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Junk Science in Federal Courts: Judicial Understanding of Scientific Principles, Daubert v. Merrell Dow Pharmaceuticals, Inc.

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CASE COMMENT

JUNK SCIENCE IN FEDERAL COURTS: JUDICIAL UNDERSTANDING OF SCIENTIFIC PRINCIPLES

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)

*Todd R. Samelman**

The parents of a deformed child, petitioners, filed suit alleging that the anti-nausea drug bendectin,[1] produced by Merrell Dow Pharmaceuticals, Inc., respondent, was the in-utero[2] teratogenic[3] cause of their child's limb-reduction[4] defects.[5] The lower courts granted respondent summary judgment because petitioners failed to prove causation, and because the *Daubert* court deemed their experts' testimony as not generally accepted and thus excluded it.[6] Petitioners appealed, challenging the inadmissibility

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1. Bendectin is a drug composed of doylamine and pyridoxine that is used to treat nausea and vomiting in pregnant women. *See* Reprotox Database, (1999), *available at* http://reprotox.org/samples/1035.html (last modified Oct. 1, 2001).

2. Within the uterus.

3. Teratogen is any type of environment or chemical agent that causes the abnormal development of the fetus. *See* IRA G. DOX ET AL., THE HARPER COLLINS ILLUSTRATED MEDICAL DICTIONARY 470 (Harper Perennial 1993).

4. *See* HENRY GRAY, GRAY'S ANATOMY 122-23 (Roger Warwick & Peter L. Williams eds., 35th British ed., W.B. Saunders Comp. 1973). At the four-week period of fetal development, limb buds appear. *Id.* The upper and lower limbs develop similarly though the upper limb development precedes lower limb by a few days. *Id.* At the end of week eight, the limbs have attained their correct position. *Id.* In this position the elbows point caudally (nearer to the feet) and the knees cranially (nearer to the head). *Id.* These limb bud growth periods are critical growth periods for limb development, as the introduction of teratogens during this time can lead to limb reduction defects. *Id.*

5. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 582 (1993).

6. Daubert v. Merrell Dow Pharms., Inc., 951 F.2d 1128, 1131 (9th Cir. 1991); Daubert v. Merrell Dow Pharms., Inc., 727 F. Supp. 570, 575 (S.D. Cal. 1989). The trial court granted respondent's motion for summary judgment, ruling that petitioners' experts failed to base their results on epidemiological studies. *See id.* at 571. Federal courts viewed epidemiological studies as the most reliable method for determining causation. *See id.* at 575. Petitioners appealed and the case was consolidated with a similar bendectin suit in the U.S. Court of Appeals for the Ninth District. *See Daubert*, 951 F.2d at 1128. That court affirmed the summary judgment ruling, basing its decision on the lack of general acceptance of the experts' testimony. *See id.* at 1130-31. It held that general acceptance was the standard for reviewing admissibility of expert testimony and that petitioners' experts failed to meet this standard. *See id.* The Court of Appeals reasoned that for a

of their experts' testimony, and the U.S. Supreme Court granted certiorari.[7] The U.S. Supreme Court reversed, remanded, and HELD, that Rule 702 of the Federal Rules of Evidence,[8] not the common law rule of general acceptance first proposed in *Frye v. United States,*[9] provided the standard for admission of expert scientific testimony in federal courts.[10]

In *Frye*, the Court of Appeals for the District of Columbia[11] established the federal courts' general acceptance standard for the admissibility of expert opinion.[12] On appeal of a murder conviction, the defendant in *Frye* claimed that the results of the so-called "deception test"[13] were admissible evidence.[14] The Court of Appeals held that the admissibility of expert testimony was limited to generally accepted theories and ideas in the relevant discipline.[15] Because the "deception test" did not have recognition within the scientific community, its results were inadmissible.[16] Federal courts have applied this standard for almost seventy years.

Over the seventy-year use of the *Frye* standard, only the admissibility of lie detector tests received negative treatment; the *Frye* standard itself was rarely challenged.[17] In 1975, the revised Federal Rules of Evidence altered the standards for the admissibility of expert testimony with Rule 702.[18] These new evidentiary standards introduced an inconsistency between the *Frye* standard and that of the Federal Rules of Evidence. Federal courts tried to reconcile this inconsistency either by following the

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given scientific methodology to be admissible, it could not significantly diverge from accepted procedures. *See id.* If the methodology did diverge, it could not be deemed a generally accepted technique. *See id.*

7. *See* Daubert v. Merrell Dow Pharms., Inc., 506 U.S. 914 (1992).

8. As a result of *Daubert*, 506 U.S. at 914, the Federal Rules of Evidence were revised in 2000. *See* Marlow, *infra* note 71. Thus, the former version of Federal Rule of Evidence 702 (1999) will be used for this part of the discussion. Federal Rule of Evidence Rule 702 (1999) stated: "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." FED. R. EVID. 702.

9. *See* Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923).

10. *See Daubert*, 509 U.S. at 588-89.

11. The present day name is the U.S. Court of Appeals for D.C. Circuit.

12. *See Frye*, 293 F. at 1014. The *Frye* court stated that "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." *Id.*

13. An early lie detector.

14. *See Frye*, 293 F. at 1013.

15. *See id.* at 1014.

16. *See id.*

17. *See, e.g.*, McMorris v. Israel, 643 F.2d 458 (1981).

18. *See* FED. R. EVID. 702 (1999).

revised Federal Rules of Evidence or by ignoring the changes and continuing to follow the *Frye* standard.[19]

In *United States v. Shorter*,[20] decided after the 1975 revision, the U.S. Court of Appeals for the District of Columbia Circuit upheld the general acceptance standard for reviewing the admissibility of expert testimony.[21] Appellant was convicted of willfully evading payment of income taxes after the exclusion of his experts' testimony.[22] According to the proffered testimony, the appellant, as a pathological gambler, lacked the criminal intent to evade the law.[23] The Court of Appeals addressed whether an error occurred in failing to admit appellant's experts' testimony that such an illness existed.[24] The Court affirmed the lower court's exclusion of the testimony stating that the scientific community did not generally accept a link between pathological gambling and tax evasion.[25]

Three years later, however, the U.S. Court of Appeals for the Third Circuit rejected the general acceptance theory in *Deluca v. Merrell Dow Pharmaceuticals, Inc.*[26] The issue at trial was whether appellant's statistical technique for proving causation was generally accepted.[27] The trial court employed the *Frye* general acceptance standard and excluded the testimony.[28] Reversing, the Court of Appeals ruled that the admission of expert testimony must be analyzed solely under Rule 702 standards.[29]

The U.S. Supreme Court granted certiorari in the instant case because of the sharp divisions in the standards used for determining the admissibility of expert testimony in federal courts.[30] The U.S. Supreme Court held that the general acceptance standard of *Frye* no longer determined the admissibility of expert testimony. Instead, federal courts should employ the admissibility requirements of Rule 702 of the Federal Rules of Evidence.[31] The instant Court stated that Rule 702 superseded the holding in *Frye*.[32]

In deciding the instant case, the U.S. Supreme Court examined the language of revised Rule 702 and reviewed the notes of the revision

19. *See e.g.*, *infra* text accompanying notes 20 and 26.
20. 809 F.2d 54 (D.C. Cir. 1987).
21. *See id.* at 59-60.
22. *See id.* at 55-56.
23. *See id.* at 59.
24. *See id.* at 55.
25. *See id.* at 60 (stating that *Frye* is still the law of the land).
26. 911 F.2d 941 (3d Cir. 1990).
27. *See id.* at 943.
28. *See id.* at 943-44. The argument centered around the confidence levels for type I and type II statistical errors. *Id.*
29. *See id.* at 954-57.
30. *See Daubert*, 509 U.S. 579, 585 (1993).
31. *See id.* at 588-89.
32. *See id.* at 587.

committee. However, the notes showed no incorporation of the general acceptance standard into the Rules.[33] According to the Court, the revision committee intended to liberalize the standards for admission of expert testimony.[34] Thus, the Court relaxed the strict standards of *Frye*, ruled incompatible with Rule 702.[35]

The replacement of general acceptance by Rule 702 did not end all standards, however.[36] Until the instant case, trial judges determined only whether the expert's methodology was generally accepted.[37] *Daubert* provided trial judges with the discretion to allow evidence if it complied with the two prongs of Rule 702 as elucidated by the U.S. Supreme Court.[38] First, the scientific testimony must be reliable, and second, it must be relevant to the case.[39] The instant case also provided trial judges with a number of non-exclusive and non-dispositive guidelines to follow when deciding whether to admit expert testimony.[40] While the Court in the instant case abandoned the general acceptance standard, widespread acceptance may still be an important factor in determining admissibility of expert testimony under these guidelines.[41] Stressing methodology over conclusions, the U.S. Supreme Court in the instant case stated that a trial judge's evaluation of expert testimony should focus on the methods and techniques of the expert, not on the results generated by the data.[42] When the U.S. Supreme Court instructed trial judges to evaluate scientific testimony in the way described above, it gave the trial judges freedom to use their gatekeeper function.[43]

Following in the footsteps of *Daubert*, the U.S. Supreme Court further explained how to apply Rule 702 in light of the instant holding.[44] Ruling

33. *See id.* at 588.

34. *See id.*

35. *See id.* at 589.

36. *See id.*

37. *See Frye*, 293 F. 1013 (D.C. Cir. 1923).

38. *See Daubert*, 509 U.S. 579, 592 (1993).

39. *See id.* at 592-93. The Court stated that the topic of the expert's testimony must be scientific for it to be reliable, whereas Federal Rule of Evidence 401 provided the definition for relevance. *Id.* The rule describes how any factual evidence that makes the determination of a suit more or less probable than without the evidence is a relevant fact. *Id.*

40. *See id.* at 593-94. The factors given by the Court include, 1) whether the scientific theory or methodology can be tested, 2) whether the data has been published in a peer reviewed journal, 3) whether the potential error rate of the technique or method in question is known, and 4) whether the theory or methodology has been generally accepted. *Id.*

41. *See id.* at 593-94.

42. *Id.* at 595; *see also* FED. R. EVID. 104(a-b) ("(a) Preliminary questions concerning the qualification of a person to be a witness, the existence of privilege or the admissibility of evidence shall be determined by the court, subject to the provision of subdivision. (b) In making its determinations it is not bound by the rules except those with respect to privilege.").

43. *Id.* at 597.

44. *See* General Elec. Co. v. Joiner, 522 U.S. 136, 139-41, 143 (1997). Petitioner brought suit alleging that his lung cancer was promoted by exposure to chemicals and fumes at his workplace.

that the Court of Appeals applied an overly stringent method of review in reversing the lower court, the U.S. Supreme Court held the abuse of discretion standard applied to the review of the admissibility of scientific testimony.[45] By upholding the abuse of discretion standard, the U.S. Supreme Court maintained the trial judge's role as the gatekeeper of scientific evidence.[46]

The U.S. Supreme Court has also examined the limitation of *Daubert* to scientific evidence.[47] Reversing a lower court ruling, the U.S. Supreme Court held that the *Daubert* standard applied to all expert testimony.[48] *Daubert* referred to scientific knowledge only because the issue in that case was one of science.[49]

While *Daubert* provides trial judges with enormous power, the U.S. Supreme Court acknowledged that with this power comes great responsibility.[50] The ruling in *Daubert*, nevertheless, left many in the scientific community with a realistic fear that trial judges were inadequately prepared to separate good science from junk science. With the ever-growing base of scientific knowledge, answering the question of what expert testimony is admissible becomes an increasingly daunting task for trial judges.[51] Because of these concerns, commentators are asking whether the federal trial courts can still effectively serve the gatekeeping function provided in *Daubert*.[52] Because of this burden created by *Daubert* and the advances in scientific research, it is an almost impossible task for district court judges to adequately understand and evaluate complex scientific methods.

Id. at 140. Summary judgment was granted to respondent, reversed by the Court of Appeals and reinstated by the U.S. Supreme Court. *Id.* at 140-41. The U.S. Supreme Court ruled the Court of Appeals "overly stringent" standard of review was incorrect and that the standard of review was abuse of discretion. *Id.* at 143.

45. *Id.*

46. *Id.* at 142.

47. *See* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141, 146 (1999). The district court excluded expert testimony of the plaintiffs because the methodology used was not based on all four *Daubert* factors. *Id.* at 145-46. The 11th Circuit Court of Appeals reversed the district court and held that the *Daubert* factors did not apply to the skill or experience-based testimony of the plaintiff's expert. *Id.* at 146. The U.S. Supreme Court reversed the 11th Circuit's ruling and stated that Federal Rule of Evidence 702 applies to testimony based on technical or other specialized knowledge as well as to scientific expertise. *Id.* at 158.

48. *Id.* at 141.

49. *See id.*

50. *See Daubert*, 509 U.S. 579, 597 (1993).

51. *See General Elec. Co.*, 522 U.S. at 147-48 (Breyer, J. concurring).

52. *See* Michael H. Gottesman, *From Barefoot to* Daubert *to* Joiner*: Triple Play or Double Error?*, 40 ARIZ. L. REV. 753, 758 (1998) (stating that under *Daubert*, the Court made the assumption that a judge was better equipped than the expert to decide whether the testimony was reliable). Michael Gottesman was the attorney that won *Daubert* at the U.S. Supreme Court level but lost on remand in the Court of Appeals for the Ninth Circuit.

Two recent examples of scientific inquiry reinforce this doubt. First, for many years the scientific community believed that stress and acid release caused stomach ulcers.[53] In 1983, Barry Marshall and Robin Warren at Royal Perth Hospital in Western Australia, proposed that a bacterium, now called *Helicobacter pylori*, caused ulcers.[54] The experts in the field literally laughed at this proposal, although it was based on sound scientific principles.[55] Dr. Marshall decided to end the controversy by volunteering as the human guinea pig, consuming a cocktail of the bacteria and recording the results.[56] This experiment confirmed the theory of bacterial induced ulcers and is now the recognized etiology of the affliction.[57]

The second instance involved the theory that high power electric lines caused cancer.[58] Dr. Robert Lidburdy, of the Lawrence Livermore National Laboratory, published studies linking the electric and magnetic fields (EMF) from power lines to changes in cellular function.[59] Published in highly respected peer reviewed scientific journals, the scientific community accepted the data in these articles as valid.[60] Although the articles helped to establish a cottage industry,[61] Dr. Lidburdy forged these data.[62] Seven years after the publication of Dr. Lidburdy's last manuscript about EMF, the Office of Research Integrity (ORI) of the Department of Health and Human Services (HHS) made its final findings regarding Dr. Lidburdy's research.[63] ORI's report stated that Dr. Lidburdy intentionally

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53. *See, e.g.*, Center for Disease Control and Prevention, *Helicobacter pylori and Peptic Ulcer Disease: History of Ulcer Diagnosis and Treatment, available at* http://www.cdc.gov/ulcer/history.htm (last reviewed Feb. 2, 2001) (providing the history of scientific thought regarding ulcers).

54. *See* J. Robin Warren & Barry Marshall, *Unidentified Curved Bacilli on Gastric Epithelium in Active Chronic Gastritis*, 335 THE LANCET 1273-74 (1983).

55. *See, e.g.*, Jim Warren, *Many Still Ignorant of Ulcer Treatment: Antibiotics Now Given to Combat the Bacterium Known to Cause Ailment*, THE AKRON BEACON J., (Sept. 1, 1998), *available at* http://www.lef.org/fda-museum/6_delay_therapies/akron_090198. html.

56. *See id.*

57. *See* Center for Disease Control and Prevention, *supra* note 53.

58. *See* Robert P. Lidburdy, *Biological Interactions of Cellular Systems with Time-Varying Magnetic Fields*, 649 ANNALS N.Y. ACAD. OF SCI. 74, 92 (1992); *see also* Robert P. Lidburdy, *Calcium Signaling in Lymphocytes and ELF Fields*, 301 FEBS LETTERS 53, 58-59 (1992).

59. *See id.*

60. Annals of the New York Academy of Science and FEBS Letters are two highly respected and well known scholarly scientific publications.

61. *See, e.g.*, John W. Farley, *Power Lines and Cancer: Nothing to Fear, at* http://www.quackwatch.com/cgi-bin/mfs/24/home/sbinfo/public_html/01QuackeryRelatedTopics/emf.html?305#mfs (last visited Dec. 19, 2001). (Entrepreneurs have prayed on the fears of the public offering items such as the "Cell Sensor," which allows consumers to instantly detect EMF or low magnetic field electronics for "electrically hypersensitive" people.)

62. National Institute of Health Guide: Findings of Scientific Misconduct (June 18, 1999), *at* http://www.grants.nih.gov/grants/guide/notice-files/not99-111.html.

63. *Id.*

falsified and fabricated data about the purported effects of EMF.[64] This misconduct led to sanctioning by the government funding agencies sponsoring his research and a ban on contributing to, advising, or consulting with HHS for a period of years.[65]

These examples of scientific inquiry demonstrate that even experts in their particular fields have difficulty in discerning good science from "junk science." If the scientific community cannot recognize the validity/invalidity of scientific theories, how can the courts? Dr. Marshall's early conclusions would be inadmissible under *Frye* and more than likely thrown out under *Daubert*. The scientific community did not generally accept the science; the data collected was not based upon reliable scientific methodology and *ipse dixit* of the scientist.[66] As in *Daubert*, only the authors of the data professed that the data provided an alternate to the established theory.[67] Thus, even though an expert in the field deduced the correct etiology of ulcers, the data would be inadmissible as expert testimony under either the *Frye* or *Daubert* standards. Alternatively, EMF and cancer causation was an accepted theory based on seemingly reliable scientific methodology and would pass the *Frye* general acceptance requirement.[68] Although, Dr. Lidburdy's data satisfied the reliability standards of *Daubert* and the general acceptance theory of *Frye*, the data still constituted junk science.

With the complex issues surrounding expert opinion and expert shopping by the litigants, trial judges must exercise great care and diligence in determining admissibility of expert testimony.[69] Many remedies exist to assist trial judges with the arduous task of evaluating scientific testimony. These remedies include bringing in court appointed experts[70] pursuant to Rule 706 of the Federal Rules of Evidence (Rule

64. *Id.*

65. *Id.*

66. *See, e.g.*, Kumho Tire Co. v. Carmichael, 526 U.S. 137, 157 (1999).

67. Center for Disease Control and Prevention, *supra* note 53.

68. Lidburdy, *supra* note 58.

69. John A. Livingood, Jr., *Admissibility and reliability of Expert Scientific Testimony after* Daubert, 61 DEF. COUNS. J. 19, 20 (1994).

70. FED. R. EVID. 706 states:

> (a) Appointment. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint expert witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by

706), *sua sponte ex parte* communications[71] between trial judges and scientists, and a change in the standard of review for admissibility of expert testimony.

Rule 706 allows trial judges to appoint their own impartial experts.[72] These experts can fill in the gaps of knowledge left by the litigants' experts[73] and offer opinions to trial judges for their Rule 104 admissibility hearings.[74] Moreover, Rule 706 experts can aid judges in their Rule 702 *Daubert* gatekeeping role.[75] Assuming adequate jury instructions are used to ameliorate the risks of infallibility and exceptional weight concerns, Rule 706 is a useful tool for trial judges.[76]

Second, one commentator has stated that *sua sponte ex parte* communication can also aid in providing a trial judge with the information necessary for admissibility decisions.[77] If the ethical[78] and the almost insurmountable due process[79] standards can be satisfied, these communications can have the same facilitating effect as appointing experts under Rule 706.

> the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness. (b) Compensation. Expert witnesses so appointed are entitled to reasonable compensation in whatever sum the court may allow. The compensation thus fixed is payable from funds which may be provided by law in criminal cases and civil actions and proceedings involving just compensation under the fifth amendment. In other civil actions and proceedings the compensation shall be paid by the parties in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs. (c) Disclosure of appointment. In the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness. (d) Parties' experts of own selection. Nothing in this rule limits the parties in calling expert witnesses of their own selection.

FED. R. EVID. 706 (2001).

71. George D. Marlow, *From Black Robes to White Lab Coats: The Ethical Implications of a Judge's Sua Sponte, Ex Parte Acquisition of Social and other Scientific Evidence During the Decision-Making Process*, 72 ST. JOHN'S L. REV. 291, 292-93 (1998) (defining sua sponte, ex parte communications as judge initiated communications with an outside party).

72. FED. R. EVID. 706, *see also supra* note 71.

73. Karen Butler Reisinger, *Court Appointed Expert Panels: A Comparison of Two Models*, 32 IND. L. REV. 225, 234 (1998).

74. *Id.* at 228.

75. *Id.* at 235.

76. *Id.* at 236.

77. Marlow, *supra* note 71, at 334.

78. *Id.* at 319. The argument for condemnation is made because the courts only consider evidence that the litigants have had an opportunity to scrutinize, test, contradict, discredit, and correct.

79. Judge Marlow describes that the ever-increasing complexity of technology and science, force trial judges to make admissibility decisions in areas where they have little if any formal training. By communicating with outside sources for an interpretation of the science involved, these trial judges can reduce their scientific deficiencies. *Id.* at 292-97.

Finally, a time may come when the courts rule that the abuse of discretion standard used in reviewing admissibility may have to be changed to a *de novo* review standard. *De novo* appellate decisions based on *Daubert* would allow examination of the expert testimony, not merely the actions of the trial judge, and thus provide a higher level of review in admissibility rulings.

The standard of admissibility of expert testimony is currently based on the ruling in *Daubert* and its progeny.[80] *Daubert* stated that expert testimony must be based on the reliability of the methodologies employed and must be relevant to the case at hand.[81] Unfortunately, trial judges, unskilled in the art of cutting edge science, make these decisions with little or no outside guidance. If objective scientists disagree on the worth of each others' methodologies, surely a lay person would be unable to determine the value of these competing methodologies.[82] Trial judges are non-scientists, yet they have the awesome responsibility of acting as gatekeepers for scientific testimony.[83] The use of Rule 706 and *sua sponte ex parte* communications would aid the trial judges in their difficult task. As science and technology advance, courts must also advance in how they evaluate, test, and admit these complex expert opinions.

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80. *See* Kuhmo Tire Co. v. Carmichael, 526 U.S. 137, 141, 146 (1999); *Daubert*, 509 U.S. at 585 (1993); General Elec. Co. v. Joiner, 522 U.S. 136, 139-41, 143 (1997); *see also* the Dec. 2000 revision to Rule 702 of the Federal Rules of Evidence. The new version states:

> 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, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702 (2000).

81. *Daubert*, 509 U.S. at 592.

82. *See* Lidburdy, *supra* note 58; National Institute of Health Guide, *supra* note 62. As was shown previously with the examples of scientists unable to determine what is junk science and what is good science.

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