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# The Crisis in Scientific Publishing and its Effect on the Admissibility of Technical and Scientific Evidence, 49 J. Marshall L. Rev. 727 (2016)

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# THE CRISIS IN SCIENTIFIC PUBLISHING AND ITS EFFECT ON THE ADMISSIBILITY OF TECHNICAL AND SCIENTIFIC EVIDENCE

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ABSTRACT

In 1993, the Supreme Court attempted to ensure the reliability of scientific, medical and technical evidence in Daubert v. Merrell Dow Pharmaceuticals, Inc. The Court held that judges act as gate keepers to, and provided various criterion to guide judges in the admissibility of, technical and scientific evidence. This article examines one criterion, peer review publication, to determine whether changes in scientific publishing over the last twenty-three years have weakened peer review's usefulness as a guide for judges.

The author analyzes the decline of peer review, as a clear standard for measuring the reliability of articles, by examining four problems scientific publishing has encountered in recent years: a parade of hoaxes; an epidemic of fraudulently published results; the apparent failure to reproduce published findings; and the growth of online, faux journals. These four problems undermine peer review as arguably the most important criteria of the Daubert approach, and bring Daubert's continuing viability into question.

## I. INTRODUCTION

The role of technical and scientific evidence in American litigation has been controversial for decades. Such evidence is crucial in cases, ranging from felony prosecutions and securities fraud, to medical malpractice. At the same time, expert testimony has been the object of scorn, with witnesses derided as "whores,"[1]

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1. R.J. Gerber, *Victory vs. Truth: The Adversary System and its Ethics*, 19 ARIZ. ST. L.J. 3, 11 (1987) ("Some experts become professional testifiers, advertising their availability and pliability in legal journals. Lawyers on both sides commonly call them 'whores.'").

and with testimony described as "junk science."[2] In 1993, the Supreme Court attempted to bolster the reliability of such evidence in *Daubert v. Merrell Dow Pharmaceuticals, Inc*.[3] The Court made clear that judges must act as gate keepers over the admissibility of technical and scientific evidence, and provided criteria to guide judges in making such a determination. This article examines one such criterion, peer review publication, to determine whether changes in scientific publishing over the last twenty-three years have weakened its usefulness as a guide for a trial court.

The article discusses *Daubert*, describes the peer review process, and analyses four trends in scientific publishing that may undermine the usefulness of peer review as a bright line test for admissibility. The article concludes with a discussion of how trial courts should treat peer reviewed articles in assessing reliability under *Daubert*.

## II. DAUBERT

To understand the problems inherent in use of scientific and technical evidence at trial, it is best to start with the seminal case in the area, *Frye v. United States*.[4] In *Frye*, the question was whether the results of a primitive polygraph test were admissible on behalf of the defense.[5] In 1923, the Court of Appeals held, that to be admissible, testimony offered by a scientific expert must be based on a discovery or principle that has "gained general acceptance" in the particular field in which it belongs.[6] Acceptance by scientists was the sole criterion for determining whether a particular domain of knowledge constituted a genuine area of scientific expertise about which a properly qualified expert could testify.[7] Underlying *Frye* were two implicit notions: first, that judges should defer to scientists as to what was deemed as scientific; second, that within science was an accepted body of knowledge or canon that constituted legitimate science. *Frye's* "general acceptance" rule became the predominant rule in both federal and state courts for seventy years.[8] It is still the rule in a

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2. *See generally* PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991); David E. Bernstein, *Junk Science in the United States and the Commonwealth*, 21 YALE J. INT'L L. 123, 124-25 (1996) (providing an overview of the issue of junk science in the courtroom); David E. Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals*, *Inc*., 15 CARDOZO L. REV. 2139 (1994).

3. Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993).

4. Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

5. *Id*.

6. *Id*. at 1014.

7. *See* U.S. v. Jakobetz, 955 F.2d 786, 799 (2d Cir. 1992).

8. *See* Paul G. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 COLUM. L. REV. 1197, 1205

minority of jurisdictions including Pennsylvania, California and New York.[9]

In contrast to *Frye*, the Supreme Court in *Daubert* held that testimony should be classified as scientific and, thus, presented as expert testimony, only if a judge first determines that the proffered testimony consists of inferences and assertions "derived by the scientific method."[10] In *Daubert*, the plaintiffs sued Merrell Dow Pharmaceuticals Inc., a subsidiary of Dow Chemical Company, in a California District Court, claiming that an anti-nausea drug, known as Bendectin, caused birth defects in their children when Mrs. Daubert took the drug while pregnant.[11] Merrell Dow had removed the case to federal court, and moved for summary judgment because their expert submitted documents showing that no published scientific study demonstrated a link between Bendectin and birth defects.[12] At issue in the case was the admissibility of eight expert opinions offered by the plaintiffs.[13]. For example, one expert witness was Dr. Shanna Swan, an epidemiologist and biostatistician specializing in reproductive epidemiology,[14] who refuted the statistical significance of published epidemiological data identifying no birth defects caused by Benedictin.[15]

In the opinion, the Court explicitly placed judges in "a gatekeeping role" to evaluate the scientific validity and reliability of scientific evidence.[16] The underlying premise of the opinion was that judges can, and must, decide whether proffered scientific testimony is based on the scientific method without taking a position on the scientific conclusions. Judges were advised that while deciding whether to admit the scientific evidence, "[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate."[17]

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(1980) (stating, "Nonetheless, the *Frye* test has dominated the admissibility of scientific evidence for more than half a century.").

9. *E.g.*, Grady v. Frito-Lay, Inc., 576 Pa. 546, 555 (2003); Ratner v. McNeill-PPC, Inc., 933 N.Y.S.2d 323, 329 (2d Dep't 2011); People v. Leahy, 862 P.2d 321 (Cal. 1994).

10. *Daubert*, 509 U.S. at 590.

11. Daubert v. Merrell Dow Pharm., Inc., 727 F. Supp. 570 (S.D. Cal. 1989).

12. Daubert v. Merrell Dow Pharm., Inc., 951 F.2d 1128, 1129 (9th Cir. 1991).

13. *Daubert*, 727 F. Supp. at 573.

14. *Id.* at 574.

15. *Id.* at 575.

16. *Daubert*, 509 U.S. at 597.

17. *Id.* at 595.

The *Daubert* Court focused on Federal Rule of Evidence 702,[18] emphasizing that the "subject of an expert's testimony must be 'scientific . . . knowledge.'"[19] The Court explained that: "'scientific' implies a grounding in the methods and procedures of science,"[20] whereas "'knowledge' connotes more than subjective belief or unsupported speculation."[21] Thus, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method"[22] and "must be supported by appropriate validation."[23] Unlike the opinion in *Frye,* the *Daubert* court treated science as defined by a process rather than as a collection of data.

The Court recognized four "guidelines" for judicial consideration in determining admissibility: (1) falsification or whether a theory or technique "can be (and has been) tested";[24] (2) "the known or potential rate of error" associated with a "particular scientific technique" and the "existence and maintenance of standards controlling the technique's operation;"[25] (3) whether the theory or technique has been the subject of "peer review and publication;"[26] and (4) whether the proposed testimony is generally accepted in the scientific community.[27] The court emphasized that the application of these guidelines had to be a flexible assessment of the scientific method and noted that "the inquiry envisioned by Rule 702 is . . . a flexible one."[28]

When the court adopted this criteria it defined science using the terms of a certain school of thought-- the testability or falsifiability approach which is generally associated with the

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18. In 1993 FED. R. EVID. 702 read, "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." In 2000 the rule was amended to reflect the Daubert test:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702.

19. *Daubert*, 509 U.S. at 589-90.

20. *Id.* at 590.

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.* at 593.

25. *Id.* at 594.

26. *Id.* at 593.

27. *Id.* at 594.

28. *Id.*

philosophers Carl Hempel and Karl Popper.[29] In its simplest form, falsifiability is the belief that any hypothesis must be inherently disprovable before it can become accepted as a scientific hypothesis or theory.[30] For example, if a scientist asserts that "men have souls," then this assertion is not scientific because it is a theory that cannot be disproven. In contrast, an assertion that all swans are white can be tested and disproved if one swan is found to be black or another color. Underlying this concept is the notion that no theory can ever be completely proven, but is only capable of acquiring a more or less high probability, or degree of confirmation, relative to the experimental evidence available at any given time. Since theories are tested experimentally or by observation, all a scientist can prove is that predictions hold true only under the conditions tested. The prediction may fail under other conditions. It is the ability to test a theory that makes it scientific.[31]

The question of whether *Daubert* was limited to scientific testimony or applied to all forms of technical, or otherwise specialized knowledge, was addressed by the Court in *Kumho Tire Co. v. Carmichael*.[32] In this case involving a tire blow out, the Court reversed the Eleventh Circuit and held that the factors for a court to use in determining the reliability of a scientific theory or technique, as set out in *Daubert*, may apply to testimony of engineers and other experts who are not scientists.[33] The Court

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29. *Id.* at 593. The Court, with apparently very little reflection, was adopting the test for science put forth by the philosopher Karl Popper in his famous book Conjectures and Refutations, which states that, for an idea to be scientific, there must be some conceivable way for it to be tested and proven false. KARL POPPER, CONJECTURES & REFUTATIONS 29 (1962). In its basic form, falsifiability is the belief that for any hypothesis to have credence, it must be inherently disprovable before it can become accepted as a scientific hypothesis or theory. Sean O'Connor, *The Supreme Court's Philosophy of Science: Will the Real Karl Popper Please Stand Up?*, 35 JURIMETRICS 263, 269 (1995). The use of Popper has not met with universal approval. Brian Leiter, *The Epistemology of Admissibility: Why Even Good Philosophy of Science Would Not Make for Good Philosophy of Evidence*, 1997 BYU L. REV. 803, 807-808 (1997). The Court also cited Carl Hempel's work, Philosophy of Natural Science for a similar proposition. CARL HEMPEL, PHILOSOPHY OF NATURAL SCIENCE 49 (1966), *cited* in *Daubert*, 509 U.S. at 593.

30. KARL POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY 316 (2002) ("In so far as a scientific statement speaks about reality, it must be falsifiable: and in so far as it is not falsifiable, it does not speak about reality.").

31. *Id.* at 28 ("In point of fact, no conclusive disproof of a theory can ever be produced; for it is always possible to say that the experimental results are not reliable or that the discrepancies which are asserted to exist between the experimental results and the theory are only apparent and that they will disappear with the advance of our understanding . . . If you insist on strict proof (or strict disproof) in the empirical sciences, you will never benefit from experience, and never learn from it how wrong you are.").

32. Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999).

33. *Id.* at 148.

noted that *Daubert* set forth a trial judge's "gatekeeping" obligation under FRE 702 to ensure that expert testimony is relevant and based on reliable scientific theories. More importantly, the court noted that FRE 702 applies to all expert testimony because the language of FRE 702 does not distinguish between "scientific," "technical," or "other specialized" knowledge.[34] The Court emphasized the discretion of the trial judge's gatekeeping role by emphasizing that the judge had "broad latitude"[35] and "considerable leeway in deciding"[36] how to assess the validity of different forms of nonscientific expert knowledge.[37]

After *Daubert*, the task presented for judges under was complex and somewhat daunting. Trial judges had to balance and weigh complicated philosophical and methodological factors in deciding the admissibility of proffered scientific evidence, rather than falling back upon the simple test of general acceptance.

How trial courts weigh the four Daubert guidelines is not clear. In one study, it appeared that judges tended to ignore falsifiability and error rate in favor of peer reviewed publication and general acceptance in the scientific community.[38] The authors of the study reported, "The majority of judges noted that they would be highly likely to reject anything not subjected to rigorous peer review analysis, and comments such as 'substantial weight should be given to peer review as it gives the evidence credibility' were frequent."[39] It is not surprising that judges would lean toward two tests that are easier to apply than the others. In contrast to evaluating failure rates, deciding whether testimony is supported or not by peer reviewed publication provides a judge with a bright line test that is easily applied.[40]

## III. THE PEER REVIEW PROCESS

Peer review, the means by which one's scientific peers evaluate the quality of one's research, has been used to determine academic merit for more than three centuries.[41] In modern science,

34. *Id*.
35. *Id*. at 153.
36. *Id*. at 154.
37. *Id*.
38. Sophia Gatowski et al., *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-Daubert World*, 25 L. & HUM. BEHAV. 433, 433 (2001).
39. *Id*. at 447.
40. For examples of courts relying on peer review, *see* NAKI v. State of Hawaii, No. CV-13-02189-PHX-JAT, 2015 U.S. Dist. LEXIS 102515, at *13 (D. Ariz. Aug. 4, 2015) (peer review articles cited by expert did not explain expert's reasoning); Mass. Mut. Life Ins. Co. v. DB Structured Prods., No. 11-30039-MGM, 2015 U.S. Dist. LEXIS 59998, at *33-34 (discussing general acceptance of expert's methodology).
41. Ray Spier, *The history of the peer-review process*, 20 TRENDS IN

peer review is generally acknowledged as the most important instrument for assessing scientific work.[42] Peer review, in this sense, means pre-publication review, the process that takes place before a study is published or a grant awarded.[43] Through the peer review process, not only are manuscripts selected for publication, but prizes like the Nobel Prize and grants are awarded, and jobs are allocated.[44] With universities needing to cut costs in recent years, the trend in research project funding has been for researchers to rely less on regular research funds from their universities, and to seek external research grants that are allocated through peer review.[45] The focus of this article, however, is on peer review for publication in scientific and medical journals. In theory, the peer review process selects the best scientific research for publication by uncovering errors in scientific papers, and recognizing scientific misconduct. In other words, the process is meant to separate the wheat from chaff.

The first scientific journal published, the French Journal des Scavans (charmingly renamed later as the *Journal des Savants*), initiated publication six weeks before that of The Philosophical Transactions of the Royal Society of London in 1665.[46] Almost immediately, the earliest journals noted the need for some kind outside review of manuscripts. As early as 1731, the Royal Society of Edinburgh adopted a review process where materials submitted for publication were vetted and evaluated by knowledgeable members.[47] However, these peer review procedures did not develop in an orderly way. For example, in 1796, Sir Joseph Banks rejected Edward Jenner's account of the first successful inoculation against smallpox. Banks had sent the manuscript to an agronomist who had not been impressed with Jenner's work. In the end, Jenner published elsewhere and the Royal Society lost an opportunity to be associated with one of the greatest discoveries in medical history.[48]

The development of peer review in the 19th and 20th centuries was also gradual and somewhat haphazard.[49] Different

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BIOTECHNOLOGY 357, 358 (2002).

42. *See* JOHN ZIMAN, REAL SCIENCE: WHAT IT IS AND WHAT IT MEANS 42 (2000) (stating, "Peer review of contributions to the primary research literature is the principal social mechanism for quality control in academic science.").

43. Fytton Rowland, *The Peer-Review Process*, 15 LEARNED PUBLISHING 247, 247 (2002).

44. Sven Hemlin & Søren Barlebo Rasmussen. *The Shift in Academic Quality Control*, 31 SCI. TECH. HUM. VALUES 173, 173 (2006).

45. *Id.* at 179-80.

46. Roger McCutcheon, *"The Journal Des Scavans" and the "Philosophical Transactions of the Royal Society"*, 21 STUD. PHILOLOGY 626 (1924).

47. Ray Spier, *supra* note 41, at 357.

48. Kendall A Smith, *Edward Jenner and the Small Pox Vaccine*, 2 FRONTIERS IN IMMUNOLOGY at 2 (2011).

49. John C. Burnham, *The Evolution of Editorial Peer Review*, 263 JAMA

editors employed varying styles of peer review. For example, the British medical journal, The Lancet, did not implement peer review until the 1970s.[50] Some journals, such as the Journal of the American Medical Association ("JAMA"), have sent their submissions through an internal review panel and, only on rare occasions, would it send manuscripts to outside experts.[51] The British Medical Journal, however, sent every outside submission to a recognized expert by at least 1893.[52] By the late 20th century, peer review became institutionalized and is currently utilized by most biomedical journals and virtually all established science journals.[53] By the twentieth century, pre-publication peer review had become the standard approach for most scientific and medical journals.[54]

While the peer review process varies among different scientific journals,[55] there is a simple model that describes most journals' procedures. Usually when a manuscript is submitted to the journal it is read and evaluated by an editor.[56] The editor may reject it out of hand either because it is not dealing with the right subject matter for that journal or because it is manifestly of such low quality that it cannot be considered at all.[57] Papers that pass this first hurdle are then sent to experts in the field of the paper,[58] usually two, who are generally asked to classify the paper as publishable immediately, publishable with changes, or not publishable. Publishable with changes is perhaps the commonest recommendation, and, in that case, the reviewers suggest the nature of the improvements that they consider is required. It is widely agreed that this improving function by reviewers is of value in maintaining the overall quality of the scholarly literature.[59] Many published papers receive some revision.[60] If the two referees

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1323, 1323 (1990).

50. Ann C. Weller, EDITORIAL PEER REVIEW: ITS STRENGTHS AND WEAKNESSES 6 (2001).

51. Drummond Rennie, *Editorial Peer Review: Its Development and* Rationale, PEER REVIEW IN HEALTH SCIENCE 1, 3 (Fiona Godlee and Tom Jefferson eds., 2003).

52. Weller, *supra* note 50, at 6.

53. Rennie, *supra* note 51, at 3.

54. Burnham, *supra* note 49, at 1323.

55. *See generally* Lowell L. Hargens, *Variation in Journal Peer Review Systems*, 263 JAMA 1348-1352 (1990).

56. Dale Benos, et al., *The Ups and Downs of Peer Revie*w, 31 ADV. PHYSIOL. EDUC. 145, 145 (2007).

57. *Id.*

58. *Id.* at 146. Active researchers in the same area of research are considered to be the persons best suited to assess the quality of their colleagues' scholarly work. Margaret Eisenhart, *The Paradox of Peer Review: Admitting too Much or Allowing too Little?*, 32 RESEARCH SCI. EDUC. 241, 241 (2002).

59. Sandra Goldbeck-Wood, *Evidence on peer review--scientific quality control or smokescreen?*, 318 BRIT. MED. J. 44, 44 (1999).

60. Benos et al., *supra* note 56, at 146.

disagree, the paper may be sent to a third, or the editor may adjudicate between them effectively acting as the third referee.[61]

Critics of the peer review process complain that, in addition to being expensive and time consuming, it reinforces scientific and medical orthodoxy,[62] is afflicted by gender bias,[63] and is unhelpful for evaluating inter-disciplinary projects.[64] Some critics find very little use in the procedure.[65] Others call for the reform or modification of the process.[66]

One major change in scientific publishing that has had an impact on peer review is the rise of open access publishing, an inexpensive method for publishing scholarly articles made possible by the Internet.[67] Publishers are spared the expense of printing hard copies and authors benefit from quick publication. As we will see below, this development has created its own set of problems for quality assurance through peer review.

## IV. THE CRISIS IN PEER REVIEWING

The last few years have been bad ones for science journals. In 2015, Biomed Central, a UK company that publishes 277 open access peer-reviewed journals, announced the retraction of 43 articles "because of 'fabricated' peer-review."[68] Science publishers Springer and IEEE have "remov[ed] more than 120 papers from their subscription services after a French researcher discovered that the works were computer generated nonsense."[69]

Generally, when a journal discovers serious flaws in an article after publication the journal does a formal retraction of the

61. STEPHEN LOCK, A DIFFICULT BALANCE: EDITORIAL PEER REVIEW IN MEDICINE 9 (1991).

62. Michael J. Mahoney, *Publication Prejudices: An Experimental Study of Confirmatory Bias in the Peer Review System*, 1 COGNITIVE THERAPY & RES. 161, 161 (1977).

63. Julie R. Gilbert, et al., *Is There Gender Bias in JAMA's Peer Review Process?*, 272 JAMA 139, 139 (1994).

64. Liv Langfeldt, *The Policy Challenges of Peer Review: Managing Bias, Conflict of Interests and Interdisciplinary Assessments*, 15 RES. EVALUATION 31, 31 (2006).

65. Richard Smith, *Peer Review: A Flawed Process at the Heart of Science and Journals,* 99 J. ROYAL SOC'Y MED. 178, 182 (2006).

66. Richard Smith, *Opening up BMJ peer review*, 318 BRIT. J. 4 (1999).

67. Mikael Laakso, et al., *The Development of Open Access Journal Publishing from 1993 to 2009*, 6 PLOS ONE, June 2011, at 1.

68. Fred Barbash, *Major Publisher Retracts 43 Scientific Papers Amid Wider Fake Peer-Review Scandal*, WASH POST, (Mar. 27, 2015), www. washingtonpost.com/news/morning-mix/wp/2015/03/27/fabricated-peer-reviews-prompt-scientific-journal-to-retract-43-papers-systematic-scheme-may-affect-other-journals/?postshare=5031427452343393.

69. Richard Van Noorden, *Publishers Withdraw More Than 120 gibberish papers*, NATURE (Feb. 25, 2014), www.nature.com/news/publishers-withdraw-more-than-120-gibberish-papers-1.14763.

article.[70] For example, Dr. Andrew Wakefield, with other authors, notoriously published an article in The Lancet that purported to link the MMR vaccine with certain gastro-intestinal problems and, most importantly, with autism.[71] Investigations of the article revealed not simply sloppiness but fraud and unethical conduct as well.[72] In 2004, ten of his co-authors retracted the autism interpretation from the article but Wakefield declined.[73] Wakefield was subsequently stripped of his medical license.[74] In 2010, The Lancet formally retracted the article.[75]

Retractions by scientific journals have steadily increased between 1950 and 2007.[76] Of course, misconduct is not the only reason for retracting an article. Some retractions are the result of innocent errors.[77] Both impugn the peer review process. A 2010 study found that, out of 742 retractions across 404 journals, "73.5% of papers were retracted for error (or an undisclosed reason) whereas 26.6% of papers were retracted for fraud."[78] Another study in 2012 analyzing "2,047 biomedical and life-science research articles indexed by PubMed as retracted", found that "67.4% of retractions were attributable to misconduct, including fraud or suspected fraud (43.4%), duplicative publication (14.2%), and plagiarism (9.8%)."[79]

Fraud is one of four related factors that are undermining of peer reviewed publication as the gold standard under *Daubert*. In addition to fraud, deliberate hoaxes point to the ineffectiveness of peer review, online faux peer review journals, and, perhaps most

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70. Richard Smith, *When to Retract?: Reserve Retraction for Fraud and Major Error*, 327 BRIT. MED. J. 883, 884 (2003).

71. Andrew J. Wakefield, et al., *Retracted: Ileal-lymphoid-nodular hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 THE LANCET 637, 637 (1998).

72. Fiona Godlee et al., *Wakefield's article linking MMR vaccine and autism was fraudule*nt, 342 BRIT. MED. J. c7452, c7452 (2011).

73. Simon H. Murch, et al., *Retraction of an Interpretation*, 363 THE LANCET 750, 750 (2004).

74. Dr. Andrew Wakefield, *Determinations On Serious Professional Misconduct and Sanctions,* GEN. MED. COUNCIL (May 24, 2010), www.gmcuk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf.

75. Editors of the Lancet, *Retraction-Ileal-lymphoid-nodular Hyper-plasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children*, 375 THE LANCET 445, 445 (2010).

76. Murat Cokol et al., *Retraction Rates are on the Rise*, 9 EMBO REPORTS 2, 2 (2008).

77. For example, the Journal of Bioethical Inquiry retracted on article in 2015 for honest errors. Subrata Chattopadhyay et al., *RETRACTED ARTICLE: Imperialism in Bioethics: How Policies of Profit Negate Engagement of Developing World Bioethicists and Undermine Global Bioethics*, 12 J. BIOETHICAL INQUIRY 727 (2015).

78. R. Grant Steen, *Retractions in the scientific literature: is the incidence of research fraud increasing?*, 37 J. OF MED. ETHICS, 249, 250 (2010).

79. Ferric C. Fang, et al., *Misconduct Accounts for the Majority of Retracted Scientific Publications*, 109 PNAS 17028, 17028 (2012).

seriously, a hotly discussed question of whether most published results are replicable.[80]

## *A. Fraud*

Arnold Relman, former editor of the New England Journal of Medicine, once noted, "Science is at once the most questioning and skeptical of activities and also the most trusting. It is intensely skeptical about the possibility of error, but totally trusting about the possibility of fraud."[81] Recent studies of retraction rates seem to confirm Relman's observation.[82]

For the purposes of this article, we limit scientific fraud to research misconduct, which is "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results"[83] and do not include contradictory or misguided interpretations, mistakes, poor scientific and unprofessional practices, or negligence.[84] In 1989, due to concerns about fraud and misconduct in government funded research, the Federal government established two oversight offices: The Office of Scientific Integrity and The Office of Scientific Integrity Review. In 1992, these two offices were combined in the Office of Research Integrity (ORI).[85]

It is difficult to obtain information about the prevalence of fraud in scientific publication or even about the number of fraud cases that are uncovered each year. Estimates range from 2%,[86] based on self-reporting of scientists, to 10%[87] of scientists having falsified data, and roughly 7.4% having observed it in colleagues, according to another survey.[88] This latter survey, conducted by

80. Monya Baker, *1,500 scientists lift the lid on reproducibility*, 533 NATURE 452, 452 (2016).

81. Alan N. Schechter, et al., *Colloquium on Scientific Authorship: Rights and Responsibilities*, 3 FASEB J. 209, 214 (1989).

82. *See* Fang, *supra* note 79, at 893 (stating "[a]lthough concerns about the relationship between pressure to publish and research fraud are not new, the frequency of retracted papers is increasing." (internal citations omitted)).

83. 42 C.F.R. § 93.103 (2005).

84. Federal Research Misconduct Policy, 65 Fed. Reg. 76260, 76262 (Dec. 6, 2000) (to be codified at 2 C.F.R. § 910.132).

85. Larry D. Claxton, *Scientific Authorship: Part 1. A Window into Scientific Fraud?*, 589 REVS. MUTATION RES. 17, 18 (2005).

86. Daniele Faneli, *How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data*, 4 PLOS ONE e5738, (May 2009), at 10.

87. Leslie K. John, et al., *Measuring the Prevalence of Questionable Research Practices with Incentives for Truth-Telling*, 23 PSYCHOL. SCI. 524, 526-27 (2012) ("One would infer from the geometric means of the three variables that nearly 1 in 10 research psychologists has introduced false data into the scientific record . . .").

88. James A. Wells, Final Report: *Observing and Reporting Suspected Misconduct in Biomedical Research*, GALLUP 40 (2008), http://ori.hhs.gov/sites/default/files/gallup_finalreport.pdf.

Gallup, may provide the most precise estimate of research misconduct. Instead of asking individuals to report on their own misconduct, it asked them to report misconduct observed in their own departments during the last 3 years.[89] The report estimated that 1.5% of all research conducted each year would be fraudulent.[90]. Based upon an estimated 155,000 researchers supported by National Institutes of Health (NIH) grants, Gallup's survey suggested there would be a total of 2,335 incidents of possible misconduct per year[91], and 60% of incidents reported in the survey involved falsification or fabrication of data.[92]

The peer review process has a particularly difficult task in detecting fraud in submitted manuscripts.[93] For example, a common form of scientific fraud is for a scientist to fabricate data in order to avoid hours of laborious experimentation or observation. A reviewer may not be able to discern whether or not a graph, a chart or a conclusion was produced from fabricated data or was the result of honest research. A reviewer usually does not replicate experiments or observations, which will come, if at all, post publication.[94] Thus a well-designed experiment with fake data is almost impossible to detect at the peer review stage.

One fraud outstripped them all, eclipsing the others with its sheer boldness. Between 2000 and 2002, Jan Hendrik Schön, a researcher at Bell Laboratories, published more than 20 articles on electrical properties of unusual materials.[95] At Schön's peak, he submitted over a dozen articles to Science in under two years, and also made submissions to Nature.[96] He hit his record in autumn 2001, turning out 7 articles that November alone. The output was staggering.[97] It's rare for a scientist to submit 7 articles in an

89. *Id.* at 7-13.

90. *Id.* at 41.

91. *Id.*

92. *Id.* at 2.

93. *See* Patricia K. Woolf, "*Deception in Scientific Research*." 29 JURIMETRICS 71-72 (1988).

94. An example of this is a series of biochemistry experiments published by Dr. Homme Helinga and his staff at the Duke University Medical Center. Reviewers did not catch errors (deliberate or negligent) until other scientists tried to replicate the study. Erika Check Hayden, *Chemistry: Designer Debacle*, NATURE NEWS (May 9, 2008), www.nature.com/news/2008/080514/full/453275a.html.

95. Geoff Brumfiel, *Misconduct Finding at Bell Labs Shakes Physics Community*, 419 NATURE 419, 419 (2002).

96. Eugenie S. Reich, *The Scientific Fraudster Who Dazzled the World of Physics*, TELEGRAPH (May 18, 2009), www.telegraph.co.uk/technology/5345963/The-scientific-fraudster-who-dazzled-the-world-of-physics.html.

97. A report issued by the committee charged with investigating Schön listed twenty five articles with titles, such as *Gate-induced Superconductivity in a Solution-Processed Organic Polymer Film* and *Hole Transport Pentacene Single Crystals*. Malcolm Beasley et al., *REPORT OF THE INVESTIGATION COMMITTEE ON THE POSSIBILITY OF SCIENTIFIC MISCONDUCT IN THE WORK OF HENDRICK SCHÖN AND COAUTHORS* 6 AMERICAN PHYSICAL SOCIETY, F-1-F-4

entire year, let alone one month. And Schön's papers were not pedestrian exercises. He announced one unbelievable discovery after another: He had created organic plastics that became superconductors or lasers; he had fashioned nanoscale transistors; and more.[98] The editors of Science hailed one of his many contributions as part of the "Breakthrough of 2001.[99]

Most interesting is that Schön's frauds actually benefitted from allegedly rigorous peer review at elite journals.[100] The critiques and suggestions that Schön received in referee reports told him exactly what it would take to convince skeptics about new findings. In other words, Schön would use the feedback to adjust his data to meet the reviewers' conceptions.[101] If his amazing plastics really did show evidence of superconductivity, reviewers pressed, had Schön checked for such and such effects or measured this or that parameter? Schön could then deliver those results right back, in perfect keeping with expectations.

Schön appeared to toy with his reviewers and the journals by playing to their expectations. He worked with a particular idea of what real or legitimate claims should look like. He sought to make his fakes fit in rather than stand out, massaging his data to better match established predictions. Ironically, the first serious inquiry into Schön's work arose when a fellow scientist thought that some of Schön's data was simply too good for the real world.[102] His data was too perfect, it had none of the noise or jitter that usually marks authentic experimental data.[103]

Schön's genius, if you can call it that, was in manipulating confirmation bias. His articles were orthodox and within the realm of possibility. He eschewed radical or revolutionary findings in favor of fairly humdrum results. Confirmation bias is a particular problem in the peer review process.[104] The bias consists of the very human tendency to accept too easily data that supports their favored hypothesis or position.[105] Schön was particularly adept at manipulating this tendency.[106]

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(2002), http://w.astro.berkeley.edu/~kalas/ethics/documents/schoen.pdf.

98. EUGENIE SAMUEL REICH, PLASTIC FANTASTIC: HOW THE BIGGEST FRAUD IN PHYSICS SHOOK THE SCIENTIFIC WORLD 1 (2009).

99. Robert Service, *Breakthrough of 2001: Nanoelectronics*, SCI. (Dec. 20, 2001), www.sciencemag.org/news/2001/12/breakthrough-2001-nanoelectronics.

100. REICH, *supra* note 98, at 67.

101. *Id.*

102. *Id.* at 194.

103. *Id.*

104. Mohammadreza Hojat et al., *Impartial Judgment by the "Gatekeepers" of Science: Fallibility and Accountability in the Peer Review Process*, 8 ADVANCES HEALTH SCI. EDUC. 75, 78 (2003).

105. Joshua Klayman, *Varieties of confirmation bias*, *in* PSYCHOL. LEARNING & MOTIVATION 385, 386 (1995).

106. *See* Ruud Abma, *Scientific Fraud and Normal Science*, SCI. IN TRANSITION-WORKSHOP QUALITY & CORRUPTION 1, 2 (May 30 2013), www.scienceintransition.nl/wp-content/uploads/2013/09/ABMA_SIT-Scientific-

We cannot know for certain what motivated Schön. A scientist may escape detection by falsifying an insignificant finding, but there are no great laurels for that. But, if a scientist fabricates an important finding, the experiment will be replicated and the fraud discovered. The answer probably lies in the pressure to publish, the competitive atmosphere in some labs and the constant struggle for funding in contemporary research science. Publishing a scientific finding is an essential part of research science. Whether a scientist is seeking, promotion, tenure, or a research grant, a C.V. with peer reviewed publications is required.[107] In his book Fact and Fraud, David Goodstein, an American physicist and professor at the California Institute of Technology, lists career pressure as a "clearly a motivating factor" in academic fraud.[108]

## *B. Hoaxes*

In the spring 1996 issue of the cultural studies journal Social Text, an article appeared that would engender considerable notoriety. Transgressing the Boundaries: Toward a Transformative Hermeneutics of Quantum Gravity, by New York University physics professor Alan Sokal, appeared to be an unlikely candidate for controversy.[109] Supported by an impressive display of footnotes, pretentious, verbose and obtuse, it was written in the typical style of the academy. When it was published, Sokal also published a short piece in the academic trade publication Lingua Frana explaining that his article was actually intended as a parody, a fact which the review process had failed to discover. Social Text was a humanities journal and Sokal's admitted goal was to demonstrate "an apparent decline in the standards of intellectual rigor in certain precincts of the American academic humanities."[110] Looking back, there is a piquant irony in a natural scientist's contempt for the standards in the humanities. Scientific publication has had its own share of hoaxes.

Hoaxes, which are distinguished from fraud by their intent to embarrass authorities or expose incompetence, have a long history

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fraud-and-normal-science-_May-2013_.pdf (*citing* DAVID GOODSTEIN, ON FACT AND FRAUD 3-5 (2010)) ("Perpetrators [of academic fraud] usually . . . know what the answer to their research question would be if they carried out their research properly . . . [and] are working in a field where individual experiments are not expected to be precisely reproducible.").

107. *See generally* Phil Clapham, *Publish or Perish*, 55 BIOSCI. 390-91 (2005).

108. GOODSTEIN, *supra* note 106, at 4.

109. Alan D. Sokal, *Transgressing the boundaries: Toward a transformative hermeneutics of quantum gravity*, 46/47 SOCIAL TEXT 217, 217 (1996).

110. Alan D. Sokal, *A Physicist Experiments with Cultural Studies*, 6 LINGUA FRANCA 62 (1996).

in academia.[111] In the fourth century B.C., Dionysius of Heraclea (also known as Dionysius "the Renegade) forged a play and attributed it to Sophocles in order to trap a rival philosopher, Heraclides of Pontus. When Heraclides pronounced the play genuine, Dionysius pointed out a hidden acrostic in the text:

> "An old monkey isn't caught by a trap, oh yes, he's caught at last, but it takes time."[112]

More recently, in 2005, three students from MIT, Jeremy Stribling, Max Krohn, Dan Aguayo, created the program SCIgen, an automatic generator of articles using the jargon of the computer science field, which allowed for the random writing of papers. With this tool they created and submitted nonsense papers to conferences (apparently more as a prank than with serious intent) with some success.[113] But French scientist Cyril Labbé took the program one step further. He created an alter-ego, Ike Antkare, and set out to make him one of the most cited authors in academia.[114] His target was not the peer review process, but citation calculators. Citation calculators are a quick and dirty way of measuring an articles impact and, indirectly, an author's academic standing.[115] When looking solely to citation calculators, the more times an article is cited, then the more important the article is rated. Rather than run the publication gauntlet, Stribling and his co-authors generated the articles by computer and submitted them to an open access archive for the deposit and dissemination of both published and unpublished research documents. The fake papers were picked up by Google Scholar, and a complex pattern of self-citations boosted Antkare's citations until he scored as one of the most cited scholar's in the world. [116]

The process of self-citation and manipulating citation counts has no direct effect on peer review and publication but, indirectly, it could potentially have a devastating effect. To the extent that editors and reviewers are influenced by an author's reputation, the ability to boot-strap citation counts could distort the peer review process and undermine its reliability.

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111. ANTHONY GRAFTON, FORGERS AND CRITICS: CREATIVITY AND DUPLICITY IN WESTERN SCHOLARSHIP 4 (1990).

112. *Id.*

113. Jeremy Stribling et al., *Scigen- An Automatic CS Paper Generator*, https://pdos.csail.mit.edu/archive/scigen/ (last visited July 7, 2016).

114. Cyril Labbé, *Ike Antkare One of the Great Stars in the Scientific Firmament*, 6 INT'L SOC'Y SCIENTOMETRICS & INFORMETRICS NEWSLETTER 48, 48 (2010).

115. *See* Fil Menczer, et al., *Scholarometer*, INDIANA UNIVERSITY SCHOOL OF INFORMATICS AND COMPUTING, http://scholarometer.indiana.edu/ (last visited July 8, 2016).

116. John Ioannidis, *A Generalized View of Self-Citation: Direct, Co-Author, Collaborative, and Coercive Induced Self-Citation*, 78 J. PSYCHOSOMATIC RES. 7, 8 (2015).

### C. Faux Peer Review

Over the last two decades more scholarly peer reviewed journals have migrated to electronic web publishing as their primary means of publication.[117] New innovative ventures, sponsored by individual, universities and small entrepreneurial publishing companies, have launched open access journals, which offer the full content of the journals to anybody with Internet access to read.[118] However, the fundamental business model used by print journals, charging readers and their intermediaries for access, remain in place.[119] Open-access journals are digitally formatted, online, free of charge, and usually free of most copyright and licensing restrictions. Rather than being supported by subscriptions, open access journals are supported by fees paid by the author, institution or research funder to cover the costs associated with publication.

The number of open access journals has exploded. As of July 2016, there were 9,097 open access Journals hosted on the Directory of Open Access Journals.[120] As traditional journals increase their subscription costs and, as library budgets shrink, open access journals appear to be the future of scientific publishing.[121]

A statement by a 2001 conference of open access advocates, known as the Budapest Open Access Initiative, articulated the goals and ideals of open access publication in stating:

> By "open access" to this literature, we mean its free availability on the public internet, permitting any users to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give

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117. Mikael Laakso, et al., *The Development of Open Access Journal Publishing from 1993 to 2009*, 6 PLOS ONE (June 2011), at 1.

118. *See Frequently Asked Questions*, DIRECTORY OPEN ACCESS REPOSITORIES (April 24, 2014), www.opendoar.org/faq.html (an example of an open access repository sponsored by a higher education institution, the University of Nottingham).

119. Glen McGuigan & Robert D. Russell, *The Business of Academic Publishing: A Strategic Analysis of the Academic Journal Publishing Industry and Its Impact on the Future of Scholarly Publishing*, 9 ELECTRONIC J. ACAD. SPECIAL LIBR. (2008), http://southernlibrarianship.icaap.org/content/v09n03/mcguigan_g01.html#_edn1; *see generally* JEAN-CLAUDE GUÉDON, *in* OLDENBURG'S LONG SHADOW: LIBRARIANS, RESEARCH SCIENTISTS, PUBLISHERS, AND THE CONTROL OF SCIENTIFIC PUBLISHING (2001).

120. DIRECTORY OPEN ACCESS J.'S, https://doaj.org (last visited July 9, 2016).

121. John Bohannon, *Secret Bundles of Profit*, 344 SCI. 1332, 1332 (2014).

authors control over the integrity of their work and the right to be properly acknowledged and cited.[122]

The Budapest Initiative articulated almost utopian hopes for open access and some of its advocates have the zeal of missionaries; but, like most utopian project, economic realities soon intervened. Most early open access journals were founded by individual scholars and used a business model based on voluntary work.[123] Subsequently, long-established journals, particularly society journals, started publishing parallel open access electronic versions.[124]

In a third wave, newly founded professional electronic publishing firms, using article-processing charges to fund their operations, have emerged. This third type of electronic journal has created a problem for peer review: journals that published for profit regardless of an articles quality. There is an obvious conflict of interest at the heart of the process of paying for publication. When a journal is supported by an institution or by subscriptions there is an incentive to maintain quality. When a journal is supported by author's payments there is an incentive to accept manuscripts regardless of quality. As a result, there is direct, financial pressure to accept otherwise unpublishable submissions.

A hoax or sting perpetrated by John Bohannon exposed an unregulated, almost anarchic world of for-profit, online journals.[125] His paper submitted to on-line, for profit journals described a simple test of whether cancer cells grow more slowly in a test tube when treated with increasing concentrations of a molecule had "fatal flaws" and used fabricated authors. Bohannon noted, "Any reviewer with more than a high-school knowledge of chemistry and the ability to understand a basic data plot should have spotted the paper's shortcomings immediately. Its experiments are so hopelessly flawed that the results are meaningless."[126] Despite the flaws, the manuscript was accepted by 157 of the journals and rejected by just 98. Shockingly, 60% of the submissions did not

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122. Leslie Chan et al., *Read the Budapest Open Access Initiative*, BUDAPEST OPEN ACCESS INITIATIVE (Feb. 14, 2002), www.budapestopen accessinitiative.org/read. Since the Budapest conference there have been similar conferences issuing similar statements in Bethesda and Berlin. Charles W. Baily, *What is Open Access*, DIGITAL SCHOLARSHIP (2006), www.digital-scholarship.org/cwb/WhatIsOA.htm.

123. *See* David J. Solomon, *Medical Education Online: A Case Study of an Open Access Journal In Health Professional Education*, 12 INFO RES. PAPER 301 (2007).

124. For example, The New England Journal of Medicine went on-line in 1996. Edward W. Campion, *The Journal's New Presence on the Internet*, 334 NEW ENG. J. MED. 1129, 1129 (1996). In another example, JAMA, the Journal of the American Medical Association, publishes twelve separate specialty journals available on the internet. *About JAMA Network*, JAMA, http://jamanetwork.com/public/about.aspx (last visited Sept. 8, 2016).

125. John Bohannon, *Who's Afraid of Peer Review*, 342 SCI. 60, 60 (2013).

126. *Id.*

undergo peer review. Of the 106 journals that did conduct peer review, 70% accepted the paper.[127]

Many open access journals bear an odd resemblance to scams on the web, such as those commonly found in "junk" e-mail. For example, one online publisher, The 5th Publisher, a subsidiary of Sophia Publishing Service, publishes a journal entitled "Animal Molecular Breeding."[128] The cost to be published in any one of these journals operated by 5th Publisher is 1200 Canadian dollars.[129] Payment is happily accepted through PayPal, Visa, MasterCard, American Express, and Discover. Unhappily, none of the journals are listed on the Directory of Open Access Journals nor can any articles from the journals be found on Google Scholar.[130] However, the journals are still described as peer reviewed.[131].

There tends to be a pattern about questionable open access journals: (1) they charge fees for publication; (2) none of them have institutional affiliations; (3) their boards of editors are often made up of fictitious or misappropriated names; (4) their titles tend to mislead the reader about their geographical locations; (5) they have reviewers who at best lack impressive credential and at worst don't exist; and (6) they are located in developing or undeveloped nations. Unfortunately, an attorney, an expert witness, or a court may not be able to distinguish the serious journal from the fakes. The journals have all the appearance of being serious academic endeavors, and it is only on close examination that it can be determined that they are simply an on-line version of a vanity press. Some journals and publishers that illustrate these points are described below.

By all appearances, the 5th Publisher is a scam. It is on the list of "Potential, possible, or probable predatory scholarly open-

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127. *Id.*

128. *Journal List*, 5TH PUBLISHER, http://5thpublisher.com/index.php/index/journal (last visited July 11, 2016). Other journals listed by 5TH PUBLISHER include AGRIC. INSPECTION, AGRICULTURE CIVILIZATION, J. ASIAN ART, J. ALTERNATIVE CROPS, AND J. GLOBAL PUB. HEALTH. *Id.*

129. *BioPublisher Publishing Policy*, 5TH PUBLISHER, http://5thpublisher.com/index.php/index/single/policy (last visited Sept. 8, 2016).

130. Searches of "ANIMAL MOLECULAR BREEDING", "AGRIC. INSPECTION", "AGRICULTURE CIVILIZATION", "J. ASIAN ART, J. ALTERNATIVE CROPS", and "J. GLOBAL PUB. HEALTH", DIRECTORY OPEN ACCESS J.'s, https://doaj.org/search?source=%7B%22query%22%3A%7B%22match_all%22%3A%7B%7D%7D%2C%22from%22%3A0%2C%22size%22%3A10%7D (follow "Search" hyperlink; then, under "Journals vs Articles," click "Journals" and search the names of journals); searches of "ANIMAL MOLECULAR BREEDING", "AGRIC. INSPECTION", "AGRICULTURE CIVILIZATION", "J. ASIAN ART, J. ALTERNATIVE CROPS", and "J. GLOBAL PUB. HEALTH, GOOGLE SCHOLAR, https://scholar.google.com (in the search box, enter in journal name, and, under each article listed, look for the journal name).

131. *See* J. GLOBAL PUB. HEALTH, http://5thpublisher.com/index.php/jgph (last visited Sept. 8, 2016) ("[The] Journal of Global Public Health is an open access international peer-reviewed journal . . . .").

access publishers" from Scholarly Open Access, a website that tries to police open access journals.[132] Another listed publisher, Academic Knowledge and Research Publishing only charges $200 per manuscript.[133] However none of the journals appear to have editorial boards or have published articles.

One on-line journal that does publish, and publishes frequently is the American Based Research Journal.[134] It lists an impressive group of editors, including "Dr. Hudson:-California State University Channel Islands USA."[135] Unfortunately, there is no Dr. Hudson at California State University Channel Islands. Nor is there a Dr. Jazzy Rolph at Mississippi State, nor is there a Dr. Aje Tu Nar at Buckner University, in Lewisburg—in fact there is not a Buckner University in Lewisburg, it is the location of *Bucknell* University, but Dr. Tu Nar does not teach there either.[136] The cost of getting published is a mere $100 (with a 50% Christmas discount available), in which an aspiring scholar gets to list an article as published in a peer reviewed journal.[137] The peer review process is probably as suspect as the list of editors.

Another online journal is the oddly named American Journal of Pharmacy and Health Research, which, despite its name, is published in India,[138] and has an Indian editorial staff with a creative command of the English language.[139] The journal states it is peer reviewed, but gives no details other than it seeks reviewers that "must have at least five years of experience in the relevant

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132. *List of Publishers*, SCHOLARLY OPEN ACCESS (July 10, 2016), https://scholarlyoa.com/publishers/.

133. *Payment Option*, ACADEMIC KNOWLEDGE & RES. PUBLISHING (2014), www.akrpub.com/Payment%20Option.php.

134. Matteo Turchetto and Andreas Viklund, AM. BASED RES. J. (2016), www.abrj.org.

135. *Editors*, AM. BASED RES. J, www.abrj.org/editorial-board/ (last visited Sept. 8, 2016).

136. Telephone calls to and web directory searches at Bucknell University, Mississippi State University and California State University Channel Islands by the author.

137. *Payment*, AM. BASED RES. J (2012), www.abrj.org/paymnet-guidlines/.

138. *American Journal of Pharmacy and Health Research*, GLOBAL IMPACT FACTOR, http://globalimpactfactor.com/american-journal-of-pharmacy-and-health-research/ (last visited Sept. 8, 2016).

139. AM. J. PHARM. & HEALTH RES., www.ajphr.com (last visited July 11, 2016). The website for the AM. J. PHARM. & HEALTH RES. states:

> AJPHR Journals inviting you to submit an manuscript which provides envisioned to publish high-quality, peer-reviewed research, reports, review articles, technical briefs, Software review, datasets briefs, product news, company news, thesis report, book review and case study in all areas of Biological, Pharmaceutical and Chemical technology that will serve to create a holistic understanding of the human dimension in these society. We are inviting authors to send for the same.

*Id.*

field after completion of the education in that field and at least three original research papers in journal."[140]

## *D. The Replication Crisis*

A fourth problem for peer reviewed publications, only tangentially related to fraud and hoaxes, is the replication crisis facing science. Researchers are finding that they are unable to reproduce studies long taken for granted in their disciplines. Replication and self-correction are considered defining characteristics of science.[141] Along with the communication of scientific information, one of the justifications for the publication process is that observations and conclusions can be verified or refuted by follow up studies.[142] Thus, published conclusions should be shown to be correct or wrong. In theory, sooner or later, if something is wrong, a replication effort will show it to be wrong and the scientific record will be corrected.[143] That is not to say science moves forward in discrete, cumulative steps; as any human endeavor, science is a messy process with false starts, blind alleys and mistakes.[144]

An example of publication and replication going awry came about in October 2015. The journal Science reported an inspiring account about how some children in India had received cataract surgery and gained, for the first time, the ability to see.[145] Superficially, there is nothing in this incident that should come as

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140. *Join As Reviewers*, AM. J. PHARM. & HEALTH, www.ajphr.com/join-as-reviewers.html (last visited July 11, 2016).

141. *See* Robert K. Merton, *Science and Technology in a Democratic Order*, 1 J. LEGAL & POL. SOC. 115 (1942), *reprinted in* ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267, 270 (Norman W. Store ed., 1973) (stating "[t]he technical norm of empirical evidence, adequate and reliable, is a prerequisite for sustained true prediction; the technical norm of logical consistency, a prerequisite for systemic and valid prediction.").

142. Jim Giles, *The Trouble With Replication*, 442 NATURE 344, 344 (2006) ("The idea that readers should be able to replicate published scientific results is seen as the bedrock of modern science.").

143. The desire for replicability is part of the reason that scientific papers almost always include a methods section, which describes exactly how the researchers performed the study. That information allows other scientists to replicate the study and to evaluate its quality, helping ensure that occasional cases of fraud or sloppy scientific work are weeded out and corrected.

144. Even the most famous scientific findings have been difficult to replicate. For instance, in the 19th Century Gregor Mendel conducted the first recorded plant experiments to establish laws of genetics, using peas. Scientists have thought that his statistical results were just a little too neat for the size of his sample but his insight was nonetheless correct. R.A. Fisher, *Has Mendel's work been rediscovered?* 1 ANNALS SCI 132-33; *but see* Ira Pilgrim, *A solution to the too-good-to-be-true paradox and Gregor Mendel*. 77 J. HEREDITY 218-220 (1986).

145. Rhitu Chatterjee, *Out of the Darkness*, 350 SCI. 372, 372 (2015).

a surprise. Cataract surgery is common in the developed world and an account of children getting the gift of sight should fill us with joy. But there is a twist to the story involving publication and replication.

The Indian children had been born with cataracts.[146] They had never been able to see. By the time their condition was diagnosed, the local doctors had told the parents that it was too late because the children were past a critical period for gaining vision.[147] The notion that there was a critical point beyond which sight could not be gained received truth in the field. Nevertheless, a team of eye specialists visited the area and arranged for the cataract surgery to be performed on teenagers. As a result, hundreds of formerly blind children are able to see. This result contradicted the accepted wisdom in the field.

The concept of a critical period for developing vision was based on studies that David Hubel and Torsten Wiesel performed on cats.[148] The results showed that without visual signals during a critical period of development, vision is impaired for life. For humans, this critical window closes tight sometime after infancy.[149] Hubel and Wiesel won a Nobel Prize for their work.[150] The data was clear, but wrong. The results of the cataract surgeries on Indian teenagers disprove the critical period thesis.

In this light, an apparent positive story becomes a horror story about the countless children who perhaps were denied the cataract surgery because they were too old. It appears that scientists and physicians put an excessive amount of faith in the studies done by Wiesel and Hubel. There was nothing wrong with their data. The study was rigorously performed. It was, however, tragically wrong. What might have happened if cataract surgery had been attempted on older children to see if the Hubel and Wiesel results were replicated on humans?[151]

When should a given theory or principle enter the scientific canon? It is fundamental that reproducibility is a defining feature of science. Reproducibility is the ability of another scientist to duplicate the experiment or study.[152] It is a fundamental principle

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146. *Id.*

147. *Id.*

148. Torsten N. Wiesal and David H. Hubel, *Effects of Visual Deprivation on Morphology and Physiology of Cells in the Cat's Lateral Geniculate Body*, 26 J. NEUROPHYSIOLOGY 978, 978 (1963).

149. For obvious ethical reasons, the results were never replicated on humans.

150. NOBEL FOUND., *The Nobel Prize in Physiology or Medicine 1981*, www.nobelprize.org/nobel_prizes/medicine/laureates/1981/.

151. There are, of course, considerable ethical consideration that need to be considered before experimental surgery should be done on human patients but that problem is beyond the scope of this article.

152. "Reproducibility" is defined as "the extent to which consistent results are obtained when an experiment is repeated." OXFORD ENG. DICTIONARY (3d

in the conduct and validation of experimental science. As Karl Popper noted, "non-reproducible single occurrences are of no significance to science."[153] If subsequent data is inconsistent with the original data, then the original data must be re-examined. If results are never reproduced, then obvious problems with reliability exist. It is for this reasons that most journals require submitted articles to include sufficient technical information to allow the experiments to be repeated.[154]

Excessive faith in unreproduced data was strikingly illustrated by another article published in 2015, in which a team of 270 researchers set out to replicate 100 high profile psychology experiments that had been performed in 2008.[155] They reported their findings in the 28 August 2015 issue of SCIENCE. According to the report, there was only a "47.4% replication success rate." A significant number of replications produced weaker evidence than the original findings.[156]

Reproducibility is a systemic problem. Researchers have few inducements to reproduce previously published results. Journal editors put a low priority on publishing replications of previous studies. Replications are not exciting. They aren't as sexy. They don't grab headlines or improve citation rates. That, in turn, decreases the incentive for researchers to carry out replications. In a perfect world, we need to have the perfect mix of researchers doing new and speculative research and researchers doing confirmatory research or applied research to replicate studies.

## V. CONCLUSION

So what effect, if any, does the current crisis in scientific publishing have on the *Daubert* standards? *Daubert*, as noted earlier, established a regime where the scientific worthiness of the evidence, was measured by multiple factors, including methodology, publication and peer review, known rate of error, standards and controls, and the general acceptance.[157] Granted, the Supreme Court has cautioned that the reliability analysis must remain flexible and the *Daubert* factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his

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ed. 2009).

153. KARL POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY 66 (1992).

154. *See* Pao-Yuan Lin and Ur-ren Kuo, *A Guide to Write a Scientific Paper for New Writers*, 32 MICROSURGERY 80, 80 (2012) (stating that a scientific paper "should provide sufficient information for assessing the observations, repeating the experiments, and evaluating the underlying intellectual processes and logic.").

155. OPEN SCI. COLLABORATION, *Estimating the Reproducibility of Psychological Science*, 349 SCI. aac4716, aac4716 (2015).

156. *Id.*

157. Daubert v. Merrell Dow Pharm., 509 U.S. 579, 592–93 (1993).

testimony."[158] However, courts are frequently drawn to the bright line test of peer reviewed publication. Even when courts apply multiple factors in assessing reliability they rarely look past the term peer reviewed publication to examine what it means. The crisis in peer review publishing makes reliance on its appearance in a peer reviewed journal problematic. The courts must start looking closer at the foundation for an expert's opinion.

First, courts must measure and weigh the reliability and reputation of the journal. Second, courts must assess the possibility of replication. Finally, the court must give more weight to the consensus of the relevant scientific community. In short, the task of a judge as gatekeeper is becoming more challenging and more difficult. There is no easy reliance on publication in a peer reviewed journal as peer review becomes unreliable.

This unfortunate situation puts a burden on attorneys litigating *Daubert* issues, as well as judges. It will require familiarity with unreliable journals. It will require assessing reproducibility. However, unfortunately, there is no easy answer for a litigator or judge if the shortcomings of peer review indicated by the hoaxes and frauds are found to be endemic in scientific and medical publishing. In the end, it seems the flaws in the peer review publication process must lead us back to *Frye's* consensus test. This would allow the courts to evaluate reliability without delving too deeply into matters that judges are not well suited to evaluate.

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158. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999).