephalopathy*, 264 JAMA 2385 (1990) (letter to the editor/comment); *see also* James D. Cherry, *Pertussis Vaccine Encephalopathy*, 264 JAMA 2386 (1990) (letter to the editor/comment from the author of the original article). Illustrating the great difficulty with loosely enforced and voluntary disclosure rules, the editors of *JAMA* also learned that the author of the editorial had testified twelve times on the issue, and authors of numerous letters written to protest the referenced editorial had themselves failed to identify their own extensive litigation roles on this issue. Drummond Rennie, *Pertussis Vaccine Encephalopathy*, 264 JAMA 2386 (1990) (editorial noting that various physicians writing to protest had respectively testified, for remuneration, once, 20 times, 25 times, and 39 times on the issue, but did not reveal that information until pressed by *JAMA*'s editors to do so).

handled during writing, peer review, and editorial decision making."[151] The *Uniform Requirements* contain a comprehensive description of potential conflicts, defined as:

> [T]ies to activities that could inappropriately influence [the researcher's] judgment, whether or not judgment is in fact affected. Financial relationships with industry (for example, through employment, consultancies, stock ownership, honoraria, expert testimony) either directly or through immediate family, are usually considered to be the most important conflicts of interest. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.[152]

Some journals, representing one end of the spectrum, simply refuse to accept certain types of submissions (*e.g.*, review articles) from authors with conflicts of interest.[153] Most journals, however, are content to require disclosure, publish the articles if they are otherwise worthy, and allow the reading public to judge the impact of the potential conflict. The *Uniform Requirements*, for instance, require authors to disclose "financial and other conflicts of interest that might bias their work. They should acknowledge in the manuscript all financial support for the work and other financial or personal connections to the work."[154] Peer reviewers and editors are likewise required to disclose conflicts.[155]

Beyond the basic tenets of the *Uniform Requirements*, the disclosure obligations journals place on authors are limited and inconsistent. Journals that do not follow the *Uniform Requirements* often do not require any disclosure or account for or report the author's potential biases, no matter how severe.[156] Even among the

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151. UNIFORM REQUIREMENTS, *supra* note 139.

152. *Id.*

153. *See id.*; Eliot Marshall, *Journals Joust over Conflict-of-Interest Rules*, 276 SCIENCE 524 (1997) (*New England Journal of Medicine* bans editorials by anyone with a financial stake in the subject). The focus of the *Journal*'s ban is on review articles, in which the author has great discretion in selecting information, greatly increasing the opportunity for bias to influence the conclusions.

154. UNIFORM REQUIREMENTS, *supra* note 139.

155. *Id.*

156. One survey found that less than one-third of the journals identified in Uhlrich's International Periodicals Directory required any sort of conflict disclosure. *See* Richard M. Glass & Mindy Schneiderman, *A Survey of Journal Conflict of Interest Policies*, INT'L CONGRESS ON BIOMEDICAL PEER REV. & GLOBAL COMM., *at* http://www.ama-assn.org/public/peer/apo.htm. The percentage of journals requiring disclosure increased with circulation size. *Id.* Another study found that only thirty-nine percent of journals surveyed required disclosure of conflicts of interest. Good et al., *supra* note 122, at 397.

journals that utilize the *Uniform Requirements*, there is variation in the degree of disclosure and the reporting of conflicts. For example, the *JAMA* has relatively strict disclosure requirements,[157] but even those requirements are confined to financial interests. *The Lancet*'s requirement that authors disclose to the editors "anything . . . that would embarrass [the author] if it were to emerge after publication" and "financial and other conflicts of interest that might bias [the author's] work"[158] is less specific but arguably requires broader disclosure than *JAMA*. The *British Medical Journal*'s website, taking the minimalist approach, simply requires that the technical editor of the article include the "source of funding" in the edited version, but actual articles contain fairly thorough disclosures of financial and other conflicts.[159] A few leading journal editors have even debated the value of bias disclosure and have recommended that disclosure be entirely voluntary and not a condition of acceptance.[160]

Authors engaged in litigation science obviously have potential conflicts of interest. They may have served, or expect to serve, as paid, testifying experts in litigation. Even if not, the lawyers or a party to the litigation may have funded the research, helped develop the protocol and design, provided the raw materials needed, or reviewed and commented on the results and the article. Some of the journal disclosure requirements discussed above would require disclosure of litigation involvement. Nonetheless, most journals would probably not require any disclosure, and few journals explicitly reference litigation activity as

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157. The "Financial Disclosure" section of *JAMA*'s author instructions requires authors to "certify that all my affiliations with or financial involvement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organization or entity with a financial interest in or in financial competition with the subject matter or materials discussed in the manuscript are completely disclosed" and that "all financial and materials support for this research and work are clearly identified in the manuscript." JAMA, MANUSCRIPT CRITERIA & INFORMATION, *at* http://jama.ama-assn.org/info/auinst.html (last modified Jan. 5, 2000) [hereinafter JAMA WEBSITE].

158. THE LANCET, WRITING FOR THE LANCET, *at* http://www.thelancet.com/authorinfo (last visited Oct. 15, 2001) [hereinafter THE LANCET WEBSITE]. *The Lancet Website* provides as well that "[a]ll sources of funding must be disclosed, as an acknowledgement in the text." *Id.*

159. BRIT. MED. J., CHECKLISTS, *at* http://www.bmj.com/advice/33.html (last visited Sept. 25, 2001). *See, e.g.*, Rumona Dickson et al., *Effects of Treatment For Intestinal Helminth Infection on Growth and Cognitive Performance in Children: Systematic Review of Randomised Trials*, 320 BRIT. MED. J. 1697, 1700 (2000) (disclosing that author was "currently supported by Unicef and the World Bank to carry out a trial of anthelmintic drugs in children" and that "[n]o author is currently receiving support from drug companies manufacturing anthelmintics").

160. *See* Marshall, *supra* note 153, at 524.

a potential conflict.[161] The lack of direct reference to litigation conflict probably reflects the scientific community's relative lack of focus on the existence of litigation science as a prime source of potentially biased research.

III. COURT APPROACHES TO PUBLICATION PEER REVIEW AND LITIGATION SCIENCE

Because of the emphasis under *Frye* and *Daubert* on peer review and general acceptance, courts have become familiar with the scientific method and have learned to look to scientists for help in assessing the validity of scientific propositions. In the growing number of instances in which a party has proffered litigation science, some courts have recognized the need for enhanced scrutiny to eliminate biased or improper studies. A particular focus on the quality and extent of peer review, both publication and otherwise, has led these courts (for the most part) to reject litigation science because of its unreliability.

A. Daubert *and Other Caselaw Approaches to Peer Review*

Most courts are familiar with the concept of peer review generally and have addressed whether a scientific methodology has been adequately peer reviewed under both the *Frye* and *Daubert* standard.

Long before *Daubert*, federal courts realized the necessity of looking to the scientific community to determine whether a scientific expert's opinion was generally accepted and thus admissible.[162] The standard for admitting scientific, technical, and medical testimony was the "general acceptance" test first enumerated in *Frye v. United States*.[163] In *Frye*, the Court of Appeals for the District of Columbia established the yardstick for *legal* acceptance as the point of *scientific* acceptance:

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161. *JAMA* is an exception. *See* JAMA WEBSITE, *supra* note 157 (requiring disclosure of "expert testimony").

162. *See, e.g.*, State v. Bullard, 322 S.E.2d 370, 376 (N.C. 1984) (looking to independent research in determining whether proffered evidence is reliable); State v. Hall, 297 N.W.2d 80, 84 (Iowa 1980) (existence of specialized literature is relevant to the admissibility determination of a novel approach).

163. 293 F. 1013 (D.C. Cir. 1923).

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.[164]

Thus, courts applying this standard were asked to decide questions of admissibility by deferring to the opinions of non-litigation scientists in the relevant field.

Publication and peer review by a scientific journal has long been a hallmark in determining whether expert testimony had gained general acceptance in the relevant community. Under *Frye* and its various incarnations, courts in both civil[165] and criminal[166] contexts reviewed various types of expert evidence in an effort to determine whether the relevant expert community sufficiently approved of the methodology utilized by the challenged expert. In certain cases, the issues presented required the court to discuss explicitly whether a scientific methodology had been the subject of sufficient peer review to warrant its admission into evidence. Courts considered many of the same factors in assessing the quality of peer

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164. *Id.* at 1014.

165. *See, e.g.*, Ellis v. Int'l Playtex, Inc., 745 F.2d 292, 302 (4th Cir. 1984) (reversing the lower court's decision to exclude from evidence toxic shock syndrome studies carried out by the federal Center for Disease Control as well as other state health organizations); Smith v. Ortho Pharm. Corp., 770 F. Supp. 1561, 1579 (N.D. Ga. 1991) (relying on several published studies finding no causal link between vaginal spermicide and certain birth defects in rejecting expert testimony to the contrary); Shield Club v. City of Cleveland, 647 F. Supp. 274, 284 (N.D. Ohio 1986) (citing the existence of published or unpublished literature on the subject as a factor in the court's *Frye* analysis).

166. *See, e.g.*, United States v. Brown, 557 F.2d 541, 557 (6th Cir. 1977) (excluding testimony discussing ion microprobic analysis because the prosecution's experts were unable "to cite any authority in the field in support of their positions"); United States v. Stifel, 433 F.2d 431, 440–41 (6th Cir. 1970) (admitting expert testimony utilizing neutron activation analysis based substantially on the court's reading of articles on the subject); United States v. Maivia, 728 F. Supp. 1471, 1474 (D. Haw. 1990) (citing various studies of spectrographic voice identification before concluding that such evidence was admissible in a criminal prosecution); United States v. Zeiger, 350 F. Supp. 685, 689–90 (D.D.C. 1972) (relying on published studies to support the admission of polygraph examination results); People v. Sandy, 544 N.E.2d 1248, 1256 (Ill. App. 1989) (permitting expert testimony on "Tin Ear Syndrome" after noting other experts had discussed this theory and that the expert's theory had been published). *Cf.* United States v. Williams, 583 F.2d 1194, 1198 (2d Cir. 1978) (admitting testimony relying on spectrographic voice analysis despite being provided with a list of ten doctors in favor and seventeen opposed to the admission of such testimony in the courtroom).

review support for an opinion that are applicable today under *Daubert.*

Daubert changed the landscape of expert evidence admissibility, but not so much that the original landscape is unrecognizable. If anything, the *Daubert* Court strengthened the need to rely on scientific processes to determine the validity of new science and justify its admissibility as courtroom evidence.

Under a *Daubert* analysis, the trial court must first determine "whether the reasoning or methodology underlying the testimony is scientifically valid."[167] This prong is generally referred to as the "reliability" test.[168] Second, the trial court must determine "whether [the expert's] reasoning or methodology properly can be applied to the facts in issue."[169] This part of the inquiry has become known as the "fit" test.[170]

As to the reliability test, all four of the non-exclusive factors[171] the trial court should consider relate to the falsification process that scientists undertake to eliminate erroneous theories.[172] Two of the four criteria focus on the broad concept of "peer review."

The first of the broad peer review questions is "whether the theory or technique has been subjected to peer review and

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167. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592–93 (1993). The Court noted that the "inference or assertion must be derived by the scientific method" and "supported by appropriate validation . . . based on what is known." *Id.* at 590. The Court defined scientific validity to be an examination of whether "the principle support[s] what it purports to show." *Id.* at 590 n.9. Later, the Court discussed the advantages of the scientific method: "[t]he scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance." *Id.* at 597. Peer review, of course, advances the ability of scientists and other experts with scientific or technical knowledge to review a theory or methodology and point out its shortcomings.

168. *Reliability* and *validity* have independent and different meanings to a scientist, but the Court seemed to use them interchangeably. For purposes of this Article, we do not try to follow the scientific distinctions but refer either to the validity or reliability of a scientific proposition as the measure of its trustworthiness for evidentiary purposes.

169. *Daubert*, 509 U.S. at 593.

170. *Id.* at 589, 591–92.

171. The Court later refused to establish a rule that "for all cases and for all time" lower courts must consider and apply each of the *Daubert* factors. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150–51 (1999) ("Too much depends upon the particular circumstances of the particular case at issue. *Daubert* itself is not to the contrary. It made clear that its list of factors was meant to be helpful, not definitive.").

172. The four criteria are (1) "whether a theory or technique . . . can be (and has been) tested;" (2) "whether the theory or technique has been subjected to peer review and publication;" (3) "the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation;" and (4) whether the theory or technique has gained general acceptance in the scientific community. *Daubert*, 509 U.S. at 593–94.

publication," a familiar inquiry under the old *Frye* cases.[173] The Court adequately recognized several important concepts that invariably apply to peer review and that should qualify any court's reliance on publication peer review for admissibility:

(1) Peer review involves more than just publication. Publication is a useful first indicia of some peer review, but as the Court stated, "[p]ublication . . . is but one element of peer review."[174] In other words, courts need to look beyond the simple fact that an article appears in a medical or scientific journal.

(2) Publication itself "does not necessarily correlate with reliability."[175] Some of the *amicus* and other briefs submitted to the Court emphasized the wide variability in publication practices and the possibility that bad science can readily find a publisher.

(3) Not all acceptable theories will necessarily have undergone publication peer review.[176] The Court identified theories that are too innovative to be

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173. *Id.* at 593. In its discussion, the Court relied heavily on scientific articles that addressed the advantages and disadvantages of peer review. *See id.* at 593–94 (citing JASANOFF, *supra* note 97, at 61–76; JOHN ZIMAN, RELIABLE KNOWLEDGE: AN EXPLORATION OF THE GROUNDS FOR BELIEF IN SCIENCE 130–33 (1978); and David Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 JAMA 1438 (1990)); *see also* Relman & Angell, *supra* note 111, at 828.

174. *Daubert*, 509 U.S. at 593.

175. *Id.*

176. *Id.* at 594. In *dictum*, several courts have espoused examples of situations where validation through published studies may not be needed. *See* Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 n.5 (9th Cir. 1995) (*Daubert II*) (citing examples such as fingerprint analysis, voice recognition, DNA analysis and other "scientific endeavors closely tied to law enforcement"); Virgin Islands v. Byers, 941 F. Supp. 513, 524 (D.V.I. 1996) (aside from publication, "the FBI has made its database and findings available to scientists for independent review"). In *Cavallo v. Star Enterprises*, the court stated that published studies may not be needed "where the temporal connection between exposure to a given chemical and subsequent injury is so compelling as to dispense with the need for reliance on standard methods of toxicology . . . [or where] a known chemical is accidentally introduced into a company's ventilation system, and all of the workers exposed immediately develop the same adverse reaction." 892 F. Supp. 756, 773–74 (E.D. Va. 1995); *see also Daubert II*, 43 F.3d at 1313–14 (causation can be proved when there is "compelling proof that the agent must have caused the damage somehow" and using an example of fifty people eating at a restaurant on one night and all getting food poisoning shortly thereafter); Nat'l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1496–97 (E.D. Ark. 1996) (quoting same language from *Daubert II*). The Supreme Court provided a more straightforward example of a situation where "the particular application at issue may never previously have interested any scientist." *Kumho*, 526 U.S. at 151. Even when an issue may have never interested scientists, the expert's opinion may still be excluded in certain circumstances. *See* United States v. Scholl, 959 F. Supp. 1189, 1194–95 (D. Ariz. 1997) (in a tax case, an expert testified that the study of pathological gambling was the "step child of addiction" studies; no studies existed measuring whether a gambler can discern whether he won money gambling).

> acceptable to publishers, or perhaps "too particular, too new, or of too limited interest to be published."[177] The Court could well have mentioned also the many studies created for regulatory purposes for which publication is not a necessity for establishing reliability or for which publication may not be possible due to concerns about proprietary data.[178]

Nevertheless, the Court gave great weight to "submission to the scrutiny of the scientific community" as a component of good science "because it increases the likelihood that substantive flaws in methodology will be detected."[179] In other words, scientific scrutiny—including publication peer review—contributes to the falsification of bad ideas.

The Court continued the theme of scientific scrutiny through peer review in the last of the four reliability criteria, *general acceptance.* The Court recognized that "general acceptance" "can yet have a bearing on the inquiry" by identifying "a relevant scientific community and an express determination of a particular degree of acceptance within that community."[180] Conversely, " 'a known technique which has been able to attract only minimal support within the community,' may properly be viewed with skepticism."[181] Though the Court used the more familiar legal terminology, the concept of "general acceptance" clearly refers to the process of broad peer review by experts in the field through which a theory or technique has successfully navigated the falsification process.[182]

The Supreme Court gave less attention to the "fit" requirement (and perhaps for that reason so have the practitioners and lower

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177. *Daubert*, 509 U.S. at 593 ("[I]n some instances well-grounded but innovative theories will not have been published. . . . Some propositions, moreover, are too particular, too new or of too limited interest to be published."); *see also* Black et al., *supra* note 67, at 42 (recognizing that where disclosure could compromise a competitive advantage, a company's strong internal controls could satisfy the requirement for peer review).

178. *See supra* notes 95–99 and accompanying text.

179. *Daubert*, 509 U.S. at 593. Indeed, courts have noted situations where peer review has found flaws in a theory. *See e.g., Daubert II*, 43 F. 3d at 1314 ("Every published study here and abroad—and there have been many—concludes that Bendectin is not a teratogen."); Frank v. New York, 972 F. Supp. 130, 135 (N.D.N.Y. 1997) ("Peer review of the MCS [multiple chemical sensitivity] theory has revealed a host of flaws in the theory, warranting skepticism as to the validity of MCS.").

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

181. *Id.* (citation omitted).

182. More recently, the Supreme Court has made clear that the *Daubert* factors—including peer review—apply even if the expert is not testifying about scientific matters. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 157 (1999) (examining whether any articles or papers validate the challenged expert's approach).

courts), but as discussed later, that requirement is also important in reviewing litigation science. The Court described "fit" as an issue of relevance, *i.e.*, "whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute."[183] Using an example of the phases of the moon, which might help if the issue is the darkness of the night but will not help if the issue is the rationality of a person's behavior, the Court concluded that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."[184] Litigation science may be perfectly valid, but its findings may not be relevant to the issues in the case or contribute to the scientific problem facing the court. The risk from such research is that the expert may attempt to extract a principle from it that *is* relevant but is not supported by the research. Such testimony should be excluded under *Daubert*'s reliability prong because it lacks any support in the scientific community, and the research itself should be excluded under the "fit" prong because it will not be helpful to the trier of fact.

Following *Daubert*, many courts, including state courts,[185] have agreed with the importance of the broad peer review process in helping determine whether an expert opinion is reliable.[186] As summarized by the Texas Supreme Court:

> Publication and other peer review is a significant indicia of the reliability of scientific evidence when the expert's testimony is in an area in which peer review or publication would not be uncommon. . . . One legal commentator has suggested that the ultimate test of the integrity of an expert witness in the scientific arena is "her readiness to publish and be damned." . . . Further, the "examination of a scientific study by a cadre of lawyers is not the same as its examination by

183. *Daubert*, 509 U.S. at 591. In the context of this article, the "fit" component may be used to ensure that the methodology of an expert's interpretation of a peer reviewed article is correct. *See* Metabolife Int'l, Inc. v. Wornick, 264 F.3d 832, 844 (9th Cir. 2001).

184. *Id.* at 591–92.

185. For a summary of state courts applying and rejecting *Daubert*, see Frederick T. Smith, *Daubert and Its Progeny: Scientific Evidence in Product Liability Litigation*, WASHINGTON LEGAL FOUNDATION 69–101 (2000).

186. The peer review component gains increased importance in cases where the challenged expert relies solely upon a review of literature and does not perform any original research or testing—thus making the testing and rate of error components of a *Daubert* analysis inapplicable. *See* Mitchell v. Gencorp, Inc., 968 F. Supp. 592, 599 (D. Kan. 1997); United Phosphorus, Ltd. v. Midland Fumigant, Inc., 173 F.R.D. 675, 628 (D. Kan. 1997); *see also* Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 597 (9th Cir. 1996); *Daubert II*, 43 F.3d at 1311.

> others trained in the field of science or medicine."... [P]ublication is [not] a prerequisite for scientific reliability in every case, but courts must be "especially skeptical" of scientific evidence that has not been published or subjected to peer review.... Publication and peer review allow an opportunity for the relevant scientific community to comment on findings and conclusions and to attempt to replicate the reported results using different populations and different study designs.[187]

Even courts that still operate under the *Frye* standard after *Daubert* have continued to examine whether peer review, and especially publication peer review, establish that the expert's methodology is generally accepted within the relevant expert community.[188] In *Berry v. CSX Transportation, Inc.*, the Florida Court of Appeals' decision to admit expert testimony on epidemiological studies was strongly influenced by the fact that those studies were peer reviewed and published in widely acknowledged medical and scientific journals.[189] The court concluded that, "[w]hile the existence of numerous peer-reviewed, published, epidemiological studies does not guarantee that the studies are without flaws, such publication here alleviates the necessity of thorough judicial scrutiny of each study at the admissibility stage to sort out the disputes over methodologic errors in studies."[190]

B. Court Review of Litigation Science

Contrary to some early predictions,[191] most of the experts whose testimony has been challenged and excluded under *Daubert* have been plaintiffs' experts.[192] In response and in order to improve

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187. Merrell Dow Pharm., Inc. v. Havner, 953 S.W.2d 706, 726–27 (Tex. 1997) (internal citations omitted).

188. *See, e.g.*, People v. Leahy, 8 Cal. 4th 587, 611–12 (1994); Castrichini v. Rivera, 669 N.Y.S.2d 140, 144 (N.Y. Sup. Ct. 1997); State v. Wesley, 633 N.E.2d 451, 456–57 (N.Y. Ct. App. 1994).

189. Berry v. CSX Transp., Inc., 709 So. 2d 552, 569–70 (Fla. Ct. App. 1998).

190. *Id.* (internal quotations and citation omitted).

191. *See e.g.*, Michael D. Green, *Relief at the Frying of* Frye*: Reflections on* Daubert v. Merrell Dow Pharm., Inc., 1 SHEPARD'S EXPERT & SCI. EVIDENCE Q. 43, 47–48 (1993); Barry J. Nace, *Reaction to* Daubert, 1 SHEPARD'S EXPERT & SCI. EVIDENCE Q. 51, 51 (1993); G. Marc Whitehead, Daubert *Will Allow More Expert Testimony, Complicate Jurors' Job, Prejudice Defense*, 21 PROD. SAFETY & LIAB. REP. (BNA) 41 (Summer–Fall 1993).

192. *See, e.g.*, David E. Bernstein, *The Admissibility of Scientific Evidence After* Daubert v. Merrell Dow Pharm., Inc., 15 CARDOZO L. REV. 2139, 2139–40 (1994); Finley, *supra* note 5,

their chances of surviving a *Daubert* challenge, plaintiffs' lawyers have begun to commission studies and submit them for publication to peer reviewed journals.[193] The few courts that have confronted litigation science to date have generally been skeptical of the value of these studies.

1. The Ninth Circuit's Decision in Daubert *on Remand* (Daubert II)—Even before the Supreme Court remanded *Daubert* to the Ninth Circuit, the Court of Appeals recognized the risks of litigation-driven scientific work by noting that the reanalysis relied upon by plaintiffs' experts in the case was "generated solely for use in litigation."[194] On remand from the Supreme Court, the Ninth Circuit stressed that lower courts should consider "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."[195] The court stated that research "conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science . . . [because it is done] in the usual course of business and must normally satisfy a variety of standards to attract funding and institutional support."[196] The court also implicitly cautioned lower courts to be wary of experts that might be biased towards a particular opinion because they were being paid for their litigation work.[197]

The court also recognized, however, that not all research that is relevant to a particular case can be conducted prior to and independent of litigation.[198] In such situations, the court held that the party proffering the litigation-generated research should provide other evidence confirming that the expert's methodology "is based

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at 351. In any event, it is certainly clear that more lawyers are moving to exclude experts and judges are granting their motions. *See Judges Are Excluding More Expert Testimony*, LAW. WKLY. USA, Oct. 30, 2000, at 11 (thirty-two percent of lawyers reported making more motions *in limine* regarding expert testimony since *Daubert*; forty-one percent of judges had excluded expert testimony, up from twenty-five percent in 1991).

193. *See infra* Parts I and III.B.3.

194. *Daubert*, 509 U.S. 579, 584 (citing the Ninth Circuit opinion, Daubert v. Merrell Dow Pharm., Inc., 951 F.2d 1128, 1131 (9th Cir. 1991)).

195. Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) (*Daubert II*). The Court highlighted the fact that "a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Id.*; *see also id.* at 1317 n.5 (noting exceptions for those involved in law enforcement).

196. *Id.* at 1317.

197. *Id.* The court also realized, however, that most experts are paid for their work and stated that the fact that an expert is being paid "does not necessarily cast doubt on the reliability of his testimony." *Id.*

198. *Id.*

on 'scientifically valid principles.' "[199] The court stated that litigation-generated research can be demonstrated to be "scientifically valid" if the expert has subjected his methodology to "normal scientific scrutiny through peer review and publication."[200] The court indicated that only those studies published in "*reputable*"[201] journals and subjected to a "*bona fide process of peer review*"[202] would satisfy its test for scientific validity when the methodology at issue was conducted for litigation purposes.[203]

If the expert's methodology was not developed independent of the litigation and his research was not published in a reputable journal with real peer review, the *Daubert II* court provided the expert with one last chance of establishing credibility: the expert must explain his methodology and "point to some objective source—a learned treatise, the policy statement of a professional association, [or] a published article in a reputable scientific journal . . . to show that [he has] followed the scientific method, as it practiced by (at least) a recognized minority of scientists" in the field of expertise.[204]

The *Daubert II* court thus required independent verification of the authenticity and validity of litigation-based scientific opinion, through thorough peer review or other objective measures of validity.[205] In this context, both the expert's own attempts (or lack thereof) to publish his methodology and the publications of others in the scientific community are relevant considerations for lower courts to use when assessing whether litigation-generated research is unbiased and therefore reliable enough for presentation to a jury.

2. Other Courts—The *Daubert II* court's concern with litigation bias is not surprising. Well before *Daubert* became the federal standard, courts had expressed concern with the independence of publications written by interested parties or experts hired during the course of litigation. In 1985, the United States Court of Appeals for the Third Circuit required lower courts to examine the

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199. *Id.* at 1317–18.

200. *Id.* at 1318 (citing PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 209 (1991)).

201. *Id.* (emphasis added).

202. *Id.* at 1318 n.6. (emphasis added).

203. The court recognized that "[p]eer review and publication do not . . . guarantee" that the reported methodology is valid but stated that publication in a peer-reviewed journal "increase[s] the likelihood that substantive flaws in methodology will be detected." *Id.* (quoting *Daubert*, 509 U.S. at 593).

204. *Daubert II*, 43 F.3d at 1318–19.

205. *Id.* at 1317–18.

"non-judicial uses to which the scientific technique" is used in assessing the reliability of an expert's proffered testimony.[206] Other courts also expressed concern that research generated solely for use in litigation might be biased.[207]

In the context of the learned treatise exception to the hearsay rule, one court summed up the same concerns that courts must address today in dealing with the reliability of an expert's opinion under a *Daubert* analysis:

> [T]he primary justification for admitting such evidence . . . is predicated upon consensus that learned treatises are inherently more trustworthy than customary forms of hearsay. . . . This view is founded upon a recognition that learned treatises are ordinarily written for members of the author's profession and, therefore, the author is thought to have no motive to misrepresent the material construed therein. A powerful incentive exists to publish a work which will be accepted by the other members of the author's profession as a fundamentally sound and authoritative exposition of the subject. Where, however, the author publishes an article with a view toward litigation, or where he possesses a personal interest in a litigable matter, a probability of bias exists which undermines the logic supporting the admission of this material in evidence as an exception to the rule against hearsay.[208]

Courts have expressed similar concerns in considering other hearsay exceptions for studies conducted for the purposes of litigation.[209]

When considering the admissibility of an expert's testimony under *Daubert*, a number of courts, including both state[210] and federal

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206. United States v. Downing, 753 F.2d 1224, 1239 (3d Cir. 1985).

207. *See* Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985) (noting that examination of a study by lawyers is not the same as by those trained in the field of science); Johnston v. United States, 597 F. Supp. 374, 415 (D. Kan. 1984) ("[T]hese witnesses say and conclude things which, in the Court's view, they would not dare report in a peer-reviewed format.").

208. *See* O'Brien v. Angley, 407 N.E.2d 490, 493–94 (N.J. 1980).

209. *See* People v. Huyser, 561 N.W.2d 481 (Mich. Ct. App. 1997) (holding that a medical expert's report of examination did not satisfy the business records exception when the examination was conducted solely for the purposes of litigation and his findings could not be duplicated in a subsequent examination).

210. *See, e.g.*, Berry v. CSX Transp., Inc., 709 So. 2d 552, 560, 569 (Fla. Ct. App. 1998); Harris v. Cropmate Co., 706 N.E.2d 55, 65 (Ill. App. Ct. 1999); Williams v. Hedican, 561 N.W.2d 817, 831 (Iowa 1997); McDaniel v. CSX Transp., Inc., 955 S.W.2d 257 (Tenn. 1997); Merrell Dow Pharm., Inc. v. Havner, 953 S.W.2d 706, 714 (Tex. 1997) (non-judicial uses of the methodology). *But see* Ford Motor Co. v. Ammerman, 705 N.E.2d 539, 554 (Ind. Ct.

courts outside of the Ninth Circuit,[211] have examined whether an expert's proffered studies or opinions were generated during litigation. While these courts do not address the propriety of submitting for peer review studies that were conducted for the purposes of litigation, they have expressed grave concerns with the reliability of studies that were conducted solely for the purposes of litigation and not for some other independent basis.

Following the *Daubert II* court's concern with the independence of opinions formed during litigation, a number of courts have excluded expert testimony based, in part, on the fact that the expert formed his opinion during the litigation and that the opinion was not otherwise reliable.[212] Not surprisingly, courts have ruled that an expert's proffered opinion does not satisfy the independence standard if the expert arrives at his conclusion during the pendency of related litigation in which he is a paid expert.[213] Courts are particu-

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App. 1999) (acknowledging the *Daubert II* line of cases but declining to consider the issue under Indiana law).

211. *See, e.g.*, Smelser v. Norfolk S. Ry. Co., 105 F.3d 299, 303 (6th Cir. 1997), *cert. denied*, 522 U.S. 817 (1997); *In re* Paoli R.R. Yard PCB Lit., 35 F.3d 717, 742 n.8 (3d Cir. 1994) (discussing non-judicial uses of the methodology); Downs v. Perstorp Components, Inc., 126 F. Supp. 2d 1090, 1124–29 (E.D. Tenn. 1999) (experts opinion raised seven "red flags" indicating that his testimony was litigation biased), *aff'd*, 2002 U.S. App. Lexis 382 (6th Cir. Jan. 4, 2002); Adams v. Ind. Bell Tel. Co., 2 F. Supp. 2d 1077, 1102 (S.D. Ind. 1998); Mitchell v. Gencorp, Inc., 968 F. Supp. 592, 600 (D. Kan. 1997); Nat'l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1516–18, 1526 (E.D. Ark 1996); Dukes v. Ill. Central R.R. Co., 934 F. Supp. 939, 948 (N.D. Ill. 1996); Valentine v. Pioneer Chlor Alkali Co., 921 F. Supp. 666, 670 (D. Nev. 1996) (before case, there was "no scientific evidence, published or otherwise, that inhaling chlorine causes neurological damage").

212. *See, e.g.*, Allison v. McGhan Med. Corp., 184 F.3d 1300, 1321 (11th Cir. 1999); *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 762 (3d Cir. 1994) (reliance on self reports of patients who are plaintiffs in litigation); *In re* Diet Drugs Prod. Liab. Litig., No. MDL 1203, 2001 U.S. Dist. LEXIS 1174, at *43–44 (E.D. Pa. Feb. 1, 2001); Stasior v. Nat'l R.R. Passenger Corp., 19 F. Supp. 2d 835, 849–50 (N.D. Ill. 1998); *In re* Breast Implant Litig., 11 F. Supp. 2d 1217, 1234 (D. Colo. 1998) (anecdotal evidence of patients not reliable because patients were litigants who were referred to the doctor); *id.* at 1243 (vast majority of expert's business came from plaintiffs involved in breast implant litigation); Adams v. Indiana Bell Tel. Co., 2 F. Supp. 2d 1077, 1102 (S.D. Ind. 1998); United Phosphorus, Ltd. v. Midland Fumigant, 173 F.R.D. 675, 686 (D. Kan. 1997) (analysis done solely for use in litigation); *Nat'l Bank of Commerce*, 965 F. Supp. at 1516–18, 1526; *Dukes*, 934 F. Supp. at 950–51; Jones v. United States, 933 F. Supp. 894, 897–98 (N.D. Cal. 1996); Rutigliano v. Valley Bus. Forms, 929 F. Supp. 779, 785–86 (D.N.J. 1996) (expert had not tested theory outside of litigation); Muzzey v. Kerr-McGee Chem. Corp., 921 F. Supp. 511, 519 (N.D. Ill. 1996) (opinion "'grounded on speculation shaped by result-oriented biases;'" no doubt that the "experts 'developed their opinions expressly for purposes of testifying'") (citations omitted); Lofgren v. Motorola, No. CV 93-05521, 1998 WL 299925, at *4, *7 (Ariz. June 1, 1998); *Valentine*, 921 F. Supp. at 678; Merrell Dow Pharm., Inc. v. Havner, 953 S.W.2d 706, 726 (Tex. 1997).

213. Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 597 (9th Cir. 1996); Nelson v. American Home Prods. Corp., 92 F. Supp. 2d 954, 959, 968–69 (W.D. Mo. 2000) (noting that published article was prepared when the expert was a "professional plaintiff's witness"

larly suspicious of litigation-generated studies when there is evidence that the expert changed his prior position to tailor it to the issues of the case or the requirements of *Daubert*[214] or when there is evidence that the expert will receive a financial payoff if his position ultimately prevails.[215]

Consistent with the *Daubert II* standard, courts have ruled that when the expert's opinion (or the basis for his opinion) is reached before the expert became involved in litigation, the expert's opinion is not biased and is thus reliable.[216] Courts have excluded expert opinions, however, when the expert purportedly relied upon non-litigation literature to support his opinion but reached the opinion *before* researching the literature,[217] or when lawyers have been forced to educate the expert because the expert had no prior experience in the area of his testimony.[218]

A few courts, when faced with unique facts, have excused an expert for forming an opinion or conducting testing as part of expected litigation.[219] Even fewer have failed to account for the

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and another expert had only made a similar diagnosis in three other patients—all of which were also made when the expert was testifying against the defendant in related litigation).

214. *See Nat'l Bank of Commerce*, 965 F. Supp. at 1517 (noting that expert's opinion for trial was stronger than that offered in her published articles); *United Phosphorus*, 173 F.R.D. at 685 (stating that, during hearing, expert abandoned conclusions he reached in his report).

215. Carnegie Mellon Univ. v. Hoffman-LaRoche, Inc., 55 F. Supp. 2d 1024, 1034, 1041 (N.D. Cal. 1999) (noting that experts were entitled to share forty percent of proceeds of litigation until they received four million dollars, and fifty percent thereafter; and excluding one expert's testimony but allowing the other); *cf.* Castrichini v. Rivera, 669 N.Y.S.2d 140, 145 & n.2 (N.Y. Sup. Ct. 1997) (holding under the *Frye* standard that the expert, an inventor, had a commercial interest in publishing articles regarding the successes of his product).

216. Berry v. CSX Transp., Inc., 709 So.2d 552, 560, 569 (Fla. Dist. Ct. App. 1998) (expert began studying issue before onset of litigation and his theory was accepted for publication by peer reviewed journals); Williams v. Hedican, 561 N.W.2d 817, 831 (Iowa 1997) (opinion based upon existing research not generated for litigation).

217. *See* Sorensen *ex rel.* Dunbar v. Shaklee Corp., 31 F.3d 638, 649 (8th Cir. 1994); Claar v. Burlington N. R.R. Co., 29 F.3d 499, 502–03 (9th Cir. 1994); Mitchell v. Gencorp, Inc., 968 F. Supp. 592, 600 (D. Kan. 1997); Cartwright v. Home Depot, 936 F. Supp. 900, 906 (M.D. Fla. 1996); Lofgren v. Motorola, No. CV 93-05521, 1998 WL 299925, at *4, *18, *27, *35 (Ariz. June 1, 1998).

218. *See* Nelson v. Am. Home Prods. Corp., 92 F. Supp. 2d 954, 968 (W.D. Mo. 2000) (noting that the only materials which an expert relied on were those supplied by plaintiff's lawyers); *Lofgren*, 1998 WL 299925, at *24; *cf.* Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *39 (Tex. Dist. Ct. June 7, 1999) (expert called "hired-gun" because he did not treat the patient nor did he have any expertise in the field before the onset of litigation).

219. For instance, one court has held that where "litigation is constant" (on an issue of abortion rights) and when a Supreme Court opinion essentially invited the subject of the expert's research, the expert's connection with the litigation would not disqualify his evidence. *See* A Woman's Choice—East Side Women's Clinic v. Newman, 904 F. Supp. 1434, 1461 (S.D. Ind. 1995).

expert's potential litigation bias. In addressing the plaintiff's expert's rollover test that was not published or otherwise externally reviewed, the court in *Ford Motor Co. v. Ammerman* acknowledged that courts have considered whether methodologies developed independent of litigation are important indications that the expert's theory is valid.[220] The court, however, rejected consideration of litigation bias in assessing the reliability of the test and opinion and instead relied upon the adversarial nature of the lawsuit itself, particularly through "cross-examination and presentation of evidence," to peer review the test.[221] Since any expert opinion would be subject to cross examination, the *Ammerman* court's holding essentially rendered meaningless the peer review component of *Daubert*.[222] Such a result makes no sense and has been rejected by other courts as an abdication of a court's gatekeeper responsibility.[223]

The court in *Fitzpatrick v. Louisville Ladder Group L.L.C.* held that an expert's testimony was created independent of litigation because he presented his theory in three previous cases prior to the case then before the court.[224] Somehow the court saw this prior testimony as growing independent of litigation. Although his opinion may have been developed independent of *that* particular case, it certainly was not developed independent of *litigation*. Perhaps realizing its earlier mistake, the court ultimately noted that the expert's testimony "barely passed the admissibility threshold under *Daubert*."[225]

3. Generating Peer Reviewed Publications to Support Litigation—As discussed in Section I above, research created for litigation—including its publication in scientific or medical journals—has

220. 705 N.E.2d 539, 554 (Ind. Ct. App. 1999).

221. *Id.* Opinions like *Ammerman*, where the court completely excluded any need for non-litigation review of a litigation-generated study, are rare in the toxic tort and health-based product liability context. The Indiana court may have felt less constrained to do so because the test involved the mechanical performance of an automobile instead of complex health-based science.

222. United States v. Plaza, 179 F. Supp. 2d, 492, 506 (E.D. Pa. 2002) (stating that relying on "'adversarial' courtroom testing" would "vitiate the gatekeeping role of federal trial judges" because "[i]f 'adversarial' testing were the benchmark [under *Daubert*]—. . . then the preliminary role of the judge in determining the scientific validity of the technique would never come into play").

223. *Id.*; *see also* Pietzmeier v. Hennessy Indus., 97 F.3d 293, 297 (8th Cir. 1996); *In re* Diet Drugs Prod. Liab. Litig., No. MDL 1203, 2001 U.S. Dist. LEXIS 1174, *44–45 (E.D. Pa. Feb.1, 2001) (rejecting argument that a challenged expert's opinion was "peer reviewed" because it was reviewed by two other experts retained in the case by the same party); Blum v. Merrell Dow Pharm., Inc., 705 A.2d 1314, 1322 (Pa. Super. Ct. 1997) (cross-examination cannot be counted on to test speciousness or accuracy of expert's testimony).

224. No. 8:99CV29, 2001 U.S. Dist. LEXIS 3305, at *14–16 (D. Neb. Mar. 19, 2001).

225. *Fitzpatrick v. Louisville Ladder Corp.*, No. 8:99CV29, 2001 U.S. Dist. LEXIS 20197, at *11 (D. Neb. Dec. 6, 2001).

already appeared in a number of recent cases.[226] Courts have been highly skeptical of such science and have taken a number of steps to ensure its reliability. For the most part, the proffered studies and accompanying testimony have been rejected under *Daubert.*

For example, in *National Bank of Commerce v. Dow Chemical Co.,*[227] Plaintiff's expert Dr. Sherman attempted to obtain external verification of her studies involving birth defects from pesticide exposure by publishing two different case report articles in journals.[228] The court was unimpressed. The court first noted Dr. Sherman's extensive litigation involvement. She had been a litigation consultant and expert witness for twenty years[229] and was a testifying expert in all of the cases at issue.[230] In addition, the research that was the subject of the articles was all litigation-connected.[231] More troubling to the court was the *nondisclosure* involved in publication. The published articles failed to reveal either Dr. Sherman's litigation connection or her personal financial interest in the cases.[232] The court also noted that Dr. Sherman had "not published her protocols, reasoning or methodology"[233] and thus foreclosed any real peer review and possible replication of her studies. Without this information, other experts in Dr. Sherman's field could not subject her theory to scientific scrutiny.[234] Dr. Sherman also failed to report "the opinion of [other] experts attributing the birth defects to genetic causes,"[235] thus implying a bias in the articles and failure to account for competent scientific disagreement with her position. The court concluded that Dr. Sherman was engaged in advocacy "based on suspicion and conjecture and litigation animus rather than science."[236]

Another good illustration of court rigor in reviewing litigation science is *Black v. Rhone-Poulenc, Inc.*, in which the challenged expert presented the results of a litigation-generated study he presented at two symposia, and thus claimed they were peer-reviewed and viable

226. *See, e.g.*, Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 597 (9th Cir. 1996) (expert published an article in non-peer reviewed journal after he became a professional witness in similar case).

227. 965 F. Supp. 1490 (E.D. Ark. 1996).

228. *Id.* at 1498.

229. *Id.* at 1516.

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.* at 1525.

234. *See id.*

235. *Id.* at 1517. As further evidence of her bias, the court also stated that Dr. Sherman's planned testimony before the jury was stronger than that stated in her published articles. *Id.*

236. *Id.* at 1516.

under *Daubert*.[237] The court did not agree.[238] In addition to noting the study's litigation role, the court dissected the plaintiffs' law firm's involvement in the studies and found that the studies were shot through with lawyer influence and insinuation.[239] As the court noted, "[t]he depth and breadth of litigation taint is so substantial the very validity of the study is compromised."[240] None of this litigation influence was revealed at the symposia,[241] thus undercutting whatever peer review may have occurred at those proceedings. The court therefore excluded the expert's testimony.[242]

Cases like *Ruffin v. Shaw Industries, Inc.*, on the other hand, are rare. In *Ruffin*, the Fourth Circuit Court of Appeals did not need to inquire deeply into the litigation taint of Dr. Anderson's carpet tests, which she claimed showed fatal toxicity to rats, because those tests attracted close inspection by independent sources.[243] In particular, the United States Environmental Protection Agency conducted its own set of studies attempting to replicate Dr. Anderson's toxicity but could not achieve even mild impacts on the rats.[244] Dr. Anderson's mentor, a professor at the University of Pittsburgh, also could not completely replicate her results.[245]The courts in the *Black* and *National Bank of Commerce* cases had to operate absent any real peer review and thus looked more closely at the nature of the proffered study, its litigation influence, and adequate disclosures to the publishing journals.[246] In *Ruffin* the court needed none of this because real peer review occurred and demonstrated Dr. Anderson's tests to be flawed.[247] Without question this is a preferable method of determining the reliability of litigation science, but courts will rarely have the benefit of such outside review.

Section I described a number of other cases involving litigation science. Most of these courts rejected the proffered evidence un-

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237. Black v. Rhone-Poulenc, Inc., 19 F. Supp. 2d 592, 600 (S.D. W. Va. 1998).

238. *Id.*; *see also supra* note 79 (discussing inadequacy of conference presentation alone as basis for peer review), note 282 (abstracts), and note 283 (poster presentations).

239. *Black*, 19 F. Supp. 2d at 601–02; *see also supra* text accompanying note 21 for details of the law firm's involvement.

240. *Black*, 19 F. Supp. 2d at 603–04.

241. *Id.* at 600.

242. *Id.* at 606.

243. Ruffin v. Shaw Indus., Inc., 149 F.3d 294, 297 (4th Cir. 1998).

244. *Id.* at 297–98.

245. *Id.* at 298–99.

246. *See Black*, 19 F. Supp. 2d at 597, 600–01; Nat'l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1494, 1497–1500 (E.D. Ark. 1996).

247. *Ruffin*, 149 F.3d at 299.

der a *Daubert* or *Frye* standard, typically because the methodology was not generally accepted, the tests were biased by the litigation link, and the tests were either not published or the publication occurred without disclosure of the litigation connection.[248]

Litigation science is not always rejected, however, particularly if there is sufficient indicia of external and independent support for the methodology or conclusions. In *Worthington City Schools v. ABCO Insulation*,[249] an asbestos case in which defendant's expert authored a published article studying airborne concentrations of asbestos,[250] the expert admitted contacting companies for whom he had previously appeared as an expert witness to utilize the data he relied upon in those cases.[251] The expert was the lead author of the article but did not disclose his role in the pending litigation.[252] Nonetheless, the court ruled that the article was trustworthy (and therefore admissible) since it was submitted for peer review and revised prior to publication.[253] The court based its reasoning on the fact that the expert relied upon other articles—including a government article and articles from the Health Effects Institute and the World Health Organization—which published similar results.[254]

IV. EVALUATING LITIGATION SCIENCE IN THE SCIENTIFIC AND LEGAL COMMUNITIES

The *Daubert* Court attempted to establish a process under which the legal system could identify and eliminate bad science, primarily

248. *See* Lust v. Merrell-Dow Pharm., Inc., 89 F. 3d 594, 596–98 (9th Cir. 1996) (rejecting published opinion on fertility drug teratogenicity because of litigation involvement in study that was not revealed during publication and because of the absence of any other publication supporting the expert's opinion); Valentine v. Pioneer Chlor Alkali Co., 921 F. Supp. 666, 673–75 (D. Nev. 1996) (rejecting published study of litigation-generated study because of test bias and flaws and failure to prove thorough peer review); E.I. DuPont de Nemours & Co. v. Castillo, 748 So. 2d 1108, 1116 (Fla. Dist. Ct. App. 2000) (rejecting an expert's *in vitro* test extrapolations, even though test results were published, because the expert's extrapolation methodology was not generally accepted under *Frye*); O'Brien v. Angley, 407 N.E.2d 490, 493–94 (Ohio 1980) (article written primarily to express opinion by testifying physician concerning a litigation issue was untrustworthy as a learned treatise); *cf.* Worthington City Sch. v. Abco Insulation, 616 N.E.2d 550, 552–53 (Ohio Ct. App. 1992) (admitting study based on data collected in previous litigations on asbestos in buildings).

249. 616 N.E.2d 550 (Ohio Ct. App. 1992).

250. *Id.* at 552–53.

251. *Id.* at 553.

252. *Id.*

253. *See id.*

254. *See id.* (concluding that the admission of the article did not prejudice plaintiff's case).

by relying on the processes scientists use to do the same in their realm. Does the *Daubert* system work, however, when the science at issue is no longer generated by independent researchers but by the very litigants before the court for the sole purpose of achieving *Daubert* acceptability? Because of the risk that litigation science could undermine a *Daubert* inquiry, we propose that both scientists and courts heighten their scrutiny and disclosure requirements when faced with litigation-generated research.

A. The Peculiar Risks of Litigation-Generated Research

It might be tempting to ask why litigation-generated research should be treated any differently than other research. After all, fraudulent and conflict-driven research existed long before *Frye* and *Daubert* and wholly independent of the legal process.[255] Litigation science may be only another point on the continuum of studies funded by entities with a vested interest in the outcome.

The litigation process, however, makes litigation science particularly susceptible to the kind of bias and misreporting most likely to generate unreliable and biased research. Because proponents in litigation are advocating a particular position, their research does them no good—and in fact may do serious harm—unless it has an outcome supportive of that position. The pressure is intense to ensure that the test comes out the "right" way. To be sure, this dynamic exists in milder forms apart from the litigation world, where researchers have reasons to underreport or misreport data.[256] Nothing in the scientific realm, however, begins to approach the strength and vigor of litigation's dual-sided advocacy, where there is little room for acknowledging errors, uncertainties, or the validity of contrary positions.

The advocacy dynamic that permeates litigation also mandates that the lawyers involve themselves in the research, either directly or through their testifying expert. That involvement may be entirely appropriate from a legal standpoint, as it is counsel's job to make sure the research is relevant to the litigation and will be defensible on cross-examination. It is easy, however, to imagine situations in which the legal involvement could become

255. *See, e.g.*, Relman & Angell, *supra* note 111, at 828; Whitley, *supra* note 114; Boffey, *supra* note 114; Garfield & Welljams-Dorof, *supra* note 114; *supra* text accompanying notes 115–17.

256. *See* FOSTER & HUBER, *supra* note 60, at 95–100 (discussing types of errors commonly found in scientific research).

inappropriate, and even impinge upon the integrity of the research. In the *Black* case, for instance, the expert appeared to exist as a tool of the law firm, and the firm intruded into the study by, among other things, helping select and process participants and by implying a litigation reward for study participants.[257] Should the lawyers dictate the protocol, determine the number and type of controls and test groups, select the statistical analysis used, or screen the outcomes that will be reported? Even if the legal system would accept such involvement, scientists would no doubt shudder at the prospect.[258]

The pressure for litigation researchers to conduct a test to achieve a predetermined outcome is anathema to proper scientific inquiry. It is fundamental that no research will be conducted to prove a predetermined point, but will instead be conducted to disprove the null hypothesis.[259] The expected or desired outcome should not be predetermined, and the results must be accepted for what they are. Litigation-driven research, if conducted without proper recognition of the null hypothesis approach, may thus well subvert the scientific process itself.

The reporting and publishing of litigation science is also problematic from the standpoint of avoiding unreliable science. Presumably, a testifying expert desiring to support novel and unproven causation theories in court would attempt to publish a study with the desired outcome in a medical or scientific journal that claims to be peer-reviewed. Because of the highly variant disclosure and peer review practices among journals, particularly with lower-tier publications, a researcher can always find a willing journal that will not ask too many questions.[260] Without disclosure and serious peer review, there is no way to determine on the face of the published article whether it is in fact litigation-funded and controlled, or whether or how the litigation interests influenced the study.

Regardless of how scientists or others feel about it, litigation science is with us for the foreseeable future. The legal system is tasked with making causation decisions on key public health issues on which scientists have not yet reached any conclusions. The stakes are enormous, and if the existing science is inconclusive or too limited, litigants can be expected to create new science to

257. Black v. Rhone-Poulenc, Inc., 19 F. Supp. 2d 592, 601–02 (S.D. W. Va. 1998).

258. *See, e.g.*, ANGELL, *supra* note 59, at 202–03 (decrying "complicity" of doctors and lawyers in supporting allegations of injury from breast implants).

259. *See* GOLDSTEIN & GOLDSTEIN, *supra* note 64, at 19.

260. *See* FOSTER & HUBER, *supra* note 60, at 170; LOCK, *supra* note 91, at 85.

support their positions. It is thus critical that both scientists and the courts adopt approaches to ensure that litigation science does not infect either system with bad science.

B. Addressing the Risks Posed by Litigation Science

To deal with the risks posed by litigation science, special attention is required in both the scientific and legal realms. We do not attempt to address here the merits and efficacy generally of either the scientific falsification process or *Daubert* analysis or reforms needed for either.[261] Instead, we focus (with the exception of our proposed Institute for Litigation Research discussed in Section IV.C) on using existing processes to deal with the unique aspects of litigation science.

The two primary risks arising from litigation science are the absence of disclosures that prevent readers from knowing about the link to litigation and resulting potential bias, and the inability to determine from a published article whether the study has been inappropriately manipulated to achieve the desired outcome. On the front end, scientific and medical publications and other peer review institutions need to pay increased attention to strengthening disclosure requirements and developing other means of forcing litigation researchers to expose their work to full and unbiased review. On the back end, courts must escalate their *Daubert* analysis to ensure that purported peer review is not a sham attempt to infect the legal system with meritless or biased science. Litigants who choose to pursue litigation science should do so with the expectation that it will be scrutinized severely and that it must conform to the tenets of quality science.

1. Scientific Review of Litigation-Generated Research—Proper examination of litigation science has to begin with the scientific community, because the courts are relying in the first instance on scientists to identify "scientific knowledge" that is sufficiently reliable for courtroom usage.[262] Beginning with publication and working through the various forms of post-publication peer review, scientists need to recognize litigation science as a unique species, with potential merit but also with special risks.

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261. *See, e.g.*, Smith, *supra* note 185 (surveying *Daubert* law and identifying outstanding issues not yet resolved by courts).

262. *See supra* notes 57–59 and accompanying text.

Requiring full disclosure. Some portion of the scientific world will likely learn of a particular litigation-based study at the point the researcher submits the study for publication. At this juncture it is critical that the journals to which the manuscript is submitted insist on disclosure of the study's basis in litigation. Initially, the journal must insist that its authors identify for the journal the nature and extent of the author's litigation connection. If this disclosure does not occur, the journal's editors risk being used as pawns by lawyers sponsoring the research who may not want any serious inquiry into the study prior to publication. The subsequent disclosure (by newspapers, for instance) of the litigation connection and any flaws in the study could be highly embarrassing to the journal.[263] Assuming the litigation connection is disclosed, the journal must then ensure that publication includes an adequate description of the litigation connection lest the journal be accused of sitting on potentially relevant and explosive information.

Considering the risks posed by litigation science published without any disclosure, it is unnerving that a large number of journals still do not require disclosure of potential conflicts of interest by their authors.[264] Nor does it seem helpful that a few eminent editors have argued recently to eliminate or restrict disclosure requirements rather than expand them.[265] Would their compunction about disclosure change if their journals were confronted with research funded and controlled by lawyers? If the courts are to obtain the help they need from the scientific community, it is imperative that disclosure requirements receive widespread support and implementation in the publishing world.

Ensuring disclosure to peer reviewers. Journals should also ensure that the litigation connection be conveyed to their peer reviewers. The reviewers have a right to know whether and to what extent they should question the unreported aspects of a study and ask for further citation, confirmation, support, and the like before approving an article. Currently, there is considerable variation, even among top journals, as to the information provided to peer

263. Witness the recent experience of the prestigious *New England Journal of Medicine*, whose editors had to confess, following a newspaper article's exposé, to a failure to identify potential conflicts of interest of several authors of a series on new drugs. *See supra* note 114.

264. *See* Good et al., *supra* note 121; Richard M. Glass & Mindy Schneiderman, *A Survey of Journal Conflict of Interest Policies*, INT'L CONGRESS ON BIOMEDICAL PEER REV. AND SCI. PUBLICATION, *at* http://www.ama-assn.org/public/peer/apo.htm (last visited Sept. 3, 2001).

265. *See* Richard Horton, *Conflicts of Interest in Clinical Research: Opprobrium or Obsession?*, 349 THE LANCET 1112 (1997); Eliot Marshall, *Journals Joust over Conflict-of-Interest Rules*, 276 SCIENCE 524 (1997); Kenneth J. Rothman, *Conflict of Interest: The New McCarthyism in Science*, 269 JAMA 2782 (1993).

reviewers. Some in the publishing world believe reviewers should examine nothing but the merits of the article before them.[266] As the only "experts" to review the article,[267] however, peer reviewers are being asked to sign off on the scientific merit of an article *based on certain assumptions* about the underlying work, including that it was conducted with reasonable impartiality and proper scientific procedure. It seems reasonable that if the circumstances surrounding a study cause it to be particularly suspect with regard to those assumptions, the reviewers should know that they may not be able to rely on those assumptions in the same way. They might then require further disclosure or discussion of study procedures, publication of more underlying raw data than would ordinarily be included, an independent statistical analysis, or more caution with regard to the researchers' conclusions about the findings of the article.[268]

Scrutiny of the merits and findings: As part of the peer review and approval process, both the editors and the peer reviewers should pay careful attention to the merits of the work. Litigation science is susceptible to false or overreaching statements that are not supported by the study. These statements are usually found in the abstract, the introduction, or the discussion sections where authors sometimes speculate about the import of their work.[269] In ordinary

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266. *See, e.g.*, Horton, *supra* note 265, at 1112; Rothman, *supra* note 265, at 2782, 2784. Even journals that require disclosure may disclaim that disclosed conflicts affect their reviews in any way. *See* Robert Goldwyn, 88 PLASTIC AND RECONSTRUCTIVE SURGERY 323–24 (1991) ("[T]his Editor and the Editorial Board will not judge the suitability of the article for publication on the basis of whether the author has or does not have any financial interests.")

267. In the highly specialized medical and scientific worlds today, even journal editors rarely have the expertise to dissect the complicated articles that come their way. The increase in specialization since World War II has made it imperative that reputable journals use experts in the fields addressed by submitting articles for external peer review. *See* Burnham, *supra* note 104, at 1324–25.

268. This would likely be a cumbersome process for unpaid, volunteer peer reviewers who have difficulty finding time to review dozens if not hundreds of articles each year. For that reason, we propose in Section IV.C, below, an alternative to the traditional peer review system to deal with litigation science.

269. One study performed in the *Bourne* litigation, *see supra* text accompanying note 21, found no statistically significant effects from pesticide gavage doses. Nonetheless, the introductory language in the study report contained numerous conclusory, erroneous statements about the teratogenicity and activity of the fungicide. *See* Paul Sibbons, Benomyl Toxicology Study, Study No. 70/4515, at 6–7 (Aug. 10, 1999) (unpublished medical research study, on file with the *University of Michigan Journal of Law Reform*). None of the statements were supported in any scientific literature, but they were consistent with the position of plaintiffs' chief causation expert. When the lead researcher was deposed, he denied any responsibility for that portion of the report and testified that it was written by the testifying expert's assistant instead. Deposition of Dr. Paul Sibbons, Study Director, NPMR, Ltd, in London, England, at 48–64, 78–79 (Oct. 22, 1999) (on file with the *University of Michigan Journal of*

research, such speculation may be harmless ruminating designed to encourage further thought and study. In litigation science, such comments have likely been carefully crafted to support the litigants' theories and may range well beyond the actual findings in the research. Publishers may think these comments unworthy of attention, but the lawyers may later argue in court that the conclusory statements have been peer reviewed along with the underlying research.

Reporting the underlying work: The study may also fail to report adequately the underlying research work. Many articles review only briefly the procedures and protocol used and the specifics of the data generated. A good peer-reviewed article will have enough of this information to help the reviewers assess the propriety of the methodology and conclusions, but not so much as to make the article unwieldy or unpublishable. Peer reviewers rarely see the bulk of the underlying study materials and must trust that the researchers have conducted the study properly.[270] Litigation science should be held to a higher standard requiring expanded disclosure of procedures and data to protect against biased or selective reporting or hiding inappropriate design and practices. The information reported should, at a minimum, provide enough information to allow other interested experts to attempt replication of the author's findings.[271]

Requiring disclosure in publication: If a journal chooses to publish litigation science, the published article must include disclosure of the litigation connection and the steps the journal has taken to ensure that the research has been properly performed and its conclusions supported.[272] If the journal does not do so, it will have become an active participant in foisting potentially biased and bad science on the scientific and legal communities.[273] Considering the

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Law Reform). Although this study has not been published, it illustrates how a research article can be manipulated to support litigation in ways that might survive peer review.

270. *See* Relman & Angell, *supra* note 111, at 828.

271. The court in *National Bank of Commerce v. Dow Chemical Co.* criticized the published reports of Dr. Sherman because she did not include information on her protocols, reasoning, or methodology. 965 F. Supp. 1490, 1525 (E.D. Ark. 1996).

272. This has in fact been the conclusion of courts that have assessed publication of litigation-generated research to date. *See* Black v. Rhone-Poulenc, Inc., 19 F. Supp. 2d 592, 600 (S.D. W. Va. 1998) (noting disclosures of litigation connection would be a factor supporting a finding of appropriate peer review); *Nat'l Bank of Commerce*, 965 F. Supp. at 1517 (citing disclosure of litigation connection as a factor in assessing value of peer review of articles); *cf.* Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 596 (9th Cir. 1996) (cross-examination revealed litigation connection of previous article).

273. Consider the opprobrium directed towards prestigious journals such as the *New England Journal of Medicine* and the *Journal of the American Medical Association* for publishing

risks involved, journals should not be permitted to hide behind their inadequate or nonexistent disclosure policies. Failure to disclose that the journal has published a litigation-funded study is tantamount to an affirmation by the journal that the study is like any other and not due any special skepticism, a practice that many readers would view as at best misleading, if not something worse.

Nondisclosure is such a critical factor that the scientific publishing community should ban the publication of research performed for purposes of litigation that is not accompanied by proper disclosure when submitted to a journal. The only reason for such nondisclosure is an attempt to manipulate a scientific publication for litigation purposes.[274] If journals continue to publish studies without requiring disclosure or reporting the litigation connection, the publishing community should deal with them in a way that allows courts to know which journals properly address litigation science and which do not. A strong statement of disapproval by the scientific community would make litigation researchers think twice before withholding disclosure when they submit litigation studies for publication, as any subsequent revelation of those researchers' nondisclosures could impact their reputation and ability to publish additional research.

Only the major journals currently engage in any of the practices suggested above. Even those journals do not require any special review or attention for litigation science other than disclosure of potential conflict. To date, the use of litigation science has been fairly isolated, so perhaps leading journals will step up their review practices as the subject gets more attention.[275] Considering the difficulty the publishing community has had in adopting any consistency among peer review and publication practices generally,[276] however, it is doubtful the courts can expect immediate help with litigation science from journal publishers.

Initiating post-litigation peer review. If the litigation basis of a study has in fact been properly disclosed, and the study has been peer

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articles without disclosure of pharmaceutical company relationships and litigation relationships, respectively. *See supra* Section II.B.2.

274. In light of the lack of a disclosure requirement by many journals, perhaps this statement is too extreme. On the other hand, it is fairly safe to assume that proponents of litigation research who do not want close scrutiny will seek out journals with no disclosure requirement, precisely for the purpose of avoiding disclosure and the resulting scrutiny.

275. Unfortunately, to avoid the stigma associated with having an article rejected for publication litigation research tends to be submitted not to leading journals but to lesser publications, where peer review may not exist and publication is less difficult. *See, e.g.*, Valentine v. Pioneer Chlor Alkali Co., 921 F. Supp. 666, 670 n.3 (D. Nev. 1996) (publication in journal not listed in *Index Medicus* or found at Johns Hopkins library).

276. *See supra* Part II.B.2.

reviewed by a respectable journal and published with disclosures, the process does not end there. To support litigation, the study (or the experts interpreting it) may claim fairly dramatic consequences—the identification of a new human teratogen (*e.g.*, Bendectin) or a widespread source of serious human injury (*e.g.*, breast implants). The scientific world would never accept a single study on such a topic as anything more than potential evidence of a connection that needs further and more extensive study on numerous fronts before the falsification process is reasonably satisfied. The courts, however, may be forced to make causation decisions on just such a single study.[277] As the system currently operates, major public health decisions with consequences for millions of people and the survival of major companies or important products can turn on such an inadequate scientific basis.

The scientific community could help the courts tremendously by getting out in front of the legal process on exploding public health issues. When a litigation public health issue first arises, either through a litigation-funded study or otherwise, ideally the entities that fund and direct scientific research should determine, through independent scientists, whether the issue merits study and then fund and direct those studies as soon as possible. This is precisely the process followed in the *Ruffin* case, in which plaintiffs' carpet testing attracted the attention of Congress, the EPA, and an independent researcher. The expert's test was thereafter subjected to (and refuted by) replicatory testing.[278] In contrast, the breast implant fiasco wandered through twelve years of litigation, multimillion dollar settlements, and bankruptcies of defendants before the scientific community got around to conducting the first independent epidemiological study addressing the existence of a connection between breast implants and connective disease.[279]

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277. Most of the cases discussed in Section I involved a single or small set of studies purportedly supporting novel theories of injury. *See, e.g.*, Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 596 (9th Cir. 1996) (alleged birth defects from fertility drug supported by single published study authored by plaintiffs' expert); *Valentine*, 921 F. Supp. at 670 (chlorine neurological damage theory supported by a single published study by plaintiffs' expert).

278. Ruffin v. Shaw Indus., Inc., 149 F.3d 294, 297–98 (4th Cir. 1998).

279. *See* Marcia Angell, *Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1515 (1996) (first lawsuit in 1982; first epidemiological study completed in 1994). Dr. Angell believes the breast implant manufacturers are to blame for not performing epidemiological studies long before. *Id.* The manufacturers would have had little reason, however, to perform such studies until the first lawsuits alleged what was until then a non-existent connection to disease, or for that matter until the lawsuits escalated to the point funding expensive studies would make sense, either medically or economically. Post-litigation research by the defendants would have to undergo scrutiny (and be criticized) as litigation-generated

Twelve years is far too long for the legal world, where the courts are confronted with the alleged victims of potentially harmful products and the pressure to provide near immediate relief is severe.

Granted, research dollars are always in short supply, and some in the scientific community will no doubt feel that their scarce resources should not be diverted to support the ugly world of lawyers battling over millions of dollars. No one can argue, however, that some of the largest public health issues of the century have been decided in, or substantially impacted by, the litigation arena, not the laboratory. If there is potential merit to some of the contentions made by plaintiff groups, the scientific community ought to investigate. If there is not, scientists ought to intervene as well to prevent biased and wholly inadequate science from driving the nation's public health decisions and consuming its resources.

The biggest hurdle to timely scientific review of breaking litigation theories is the lack of any mechanism to trigger early review. The publication of early litigation research, if it is published at all, will likely occur in minor journals and in quiet ways that will not attract serious scientific attention—"publish and be ignored," rather than "publish and be damned." Interest in the novel theories will not arise until lawsuits are filed and won in large numbers, and by then the allegations have taken on a life of their own that even good science may not stop.[280] By the time scientific interest develops, manufacturers may have been forced into bankruptcy even though plaintiffs' evidence later turns out to be scientifically worthless. No institution currently has a mandate to monitor litigation science, and the attention and conclusions of entities such as the EPA or FDA will be sporadic and often equivocal. Section IV.C addresses this problem with a proposal for an external review mechanism.

2. Legal Review of Litigation Science—Whether or not scientists properly address litigation science, courts must do so because they

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research funded by the defendant company. In fact, plaintiffs' attorneys in the breast implant cases immediately criticized even the Mayo Clinic study in 1994 because it was partially funded by a foundation that received money from breast implant makers. *See* ANGELL, *supra* note 59 at 142–43. More preferable would be independent research or literature reviews, as in the *Ruffin* case, *supra* note 278.

280. The Bendectin cases have been going on since at least 1977, despite the absence of any study confirming that the drug causes birth defects in humans and the presence of multiple epidemiological studies supporting the lack of any connection. *See* FOSTER & HUBER, *supra* note 60, at 2–4. Merrill-Dow has won almost all of the lawsuits, yet they continue to be filed. *Id.* Despite its success in litigating the cases, Merrell-Dow was forced to take the product off the market in 1983 because of the extraordinary costs of litigating these baseless claims. *Id.*

are certain to be confronted with it. Court review of litigation studies follows the same paths as scientific review, but may be complicated because courts are not well equipped to identify the flaws in such research.

Initial identification: Initially, the court (and opposing parties) will have to question the source of a relatively recent study offered in support of a proponent's case. The proponent may not reveal that the study was performed with a litigation connection. If the opposing lawyers are doing their job properly, they will have conducted discovery and can provide the court with relevant funding information and the details of litigation's influence on the study.[281] If not, the court must ensure that biased science is not introduced in disguise.

Reliance on the scientific process: If the study has a litigation genesis, the court should inquire into the level of review of the study and its proposed theory by the scientific community. In the same way that the publishing community should conduct a heightened review, the court must not accept the fact of publication as sufficient to ensure the integrity of the study. The court's ability to rely on the scientific falsification process depends upon the degree to which that process has actually occurred and achieved some measure of scientific acceptance of the approach or methodology used.

If the article in question does not meet certain benchmarks, the court should give it little or no consideration in deciding whether the expert's testimony should be excluded. Benchmarks that leave an article short of even the most basic reliability should include:

> The authors did not disclose the litigation connection to the journal.
>
> The journal did not disclose the litigation connection to its peer reviewers.
>
> The journal did not use external peer reviewers who are experts in the field.
>
> The peer review process does not have other sufficient earmarks of a serious and quality review.

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281. *See Lust*, 89 F.3d at 596 (expert admitted litigation connection of prior study on cross-examination). In the *Bourne* matter, *supra* note 21, the law firm funding and other litigation connections of two published *in vitro* studies relied on by plaintiffs' expert was not known until counsel deposed the lead researcher (not an expert in the case) in England. *See* Dep. of W.G. McLean, *supra* notes 22, 23, 26.

> The journal failed to publish the article with disclosure of its litigation connection, thus preventing other scientists from conducting appropriate post-publication peer review.

Beyond these basic "first blush" tests, the court should inquire into the degree to which the scientific community has attempted to falsify the methodology or results reported in the study. Through reviews, letters to the editor, subsequent research, and the like, other scientists may have already identified flaws in the work and can provide the court a roadmap. If the article has received little or no attention, however, the court will find no help there and must use its own attempts to judge the expert's methodology. In addition, standing alone, some means of addressing new methodologies cannot properly be called peer review. Courts should give little or no weight to abstracts and case reports,[282] poster presentations at conferences,[283] anecdotal evidence or personal experience,[284] or legislative testimony.[285] Courts should also reject arguments that cross-examination of the challenged expert or a contrary opinion by an opposing testifying expert during the case can substitute for peer review in a *Daubert* analysis.[286]

Apart from direct review of the research itself, the consistency or inconsistency of the article's conclusions with related scientific

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282. *See, e.g.*, Nelson v. Am. Home Prods. Corp., 92 F. Supp. 2d 954, 969 (W.D. Mo. 2000) (noting that case reports do not attempt to investigate alternative causes and that at most they "relay a basis for scientific hypotheses" rather than a "a causal link sufficient for admission to a finder of fact"); Bushore v. Dow Corning-Wright Corp., No. 92-344-Civ-T-26C, 1999 U.S. Dist. LEXIS 20697, *15–16 (M.D. Fla. Nov. 15, 1999) (remarking that "anecdotal or clinical data may be appropriate for treatment . . . [but] such methodology is not generally accepted in the scientific community as sufficiently reliable to determine causation"); Cartwright v. Home Depot, 936 F. Supp. 900, 903 n.6 (M.D. Fla. 1996) ("[C]ase reports are no substitute for scientific study."); Jones v. United States, 933 F. Supp. 894, 899 n.8 (N.D. Cal. 1996) (abstracts insufficient); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1405–06 (D. Or. 1996) (abstracts insufficient); Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (explaining reasons why case reports fail as scientific evidence of causation). One court has found case reports sufficiently reliable but then only if combined with other causation evidence such as published articles, regulatory findings and animal studies. *See* Eve v. Sandoz Pharm. Corp., No. IP 98-1429-C-Y/s, 2001 U.S. Dist. LEXIS 4531, *60–74 (S.D. Ind. March 7, 2001)

283. *See* Minn. Mining & Mfg. v. Atterbury, 978 S.W.2d 183, 200–01 (Tex. Ct. App. 1998).

284. *In re* Breast Implant Litig., 11 F. Supp. 2d 1217, 1234–36 (D. Colo. 1998); FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 344 n.25 (1994).

285. At least one court has given credence to legislative testimony as supporting admissibility under *Daubert*. *See* Hall v. Babcock & Wilcox Co., 69 F. Supp. 2d 716, 725 (W.D. Pa. 1999). Legislative cross-examination at the hands of politically minded members of Congress, however, hardly qualifies as the kind of scientific review and inquiry needed to assess the reliability of litigation research.

286. *See* cases cited *supra* notes 222–23.

knowledge should be an indication as to whether the test was conducted within the realm of acceptable scientific methodologies or is on the periphery. If the research is not consistent with other existing science that supports the same conclusion, demonstrates its plausibility, or otherwise offers external indicia of the litigation science's validity, the article may pose too great a risk of bad science to justify its use in court or to support an expert's admissibility under *Daubert*.[287]

Alternatives to traditional peer review: The court may be able to find indicia of trustworthiness outside the normal processes of peer review. For instance, under the right circumstances, regulatory or agency review may suffice as a form of study validation.[288] As noted above, agency review is ordinarily substantially more demanding than publication peer review. In addition, studies conducted pursuant to Good Laboratory Practices (GLP), as often required by agencies for data submission, offer evidence that the study was rigorously conducted. At least one court has questioned the reliability of testing that did not comport with GLP.[289] In addition to GLP and regulatory review, courts have also recognized that detailed presentations to qualified participants at societal meetings or conferences may satisfy *Daubert's* peer review requirement.[290] Governmental studies or commissions appointed by the government may also constitute "peer review" even if they do not occur in the typical peer review publication sense.[291]

Independent validation of the research: Because of the peculiar risks of manipulation posed by litigation science, courts may need to require that the proponents of a theory have obtained some form

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287. *See* Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 596 (9th Cir. 1996) ("[Expert] admitted that no peer-reviewed article [supported expert's conclusion] that Clomid is a human teratogen."); Nat'l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1520 (E.D. Ark. 1996) (expert's hypothesis "has not to date been legitimized by further research and studies"); *cf.* Daubert v. Merrell Dow Pharm., Inc. 43 F.3d 1311, 1318 (9th Cir. 1995) (*Daubert II*) (noting that despite years of litigation, no scientist not involved in the litigation found plaintiffs' studies worthy of comment or support).

288. *See* United States v. Chischilly, 30 F.3d 1144, 1155 (9th Cir. 1994). Likewise, agency positions contrary to those espoused by a litigation study are evidence supporting rejection under *Daubert*. *See* Ruffin v. Shaw Indus., Inc., 149 F.3d 294, 299 (4th Cir. 1998); *Daubert II*, 43 F.3d at 1314.

289. *See* Metabolife Int'l, Inc. v. Wornick, 264 F.3d 832, 859 (9th Cir. 2001) (concluding that Chinese tests were not reliable because protocols were "not developed through scientific consensus" and the tests were not subject to government oversight or good laboratory practice).

290. *See* Frank v. New York, 972 F. Supp. 130, 135 (N.D.N.Y. 1997).

291. *See, e.g.*, Pozefsky v. Baxter Healthcare Corp., No. 92-CV-0314, 2001 U.S. Dist. LEXIS 11813, at *9–12 (N.D.N.Y. Aug. 16, 2001) (relying on court ordered panels and domestic and international government commissioned panels who studied the association between breast implant use and systematic illness).

of independent review and validation of the entire study, not merely the published article. If the circumstances under which the study was performed raise a risk of manipulation and indicate a lack of adequate procedures, an open and independent review by an unbiased source, obtained by the litigant,[292] may be necessary to guarantee that the research is scientifically based and not outcome-driven.

Reliability inquiry by the court: It is unlikely that the court will find enough information available in the scientific community on a newly-conducted litigation study to resolve an admissibility inquiry. In most instances, even if the article passes the first blush test above, the court will need to proceed to a serious inquiry into the manner in which the study was conducted; the role of the lawyers in the work; the completeness and accuracy of reporting of the test data; the propriety of the protocol and hypothesis (including whether the researchers predetermined the outcome and set out to prove it); and all the other factors that place litigation research at risk of generating biased science.

At this point, the discovery conducted by the parties becomes critical, and counsel would be well advised to conduct the discovery appropriately. The discovery effort is likely to include depositions of the principal researchers, who may not be identified as testifying experts,[293] and possibly of the journal editors if the study is published.[294]

Assessing the "fit": Apart from the reliability of the study, the court should also inquire into whether the research itself is sufficiently related to the theory espoused by the litigants to merit submission

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292. The funding of such an inquiry, is, of course, the Achilles' Heel to this proposal because the unbiased nature of the independent review could at least potentially be compromised by one side's funding of the work. We refer the reader to the alternative proposed in Section IV.C.

293. Discovery of the non-testifying researcher should focus not only on the details of the study but also on the litigation connection of the study, including the researcher's relationship with the testifying expert, meetings involving the testifying expert or lawyers, the litigation purpose of the study, the testifying expert's control over the study and protocol, and funding sources for the researcher's work.

294. Discovery of the journal should be directed towards the editor most knowledgeable about the peer review and publication of the article in question. The discovery should focus on the journal's disclosure and peer review practices, including whether the journal adheres to the *Uniform Requirements for Manuscripts Submitted to Biomedical Standards*, *see* UNIFORM REQUIREMENTS, *supra* note 139; the disclosure of the litigation connection and funding sources of the research; the nature and extent of the journal's peer review of the article in question, including use of external reviewers; and the peer reviewers' comments and changes made to the article. The peer reviewers themselves will be difficult to depose because of the confidentiality that surrounds the peer review system and the need to protect journals and their peer reviewers from litigation intrusion into that confidentiality.

to the jury. This is the *Daubert* "fit" requirement,[295] which may be dispositive if the study, despite its publication and general acceptance, actually has little relevance to the theory or use of the theory proffered by the testifying expert. Experts with weak theories may only submit a portion of their opinion or methodology (i.e., selected study results) to peer review, but refrain, for fear of rejection, from submitting their entire theory and its underpinnings (e.g., the extrapolation of causation from the study results).[296] In such cases, the expert's ultimate opinion/methodology has *not* been subjected to peer review and may not "fit" with the litigation science upon which the expert relies, and thus may not meet the requirements of *Daubert*.

Court-appointed expert review. As commentators have frequently noted, the court system is ill equipped to make complex scientific determinations.[297] Nonetheless, in the realm of litigation science, the judge may have to fill the role of peer reviewer of the litigation science. To cross over into its own scientific inquiry, however, the court must ask the same kinds of questions a peer reviewer would ask. Is it a good study? Does the data support the conclusions? Are there holes or flaws in the reasoning? Was the design appropriate for the hypothesis presented?

In some instances, judges should be capable of answering the queries regarding whether the methodology is properly peer reviewed and generally accepted. In the instances in which the science is sufficiently complicated or the merits of a study are too uncertain, however, this type of inquiry seems tailor-made for a court-appointed expert. Under either Rule 706 of the Federal Rules of Evidence[298] or a court's inherent powers under Rule

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295. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 591–93 (1993).

296. *See, e.g.*, Black v. Rhone-Poulenc, Inc., 19 F. Supp. 2d 592, 600 (S.D. W. Va. 1998) (noting that presentation at symposia was "quite sketchy" and not accurate depiction of actual study).

297. *See* Marcia Angell, *Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1513 (1996) (discussing courts' comfort with using methods to decide scientific issues "that can only be described as antiscientific and irrational"); Bert Black et al., *Science and the Law in the Wake of* Daubert*: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 716–17 (1994); Edward V. Di Lello, Note, *Fighting Fire with Firefighters: A Proposal for Expert Judges at the Trial Level*, 93 COLUM. L. REV. 473, 474–90 (1993) (addressing inadequacies of current system to address technical science questions). The *Daubert* Court, on the other hand, stated rather facilely that "we are confident that federal judges possess the capacity to undertake this review." *Daubert*, 509 U.S. at 593. Trial judges faced with complex scientific studies and allegations may find little comfort in the Court's confidence.

298. *See In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL 926, Order No. 31 (N.D. Ala. May 30, 1996).

104(a) of the Federal Rules,[299] federal courts can appoint an independent expert or panel of experts to advise the court or even testify as to complex scientific matters.[300] This power has been used sparingly,[301] probably in part because of the feared complexity of such a process or the lack of established rules for its use, thus creating a risk of appellate reversal. To be sure, the Rule 706 process has its difficulties, a subject beyond the scope of this Article.[302]

Nevertheless, an expert with the narrow mandate of determining whether a study was acceptably performed and supportive of the conclusions reached may be particularly appropriate to assess the validity of science developed by courtroom advocates. Independent review, for instance, of all study raw data and background materials, accompanied by a report to the court, may help the

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299. *See* Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387 (D. Or. 1996).

300. *See* Smith, *supra* note 185, at 66–69 (highlighting cases using court-appointed experts). The *Daubert* court in fact suggested just such a possibility. *Daubert*, 509 U.S. at 595. Justice Breyer expanded on this in *General Electric Co. v. Joiner* with a full-blown plea for courts to begin utilizing Rule 706 in greater fashion. 522 U.S. 136, 149–50 (1997) (Breyer, J., concurring). Commentators have also issued calls for greater use of court-appointed experts. *See* Marc S. Klein et al., *Empowering the Gatekeeper in the Post-Daubert Regime: Court-Appointed Experts and Special Masters*, *in* EXPERT EVIDENCE, *supra* note 67 at 436; Joe S. Cecil & Thomas E. Willging, *Accepting Daubert's Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995 (1994); Lawrence S. Pinsky, Comment, *The Use of Scientific Peer Review and Colloquia to Assist Judges in the Admissibility Gatekeeping Mandated by Daubert*, 34 HOUS. L. REV. 527 (1997) (examining several alternatives for using peer reviewers to assist courts in a *Daubert* analysis); Note, *Improving Judicial Gatekeeping: Technical Advisors and Scientific Evidence*, 110 HARV. L. REV. 941 (1997).

Selection of an appropriate expert may soon become easier through efforts of the American Association for the Advancement of Science, which has launched a five-year project to supply judges with experts available to advise courts on specific complicated subjects. *See* Jocelyn Kaiser, *Project Offers Judges Neutral Science Advice*, 284 SCIENCE 1600 (1999). The National Institutes of Health already maintains a list of potential scientific reviewers who have been checked for conflicts of interest. *See* James T. Rosenbaum, *Lessons from Litigation over Silicone Breast Implants: A Call for Activism by Scientists*, 276 SCIENCE 1524, 1525 (1997).

301. *See* Samuel H. Jackson, *Technical Advisors Deserve Equal Billing with Court Appointed Experts in Novel and Complex Scientific Cases: Does the Federal Judicial Center Agree?*, 28 ENVTL. L. 431, 444 (1998).

302. The most extensive use of a Rule 706 panel to date occurred in the breast implant litigation before Judge Samuel Pointer in Alabama. *In re* Silicone Gel Breast Implants Prods. Liab. Litig., MDL 926, Order No. 31 (N.D. Ala. May 30, 1996). That panel reviewed existing literature on the alleged connection between breast implants and connective tissue diseases. The panel encountered considerable difficulty created by the litigation process, and several of its members have recommended changes for future panels. *See* Barbara S. Hulka et al., *Experience of a Scientific Panel Formed to Advise the Federal Judiciary on Silicone Breast Implants*, 342 NEW ENG. J. MED. 812 (2000). Nonetheless, the panel members encouraged greater use of such panels to "bring unbiased information about complex scientific and medical issues into the courtroom." *Id.* at 815. The suggestion here is that a modest version of a Rule 706 panel (perhaps even one expert) could usefully review complex litigation science and provide the court with a view on the scientific worthiness of that particular study, for the sole purpose of independently verifying the study's design, performance, and conclusions and ultimately the admissibility of the expert's testimony.

court determine whether the study was properly conducted, recorded, and reported. The narrow focus of the independent expert's review should alleviate some of the difficulties of using similar experts for the ultimate issues to be resolved in the case (such as causation).[303] This is particularly true since the Rule 706 expert would not offer opinions that go to the fact finder's role, but instead to the judicial role of determining admissibility of expert testimony. Further, the difficulties of locating such an expert may be alleviated in the near future by the efforts of groups that are creating lists of acceptable independent court experts in various fields.[304]

C. The Need for an External, Institutionalized Review Process

The risks and problems attendant with litigation science heighten the need for an external review process that judges can readily tap for advice and input. Because litigation science is not going away, the trick is to ensure that the studies are properly conducted and interpreted to avoid error from litigation bias. More idealistically, it is at least conceivable that litigation-funded research could offer a positive contribution to public health issues if it is judged reliable by independent scientific review.

The solution would appear to be the creation of an independent body of experts whose role will encompass consideration of litigation-based studies and verification of their validity and the author's conclusions. If such a process were readily available, and were integrated into the court process, judges could prevent the

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303. A good example of a narrow use of a court-appointed expert is found in *Renaud v. Martin Marietta Corp.*, in which the court relied on an independent expert to assess the acceptability within the scientific community of the methodology used by one of the testifying experts. 749 F. Supp. 1545, 1552–53 (D. Colo. 1990), *aff'd*, 972 F.2d 304 (10th Cir. 1992). We do not take lightly the likelihood that the litigation itself may well rise or fall with the admissibility of the litigation science, which may be the only link to causation. Even so, asking an independent expert to review and comment on the reliability of one study or a handful of studies is far less complicated and onerous than asking for an opinion on causation from all available evidence, as required of the breast implant panel in the Alabama case.

304. Chief among these are Duke University School of Law's Private Adjudication Center, which is developing a registry of independent experts, *see About the Registry*, *in* THE REGISTRY OF INDEPENDENT SCIENTIFIC AND TECHNICAL ADVISORS, *at* http://www.law.duke.edu/pac/registry/about.html (last visited Nov. 3, 2001); Pinsky, *supra* note 300, at 545; the American Association for the Advancement of Science, which has launched a five-year project to supply judges with experts available to advise courts on specific complicated subjects, *see* Kaiser, *supra* note 300; and the National Institutes of Health, which already maintains a list of potential scientific reviewers who have already been checked for conflicts of interest, *see* Rosenbaum, *supra* note 300, at 1525.

introduction of unreliable science without engaging in their own version of inexpert peer review. In fact, the growing use of science in court generally has already prompted a chorus of voices calling for institutionalized and increased usage of independent experts.[305] A few such institutions already exist. For instance, Duke University School of Law's Private Adjudication Center is compiling a "Registry" of independent medical and health experts and has established guidelines to address payments to the experts, conflicts, and interaction with courts.[306] In general, however, the use of independent experts in any form by courts is still limited and does not show significant signs of increasing.[307]

The peculiar risks and growing use of litigation science only heighten the need for an external body and institutionalized process to assist courts. To address this concern, it may be necessary to create an independent body, called perhaps the "Institute for Litigation Research" (ILR). The ILR would function as a non-profit group to be comprised of a board of independent legal and scientific trustees, an administrative staff, and a body of essentially conflict-free experts. Initially, proponents of litigation science who seek to use such science in court would have the opportunity to submit their research, along with all supporting documentation, to a relevant panel of ILR experts. In this role, the ILR would not only review the basic methodology and conformity with the scientific method of the study, similar to a quality publication peer review process, but the ILR would also assess the test data and performance of the study in a manner designed to ensure the integrity of the underlying work. The panel could also ensure that the research is not "overinterpreted" to prove more than it actually supports. The ILR would thus provide the independent verification of the research's reliability and fit so necessary to legitimize this type of work. An imprimatur of approval from the ILR panel would undoubtedly play a significant role in a *Daubert* hearing.

Courts could make the use of the ILR more of an imperative by requiring submission of litigation studies to the ILR before they

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305. *See, e.g.*, Black et al., *supra* note 297; E. Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. REV. 487, 507–11 (1989); Samuel R. Gross, *Expert Evidence*, 1991 WIS. L. REV. 1113, 1213 (1991).

306. *See* Pinsky, *supra* note 300, at 545.

307. *See, e.g.*, MANUAL FOR COMPLEX LITIGATION (SECOND) § 21.5 (1985); JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN'S EVIDENCE § 706.02[1] (Joseph M. McLaughlin ed., 1997); Cecil & Willging, *supra* note 300, at 1004 (noting that although "[m]any commentators have mentioned that the use of court-appointed experts appears to be rare," twenty percent of federal judges responding to a survey reported having appointed an expert at least once).

are used in court. Currently, the authority for such a requirement could fall under either Federal Rule of Civil Procedure 706 (the court would simply appoint the ILR as its Rule 706 expert), or perhaps the court could make submission a requirement for *Daubert* admissibility under Federal Rules of Evidence 104 and 702. Far better would be an amendment of the Federal Rules of Civil Procedure to institutionalize the use of outside scientific review, but that development would probably have to await a certain amount of positive experience with the ILR or a similar body such as Duke's Registry.[308]

An ILR panel could also fulfill a broader role by taking on the review of existing (*i.e.*, non-litigation) research in addition to litigation studies to assess the impact of the litigation research in the context of the full literature. This type of panel begins to approach the role of a full-scale Rule 706 panel, similar to the breast implant panel appointed by Judge Pointer in Alabama. At an even more aggressive level, the ILR could conceivably design and conduct its own research on an issue raised by significant litigation. If justified, such an effort could either identify, through compelling science, an important public health risk, or short circuit the wasteful and highly damaging process experienced in the breast implant cases.[309]

Perhaps the experiments initiated by Duke and others will grow into something approaching the ILR concept described above. In any event, the growing use of litigation-funded and driven research should help invigorate the discussion around science in the courtroom and perhaps give these proposals some urgency. The experience of courts over the next decade in dealing with litigation science will likely crystalize that discussion and potentially lead to some sort of institutionalized review mechanism, whether an ILR is part of that mechanism or not.

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308. Other commentators have made similar proposals. *See, e.g.*, Black et al., *supra* note 297, at 786 n.454 (reviewing proposals); Cecil & Willging, *supra* note 300, at 1057, 1063 (recommending change to pre-trial procedure); Jackson, *supra* note 301, at 456–60 (reviewing alternative proposals).

309. Numerous issues would have to be resolved to make an ILR-type institution work. Funding is a major concern, but a "user pays" system could potentially be funded by industries heavily involved in defending against toxic tort and product litigations, and by a fee assessed against plaintiff verdicts in excess of a certain amount, a co-funding arrangement that would obviate allegations of funding bias. Overuse of such a valuable resource would also be a concern, particularly if cases were filed on nothing but speculation in hopes the ILR would discover the science to support the case. Courts and/or the ILR itself could prevent misuse by requiring a prima facie showing sufficient to justify expenditure of resources and/or partial funding of ILR expenditures. A shared funding arrangement in which the party submitting research would significantly fund the ILR work might also minimize wasteful, speculative uses of the ILR process.

CONCLUSION

Litigation science may someday prove to be a boon to science and the law if it provides a source of funding for studies of important public health issues that otherwise would not be available. Such studies could help solve thorny legal causation issues, which independent scientists have not yet addressed. Neither the scientific world nor the legal world, however, will begin to trust litigation science until both communities take steps to ensure the legitimacy and integrity of such research. In the interim, in light of the likely increased usage of litigation science, it is time for scientists and courts alike to take account of the peculiar risks of litigation science and account for those risks in their respective truth-finding processes.