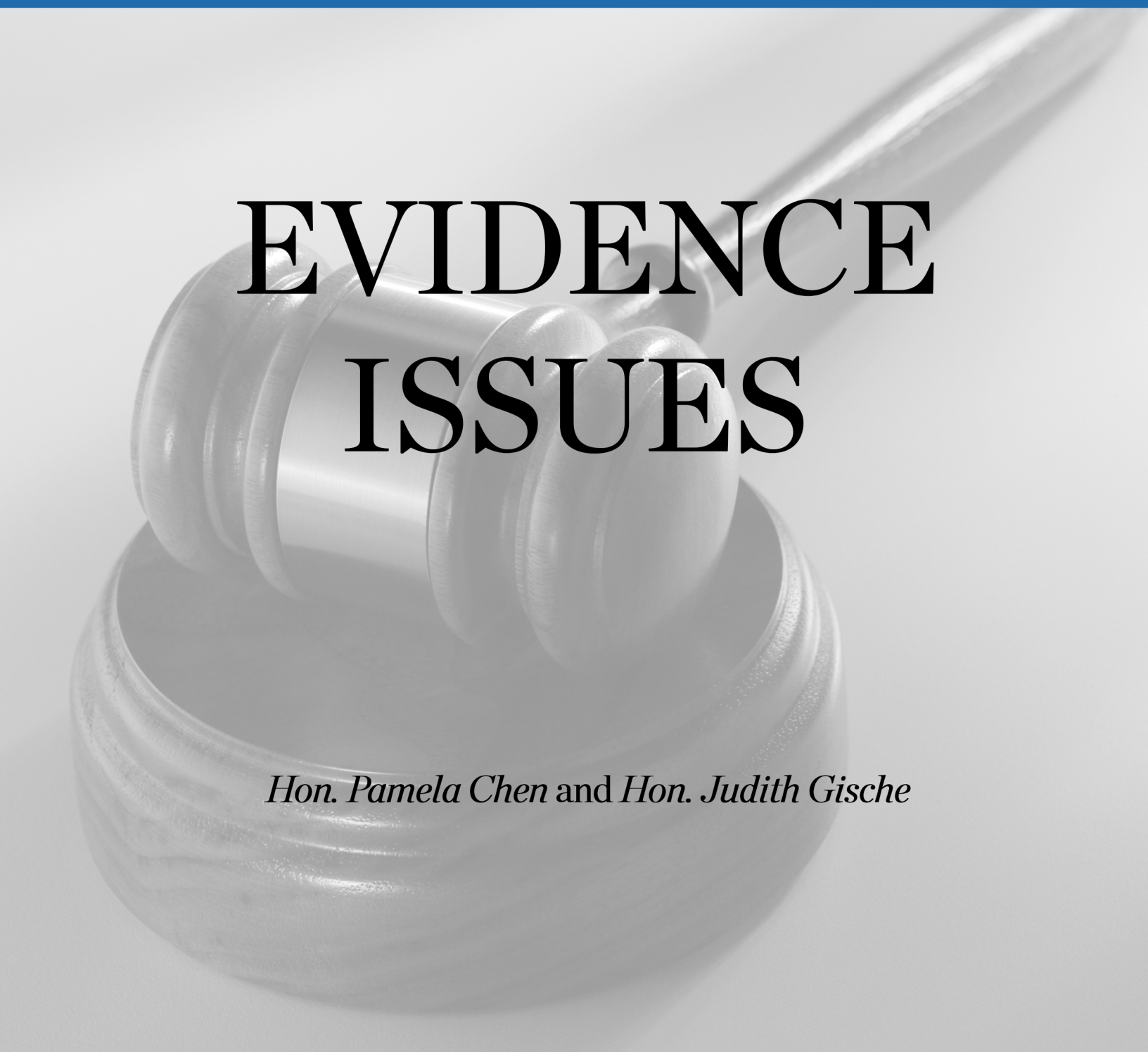
American Inns of Court

PART 2

EVIDENCE ISSUES



Hon. Pamela Chen and *Hon. Judith Gische*

Court of Appeals of District of Columbia.
FRYE
v.
UNITED STATES.

No. 3968.
Submitted November 7, 1923.
Decided December 3, 1923.

Appeal from the Supreme Court of the District of Columbia.

James Alphonzo Frye was convicted of murder, and he appeals. Affirmed.

West Headnotes

Criminal Law 110 488

110 Criminal Law
110XVII Evidence
110XVII(R) Opinion Evidence
110k482 Examination of Experts
110k488 k. Experiments and Results Thereof. Most Cited Cases
(Formerly 110k472)

The systolic blood pressure deception test, based on the theory that truth is spontaneous and comes without conscious effort, while the utterance of a falsehood requires a conscious effort, which is reflected in the blood pressure, held not to have such a scientific recognition among psychological and physiological authorities as would justify the courts in admitting expert testimony on defendant's behalf, deduced from experiments thus far made.

Criminal Law 110 488

110 Criminal Law
110XVII Evidence
110XVII(R) Opinion Evidence
110k482 Examination of Experts
110k488 k. Experiments and Results Thereof. Most Cited Cases
(Formerly 110k472)

While the 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.

****1013 *46** Richard V. Mattingly and Foster Wood, both of Washington, D.C., for appellant.

Peyton Gordon and J. H. Bilbrey, both of Washington, D.C., for the United States.

Before SMYTH, Chief Justice, VAN ORSDEL, Associate Justice, and MARTIN, presiding Judge of the United States Court of Customs Appeals.

VAN ORSDEL, Associate Justice.

Appellant, defendant below, was convicted of the crime of murder in the second degree, and from the judgment prosecutes this appeal.

A single assignment of error is presented for our consideration. In the course of the trial counsel for defendant offered an expert witness to testify to the result of a deception test made upon defendant. The test is described as the systolic blood pressure deception test. It is asserted that blood pressure is influenced by change in the emotions of the witness, and that the systolic blood pressure rises are brought about by nervous impulses sent to the sympathetic branch of the autonomic nervous system. Scientific experiments, it is claimed, have demonstrated that fear, rage, and pain always produce a rise of systolic blood pressure, and that conscious deception or falsehood, concealment of facts, or guilt of crime, accompanied by fear of detection when the person is under examination, raises the systolic blood pressure in a curve, which corresponds exactly to the struggle going on in the subject's mind, between fear and attempted control

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of that fear, as the examination****1014 *47** touches the vital points in respect of which he is attempting to deceive the examiner.

In other words, the theory seems to be that truth is spontaneous, and comes without conscious effort, while the utterance of a falsehood requires a conscious effort, which is reflected in the blood pressure. The rise thus produced is easily detected and distinguished from the rise produced by mere fear of the examination itself. In the former instance, the pressure rises higher than in the latter, and is more pronounced as the examination proceeds, while in the latter case, if the subject is telling the truth, the pressure registers highest at the beginning of the examination, and gradually diminishes as the examination proceeds.

Prior to the trial defendant was subjected to this deception test, and counsel offered the scientist who conducted the test as an expert to testify to the results obtained. The offer was objected to by counsel for the government, and the court sustained the objection. Counsel for defendant then offered to have the proffered witness conduct a test in the presence of the jury. This also was denied.

Counsel for defendant, in their able presentation of the novel question involved, correctly state in their brief that no cases directly in point have been found. The broad ground, however, upon which they plant their case, is succinctly stated in their brief as follows:

'The rule is that the opinions of experts or skilled witnesses are admissible in evidence in those cases in which the matter of inquiry is such that inexperienced persons are unlikely to prove capable of forming a correct judgment upon it, for the reason that the subject-matter so far partakes of a science, art, or trade as to require a previous habit or experience or study in it, in order to acquire a knowledge of it. When the question involved does not lie within the range of common experience or common knowledge, but requires special experience or special knowledge, then the opinions of witnesses skilled in that particular science, art, or trade to which the question relates are admissible in evidence.'

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

We think the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made.

The judgment is affirmed.

C.A.D.C 1923.
Frye v. U.S.
54 App.D.C. 46, 293 F. 1013, 34 A.L.R. 145

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N.Y. Pattern Jury Instr.--Civil 1:90

New York Pattern Jury Instructions--Civil December 2017 Update
Committee on Pattern Jury Instructions Association of Supreme Court Justices

Division 1. General Charges
C. General Instructions Not Applicable to All Cases
6. Witnesses
a. Expert

PJI 1:90 General Instruction—Expert Witness

You will recall that [*state name(s) of expert witness(es)*] testified concerning (his, her, their) qualifications in the field(s) of [*state profession(s)*] and gave (his, her, their) opinion(s) concerning issues in this case. When a case involves a matter of science or art or requires special knowledge or skill that most people do not have, a qualified witness is permitted to state (his, her) opinion(s) for the information of the court and jury. The opinion(s) stated by [*state name(s) of expert witness(es)*] (was, were) based on particular facts, as (he, she, they) obtained knowledge of them and testified about them or as the attorney(s) who questioned (him, her, them) asked (him, her, them) to assume. You may reject any opinion if you find the facts to be different from the facts that formed the basis for the opinion. You may also reject an opinion if, after careful consideration of all the evidence in the case, including the cross-examination of [*state name(s) of expert witness(es)*], you decide that an opinion is not convincing. In other words, you are not required to accept any opinion to the exclusion of the facts and circumstances disclosed by other evidence. Opinion testimony should be evaluated in the same way as the testimony of any other witness. It is given to assist you in reaching a proper conclusion; it is entitled to such weight as you find the witness's qualifications in the field warrant and must be considered by you, but is not controlling upon your judgment.

Comment

Based on De Long v Erie, 60 NY2d 296, 469 NYS2d 611, 457 NE2d 717 (1983); Matott v Ward, 48 NY2d 455, 423 NYS2d 645, 399 NE2d 532 (1979); Selkowitz v Nassau, 45 NY2d 97, 408 NYS2d 10, 379 NE2d 1140 (1978); Matter of Estate of Sylvestri, 44 NY2d 260, 405 NYS2d 424, 376 NE2d 897 (1978); Commercial Casualty Ins. Co. v Roman, 269 NY 451, 199 NE 658 (1936); Dougherty v Milliken, 163 NY 527, 57 NE 757 (1900); Herring v Hayes, 135 AD2d 684, 522 NYS2d 583 (2d Dept 1987); see Hambsch v New York City Transit Authority, 63 NY2d 723, 480 NYS2d 195, 469 NE2d 516 (1984); People v Cronin, 60 NY2d 430, 470 NYS2d 110, 458 NE2d 351 (1983); Prince, Richardson on Evidence (11th Ed Farrell) § 7-305.

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2. On Summary Judgment

Ordinarily, a qualified expert's opinion, such as a conclusion that plaintiff's injuries were caused by a deviation from relevant industry standards would preclude a grant of summary judgment in favor of defendants but not where the expert's affidavit is conclusory and nonspecific, Murphy v Conner, 84 NY2d 969, 622 NYS2d 494, 646 NE2d 796 (1994). An expert's affidavit proffered as the sole evidence to defeat summary judgment must contain sufficient allegations to demonstrate that its conclusions are more than mere speculation and would, if offered alone at trial, support a verdict in the proponent's favor, Romano v Stanley, 90 NY2d 444, 661 NYS2d 589, 684 NE2d 19 (1997); see Diaz v New York Downtown Hosp., 99 NY2d 542, 754 NYS2d 195, 784 NE2d 68 (2002); Grynberg v Giffen, 119 AD3d 526, 989 NYS2d 103 (2d Dept 2014); Clarke v Helene Curtis, Inc., 293 AD2d 701, 742 NYS2d 325 (2d Dept 2002); Bova v Saratoga, 258 AD2d 748, 685 NYS2d 834 (3d Dept 1999) (expert's affidavit lacking both reference to outside material supporting conclusions and litany of witness's professional licenses, degrees, or other affiliations insufficient); Marconi v Reilly, 254 AD2d 463, 678 NYS2d 785 (2d Dept 1998) (toxicologist's affidavit regarding effects of alcohol sufficiently probative to defeat summary judgment where opinion based on knowledge acquired through expert's personal professional experience and affidavit included scientific data underlying conclusions); see also People v Oddone, 22 NY3d 369, 980 NYS2d 912, 3 NE3d 1160 (2013) (expert may base opinion on experience). Thus, the "expert" affidavit of a registered architect and licensed engineer indicating that the window through which decedent fell lacked necessary safety features was insufficient to defeat summary judgment, where the affidavit cited no authority, treatise, standard, applicable building code provision, article or other corroborating evidence, Buchholz v Trump 767 Fifth Ave., LLC, 5 NY3d 1, 798 NYS2d 715, 831 NE2d 960 (2005). Similarly, a meteorologist's affidavit opining that there was a storm in progress when the plaintiff fell on ice and snow was insufficient where it was not accompanied by the meteorological data on which the opinion was based, Schuster v Dukarm, 38 AD3d 1358, 831 NYS2d 619 (4th Dept 2007).

Although an expert's affidavit cannot be merely speculative, a medical expert's opinion on deviation from relevant standards need not be based on medical literature, studies or professional group rules if it does not involve a novel scientific theory, Mitrovic v Silverman, 104 AD3d 430, 961 NYS2d 75 (1st Dept 2013). Such an opinion may be based instead on personal knowledge acquired through professional experience, id.

IV. Novel Scientific Evidence

A. Background

In determining admissibility of novel scientific evidence, New York State courts have adhered to the test set forth in Frye v United States, 293 F 1013 (DC Cir 1923), which holds that, to be sufficiently reliable to be admissible, novel evidence must be generally accepted in the relevant scientific community, Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014); People v Angelo, 88 NY2d 217, 644 NYS2d 460, 666 NE2d 1333 (1996); People v Wesley, 83 NY2d 417, 611 NYS2d 97, 633 NE2d 451 (1994); Nonnon v New York, 32 AD3d 91, 819 NYS2d 705 (1st Dept 2006), aff'd, 9 NY3d 825, 842 NYS2d 756, 874 NE2d 720 (2007); Johnson v Guthrie Medical Group, P.C., 125 AD3d 1445, 3 NYS3d 828 (4th Dept 2015); see Sean R. ex rel. Debra R. v BMW of North America, LLC, 26 NY3d 801, 28 NYS3d 656, 48 NE3d 937 (2016). The general-acceptance test is ordinarily used to determine the reliability of the expert's methodologies used to reach deductions and conclusions, Sean R. ex rel. Debra R. v BMW of North America, LLC, supra; Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006); People v Wernick, 89 NY2d 111, 651 NYS2d 392, 674 NE2d 322 (1996); Nonnon v New York, supra; Frye v Montefiore Medical Center, 100 AD3d 28, 951 NYS2d 4 (1st Dept 2012); Muhammad v Fitzpatrick, 91 AD3d 1353, 937 NYS2d 519 (4th Dept 2012); Ratner v McNeil-PPC, Inc., 91 AD3d 63, 933 NYS2d 323 (2d Dept 2011); Lugo v New York City Health and Hospitals Corp., 89 AD3d 42, 929 NYS2d 264 (2d Dept 2011). "General acceptance" does not necessarily require that a majority of scientists in the discipline subscribe to the expert's conclusion; rather, the test demands only that those espousing the theory or conclusion must have followed generally accepted scientific principles and methodology in evaluating data and reaching conclusions, Johnson v Guthrie Medical Group, P.C., supra; Ratner v McNeil-PPC, Inc., 91 AD3d 63, 933 NYS2d 323 (2d Dept 2011); Lugo v New York City Health and Hospitals Corp., supra; Zito v Zabarsky, 28 AD3d 42, 812 NYS2d 535 (2d Dept 2006); see Sean R. ex rel. Debra R. v BMW of North America, LLC, supra; Sadek v Wesley, 117 AD3d 193, 986 NYS2d 25 (1st Dept 2014), aff'd, 27 NY3d 982, 32 NYS3d 42, 51 NE3d 553 (2016).

Before 1993, the Frye analysis was almost exclusively confined to the admissibility of scientific evidence in criminal cases, and the opinion in Frye v United States, 293 F 1013 (DC Cir 1923), was cited in only a few instances, see People v Taylor, 75 NY2d 277, 552 NYS2d 883, 552 NE2d 131 (1990) (rape trauma syndrome); People v Smith, 63 NY2d 41, 479 NYS2d 706, 468 NE2d 879 (1984) (bite mark analysis); People v Hughes, 59 NY2d 523, 466 NYS2d 255, 453 NE2d 484 (1983) (hypnotic induced memory); People v Middleton, 54 NY2d 42, 444 NYS2d 581, 429 NE2d 100 (1981) (bite mark comparisons). In 1993, however, the United States Supreme Court held in Daubert v Merrell Dow Pharmaceuticals, Inc., 509 US 579, 113 SCt 2786 (1993), that Federal Rule of Evidence 702 did not require rigid adherence to the general-acceptance standard of Frye. Instead, the Daubert Court set forth four non-exclusive factors for determining admissibility: (1) general acceptance in the relevant scientific community, (2) peer review and publication, (3) known error rate, and (4) maintenance of proper standards. Although the Daubert Court eschewed a strict test for admissibility, it

stressed that federal trial judges must still act as "gatekeepers" to prevent unreliable and irrelevant scientific data from being placed before juries in civil as well as criminal cases. The importance of "gatekeeping" was emphasized in General Elec. Co. v Joiner, 522 US 136, 118 SCt 512 (1997), and expanded to include non-scientific technical evidence in Kumho Tire Co., Ltd. v Carmichael, 526 US 137, 119 SCt 1167 (1999). In General Elec. Co. v Joiner, supra, a case involving allegations that the plaintiff's exposure to PCB's caused his cancer, the court stated, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert." After Daubert, New York State and federal trial courts began holding hearings or reviewing paper submissions in a variety of civil contexts before admitting expert evidence based on novel science, see Bennett v Saeger Hotels, Inc., 209 AD2d 946, 619 NYS2d 424 (4th Dept 1994) (stating that Frye test applies in civil cases).

Notwithstanding the decision in Daubert v Merrell Dow Pharmaceuticals, Inc., 509 US 579, 113 SCt 2786 (1993), the New York Court of Appeals reiterated its adherence to the Frye standard for admissibility of scientific evidence in People v Wesley, 83 NY2d 417, 611 NYS2d 97, 633 NE2d 451 (1994), and has repeatedly applied that standard in both criminal, People v Abney, 13 NY3d 251, 889 NYS2d 890, 918 NE2d 486 (2009)(abuse of discretion to exclude expert on eye witness identification); People v LeGrand, 8 NY3d 449, 835 NYS2d 523, 867 NE2d 374 (2007); People v Lee, 96 NY2d 157, 726 NYS2d 361, 750 NE2d 63 (2001); People v Wernick, 89 NY2d 111, 651 NYS2d 392, 674 NE2d 322 (1996) ("neonaticide syndrome" evidence); People v Angelo, 88 NY2d 217, 644 NYS2d 460, 666 NE2d 1333(1996) (polygraph results); People v Wesley, supra (DNA evidence), and civil cases, Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014); see Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006). However, while the *Frye* general-acceptance standard continues to control in New York, the State's trial judges have embraced the "gatekeeper" role and have increasingly taken an active part in assessing the admissibility of "novel" scientific evidence in formal hearings, see People v Santiago, 17 NY3d 661, 934 NYS2d 746, 958 NE2d 874 (2011); People v LeGrand, 8 NY3d 449, 835 NYS2d 523, 867 NE2d 374 (2007); Styles v General Motors Corp., 20 AD3d 338, 799 NYS2d 38 (1st Dept 2005) (remitting for *Frye* hearing to determine reliability of trial expert's theory, which combined two different, previously accepted crash tests); DeMeyer v Advantage Auto, 9 Misc3d 306, 797 NYS2d 743 (Sup 2005); Clemente v Blumenberg, 183 Misc2d 923, 705 NYS2d 792 (Sup 1999).

B. Application of the Frye Test in New York

The Frye test has traditionally asked whether the expert's methodologies and deductions have gained general acceptance as reliable in the relevant scientific community, Sean R. ex rel. Debra R. v BMW of North America, LLC, 26 NY3d 801, 28 NYS3d 656, 48 NE3d

937 (2016); see Frye v Montefiore Medical Center, 100 AD3d 28, 951 NYS2d 4 (1st Dept 2012) (plaintiff's expert's opinion on causation inadmissible where other experts on whose work plaintiff's expert relied submitted affidavits directly controverting plaintiff's expert's theories and explaining how plaintiff's expert had misinterpreted their work); see State v Ian I., 127 AD3d 766, 7 NYS3d 199 (2d Dept 2015) (court should have held Frye hearing where, although use of actuarial risk assessment instruments is scientifically accepted as means to measure risk of recidivism, use of such instruments to determine existence of mental abnormality as defined in Mental Hygiene Law § 10.03[i] is novel). The burden of proving general acceptance rests upon the party offering the disputed expert testimony, Nonnon v New York, 32 AD3d 91, 819 NYS2d 705 (1st Dept 2006), aff'd, 9 NY3d 825, 842 NYS2d 756, 874 NE2d 720 (2007); Lugo v New York City Health and Hospitals Corp., 89 AD3d 42, 929 NYS2d 264 (2d Dept 2011); Zito v Zabarsky, 28 AD3d 42, 812 NYS2d 535 (2d Dept 2006); Saulpaugh ex rel. Saulpaugh v Krafte, 5 AD3d 934, 774 NYS2d 194 (3d Dept 2004). In determining whether a theory has gained general acceptance in the relevant scientific community, the court may consider controlled studies, clinical data, professional literature, recognized text books, peer review and judicial opinions indicating general acceptance of the theory, see Lahey v Kelly, 71 NY2d 135, 524 NYS2d 30, 518 NE2d 924 (1987); Lewin v Suffolk, 18 AD3d 621, 795 NYS2d 659 (2d Dept 2005); Pauling v Orentreich Medical Group, 14 AD3d 357, 787 NYS2d 311 (1st Dept 2005); Saulpaugh ex rel. Saulpaugh v Krafte, supra; People v Scoon, 303 AD2d 525, 756 NYS2d 100 (2d Dept 2003); People v Morales, 227 AD2d 648, 643 NYS2d 217 (2d Dept 1996); see also Heckstall v Pincus, 19 AD3d 203, 797 NYS2d 445 (1st Dept 2005) (unverified listings and reporting of adverse reactions from drug not generally accepted in scientific community as evidence of causation).

Where the scientific evidence proffered is not novel but there may be insufficient foundation for its application in the specific case, the court focuses not on the general reliability concerns addressed in the Frye test but on the specific reliability of the procedures followed to generate the evidence, Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006); Lugo v New York City Health and Hospitals Corp., 89 AD3d 42, 929 NYS2d 264 (2d Dept 2011); Jackson v Nutmeg Technologies, Inc., 43 AD3d 599, 842 NYS2d 588 (3d Dept 2007). In such cases, there must be a separate inquiry concerning whether there is a sufficient foundation to apply the science to a particular case before the expert evidence is admissible, Parker v Mobil Oil Corp, supra; see Sean R. ex rel. Debra R. v BMW of North America, LLC, 26 NY3d 801, 28 NYS3d 656, 48 NE3d 937 (2016). However, the court may conduct a preliminary assessment as to whether there is a sufficiently reliable basis for the evidence, Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006); Nonnon v New York, 32 AD3d 91, 819 NYS2d 705 (1st Dept 2006), aff'd, 9 NY3d 825, 842 NYS2d 756, 874 NE2d 720 (2007); Muhammad v Fitzpatrick, 91 AD3d 1353, 937 NYS2d 519 (4th Dept 2012); Ratner v McNeil-PPC, Inc., 91 AD3d 63, 933 NYS2d 323 (2d Dept 2011); Lugo v New York City Health and Hospitals Corp., 89 AD3d 42, 929 NYS2d 264 (2d Dept 2011);

Ellis v Eng, 70 AD3d 887, 895 NYS2d 462 (2d Dept 2010); Jackson v Nutmeg Technologies, Inc., 43 AD3d 599, 842 NYS2d 588 (3d Dept 2007); see Sadek v Wesley, 117 AD3d 193, 986 NYS2d 25 (1st Dept 2014), aff'd, 27 NY3d 982, 32 NYS3d 42, 51 NE3d 553 (2016).

In ruling upon whether a proper foundation has been established, the court should not make a determination on whether the evidence is true, Nonnon v New York, 32 AD3d 91, 819 NYS2d 705 (1st Dept 2006), aff'd, 9 NY3d 825, 842 NYS2d 756, 874 NE2d 720 (2007); Lugo v New York City Health and Hospitals Corp., 89 AD3d 42, 929 NYS2d 264 (2d Dept 2011). Once the Frye reliability test and foundation requirements have been satisfied, it is for the jury to consider the weight of the evidence, including any possible infirmities in the collection and analysis of data, Nonnon v New York, supra. The fact that there is no textual material to directly support the expert's testimony may be relevant to the weight, not the admissibility, of the testimony, Lugo v New York City Health and Hospitals Corp., supra; Zito v Zabarsky, 28 AD3d 42, 812 NYS2d 535 (2d Dept 2006). Testimony from an expert who gives an opinion based on personal experience rather than published studies is admissible without regard to established scientific basis as long as it is subject to cross-examination and the jury is not misled into thinking that the opinion reflects generally accepted principles, People v Oddone, 22 NY3d 369, 980 NYS2d 912, 3 NE3d 1160 (2013).

There is a question whether Frye's "general acceptance" standard should be applied to the theory or conclusion reached by the expert, or to the principles and methodology used in arriving at the theory or conclusion, or to both. The courts have sometimes used terms such as "theory," "methodology," "principles" and "conclusion." Before its decision in Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014), the Court of Appeals appeared to limit Frye's "general acceptance" standard to the methodology upon which the expert's opinion was based, see Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006); People v Wesley, 83 NY2d 417, 611 NYS2d 97, 633 NE2d 451 (1994); People v Middleton, 54 NY2d 42, 444 NYS2d 581, 429 NE2d 100 (1981); see also People v Oddone, 22 NY3d 369, 980 NYS2d 912, 3 NE3d 1160 (2013) (expert opinion based upon personal experience, and not scientific principle supported by published studies or texts, not barred by Frye); Doviak v Finkelstein & Partners, LLP, 137 AD3d 843, 27 NYS3d 164 (2d Dept 2016) (same). In Cornell, however, the Court of Appeals noted that, in the area of social science, it has gone beyond consideration of methodology and measured the reliability of experts' conclusions and theories against the Frye standard, Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014) (citing People v LeGrand, 8 NY3d 449, 835 NYS2d 523, 867 NE2d 374 (2007); People v Taylor, 75 NY2d 277, 552 NYS2d 883, 552 NE2d 131 (1990)). The Cornell Court noted that the expert in that case failed to show that his "theory of causation enjoyed general scientific acceptance" because he "departed from the generally accepted methodology for evaluating epidemiological evidence." Cornell cited both Daubert v Merrell Dow Pharmaceuticals, Inc., 509 US 579, 113 SCt 2786 (1993),

and General Elec. Co. v Joiner, 522 US 136, 118 SCt 512 (1997), for the proposition that "even where the expert is using reliable principles and is extrapolating from reliable data, a court may exclude opinion if there is 'too great an analytical gap between the data and the opinion proffered'" or "if the opinion evidence is connected to existing data only by the *ipse dixit* of the expert," see Fraser v 301-52 Townhouse Corp., 57 AD3d 416, 870 NYS2d 266 (1st Dept 2008).

Subsequently, some courts have applied the Frye "general acceptance" standard to an expert's "causation theory" outside of the social science context, Matter of Bausch & Lomb Contact Lens Solution Index Product Liability Litigation, 125 AD3d 461, 999 NYS2d 743 (1st Dept 2015) (citing Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014)); Pullman v Silverman, 125 AD3d 562, 5 NYS3d 38 (1st Dept 2015) ("general acceptance" applied to both theory and methodology); see Marso v Novak, 42 AD3d 377, 840 NYS2d 53 (1st Dept 2007) (rejecting "methodology-only approach, noting that Frye also applies "when there is a generally or widely held view in the scientific community rejecting [the expert's] conclusions outright"). Other courts, however, have refused to apply the "general acceptance" standard to an expert's theory or conclusion, see Johnson v Guthrie Medical Group, P.C., 125 AD3d 1445, 3 NYS3d 828 (4th Dept 2015); Keilany B. ex rel. Xiomara S. v New York, 122 AD3d 424, 997 NYS2d 372 (1st Dept 2014) (expert's opinion regarding standard of care in treating injured's condition not "the type of novel theory that necessitates [Frye] hearing"); Ratner v McNeil-PPC, Inc., 91 AD3d 63, 933 NYS2d 323 (2d Dept 2011) (discussing applicability of Frye); see also Sadek v Wesley, 117 AD3d 193, 986 NYS2d 25 (1st Dept 2014) (same), affd 27 NY3d 982, 32 NYS3d 42, 51 NE3d 553 (2016).

In the medical malpractice context, courts have, with increasing frequency, applied the Frye and Parker analyses to exclude expert theories of causation that are not derived from sound or generally accepted methodology, Frye v Montefiore Medical Center, 100 AD3d 28, 951 NYS2d 4 (1st Dept 2012); Ratner v McNeil-PPC, Inc., 91 AD3d 63, 933 NYS2d 323 (2d Dept 2011); Lugo v New York City Health and Hospitals Corp., 89 AD3d 42, 929 NYS2d 264 (2d Dept 2011); Marso v Novak, 42 AD3d 377, 840 NYS2d 53 (1st Dept 2007); Cumberbatch v Blanchette, 35 AD3d 341, 825 NYS2d 744 (2d Dept 2006); Saulpaugh ex rel. Saulpaugh v Krafte, 5 AD3d 934, 774 NYS2d 194 (3d Dept 2004); Lara v New York City Health and Hospitals Corp., 305 AD2d 106, 757 NYS2d 740 (1st Dept 2003); Selig v Pfizer, Inc., 290 AD2d 319, 735 NYS2d 549 (1st Dept 2002); Stanski v Ezersky, 250 AD2d 422, 673 NYS2d 90 (1st Dept 1998). However, the application of Frye in Zito v Zabarsky, 28 AD3d 42, 812 NYS2d 535 (2d Dept 2006), was found to be too restrictive where the expert's "novel" causation theory was supported by an extrapolation from certain generally accepted scientific principles. Similarly, the trial court's determination to exclude plaintiff's expert's causation theory after a Frye hearing was found to be error in Marsh v Smyth, 12 AD3d 307, 785

NYS2d 440 (1st Dept 2004), and Sadek v Wesley, 117 AD3d 193, 986 NYS2d 25 (1st Dept 2014), affd 27 NY3d 982, 32 NYS3d 42, 51 NE3d 553 (2016).

V. Specific Issues for Expert Testimony

A. Causation

Expert testimony has been admitted as to the cause or effect of a particular event, Nallan v Helmsley-Spear, Inc., 50 NY2d 507, 429 NYS2d 606, 407 NE2d 451 (1980) (effect presence of lobby attendant may have on deterring criminal activity); Tarlowe v Metropolitan Ski Slopes, Inc., 28 NY2d 410, 322 NYS2d 665, 271 NE2d 515 (1971) (cause of skiing accident); Karasik v Bird, 98 AD2d 359, 470 NYS2d 605 (1st Dept 1984) (effect of medication); Ward v Kovacs, 55 AD2d 391, 390 NYS2d 931 (2d Dept 1977) (effect that taking LSD may have had on hand infection).

In toxic tort cases, expert opinion is often introduced to establish the causative relationship between the injured's exposure and his or her symptoms. In such cases, both "general causation" and "specific causation" must be shown, Sean R. ex rel. Debra R. v BMW of North America, LLC, 26 NY3d 801, 28 NYS3d 656, 48 NE3d 937 (2016); Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014); see Nonnon v New York, 88 AD3d 384, 932 NYS2d 428 (1st Dept 2011). "General causation" refers to the conclusion, generally accepted in the scientific community, that there is a cause-and-effect relationship between exposure to a toxin and particular symptoms, Cornell v 360 West 51st Street Realty, LLC, supra; see Sean R. ex rel. Debra R. v BMW of North America, LLC, supra. "Specific causation" refers to the conclusion that plaintiff was exposed to the toxin and that it actually caused his or her symptoms, id. Notably, an expert's testimony establishing an "association" or "linkage" between exposure and certain symptoms is not alone sufficient to prove "general causation," Cornell v 360 West 51st Street Realty, LLC, supra; see Sean R. ex rel. Debra R. v BMW of North America, LLC, supra; Fraser v 301-52 Townhouse Corp., 57 AD3d 416, 870 NYS2d 266 (1st Dept 2008). Standards promulgated by regulatory agencies as protective measures are also not sufficient to demonstrate legal causation, Cornell v 360 West 51st Street Realty, LLC, supra; Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006); see Hamilton v Miller, 23 NY3d 592, 992 NYS2d 190, 15 NE3d 1199 (2014) (in scientifically complex cases such as those involving lead paint injuries, general causation requires proof through scientific evidence that exposure can cause plaintiff's alleged injuries; plaintiff's burden of proving general causation not satisfied by court's taking judicial notice of legislative statutory preamble opining on dangers of exposure).

Generally, the foundation for opinion evidence on causation should include a statement that (a) the injured was exposed to a particular toxin, (b) the toxin is capable of causing the

injured's illness or symptoms (general causation) and (c) the injured was exposed to sufficient levels of the toxin to cause his or her illness or symptoms (specific causation), Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014); Parker v Mobil Oil Corp., 7 NY3d 434, 824 NYS2d 584, 857 NE2d 1114 (2006); Nonnon v New York, 88 AD3d 384, 932 NYS2d 428 (1st Dept 2011); see Sean R. ex rel. Debra R. v BMW of North America, LLC, 26 NY3d 801, 28 NYS3d 656, 48 NE3d 937 (2016). However, it is not always necessary for plaintiff's expert precisely to quantify the exposure level, as long as whatever method of establishing causation used is generally accepted in the scientific community, Parker v Mobil Oil Corp., supra; Nonnon v New York, supra; Jackson v Nutmeg Technologies, Inc., 43 AD3d 599, 842 NYS2d 588 (3d Dept 2007); see Sean R. ex rel. Debra R. v BMW of North America, LLC, supra; Kendall v Amica Mut. Ins. Co., 135 AD3d 1202, 23 NYS3d 702 (3d Dept 2016). At a minimum though, there must be evidence from which the factfinder can conclude that the plaintiff was exposed to levels of the agent that are known to cause the kind of harm that the plaintiff claims to have suffered, Sean R. ex rel. Debra R. v BMW of North America, LLC, supra. For example, in a case involving an alleged injury from exposure to benzene at the workplace, the Court of Appeals suggested that exposure levels could be estimated through the use of a mathematical model, comparison to the exposure levels of study subjects and qualitative means, Parker v Mobil Oil Corp., supra; see Nonnon v New York, supra. In Jackson v Nutmeg Technologies, Inc., supra, the court held that an adequate foundation was laid despite the fact that only marginal levels of toxin were found in the air and surfaces at plaintiff's work site, where there was evidence that the particular toxin dissipates rapidly, plaintiff's expert affirmed that the manner in which the toxin had been fed into the steam system caused concentrated levels to be released, the expert's conclusion on causation was based on a report that detailed the epidemiological methods he used to conduct the study and the facts relating to plaintiff's accident were compared to those recorded in other studies.

In contrast, in a case involving symptoms allegedly resulting from exposure to dampness and mold, the expert evidence of causation was insufficient where the expert failed to specify the level of exposure needed to produce plaintiff's symptoms and plaintiff failed to offer a reliable measurement of the level of mold in the apartment, Fraser v 301-52 Townhouse Corp., 57 AD3d 416, 870 NYS2d 266 (1st Dept 2008); see Cleghorne v New York, 99 AD3d 443, 952 NYS2d 114 (1st Dept 2012). In Cornell v 360 West 51st Street Realty, LLC, 22 NY3d 762, 986 NYS2d 389, 9 NE3d 884 (2014), plaintiff could not establish general causation where defendant's expert opined that it is not generally accepted within the relevant scientific community that exposure to mold can cause the particular illnesses of which plaintiff complained. In Cornell, plaintiff's expert made no effort to identify the specific disease-causing agent to which plaintiff was allegedly exposed, nor did he attempt to quantify plaintiff's level of exposure to an allegedly "unusual mixture" of molds. The Cornell Court declined on the evidence presented to accept the view that the performance of a differential

diagnosis was sufficient to prove that plaintiff had been exposed to enough of a toxic agent to establish specific causation where general causation had not been established. However, the Cornell Court noted that there is no categorical rule that exposure to dampness and mold cannot be considered a cause of a plaintiff's disease, Cornell v 360 West 51st Street Realty, LLC, supra.

As to the use of an "odor threshold analysis" to show that a plaintiff was exposed to a certain level of a substance, see Sean R. ex rel. Debra R. v BMW of North America, LLC, 26 NY3d 801, 28 NYS3d 656, 48 NE3d 937 (2016) (concluding that "symptom-threshold" methodology, unlike "odor threshold analysis," has not been shown to be generally accepted in scientific community).

B. Malpractice

In malpractice cases, plaintiff must present expert testimony to support the allegations of malpractice, unless the alleged act of malpractice is within the competence of a lay jury, 530 East 89 Corp. v Unger, 43 NY2d 776, 402 NYS2d 382, 373 NE2d 276 (1977) (architectural malpractice); McDermott v Manhattan Eye, Ear and Throat Hospital, 15 NY2d 20, 255 NYS2d 65, 203 NE2d 469 (1964) (medical malpractice); see States v Lourdes Hosp., 100 NY2d 208, 762 NYS2d 1, 792 NE2d 151 (2003) (same); Kambat v St. Francis Hosp., 89 NY2d 489, 655 NYS2d 844, 678 NE2d 456 (1997) (discussing necessity of expert testimony in medical malpractice cases based upon res ipsa loquitur); Koehler v Schwartz, 48 NY2d 807, 424 NYS2d 119, 399 NE2d 1140 (1979) (medical malpractice); Columbus v Smith & Mahoney P.C., 259 AD2d 857, 686 NYS2d 235 (3d Dept 1999) (negligent design); PJI 2:150; PJI 2:152, PJI 2:153 and PJI 2:154. Failure to adduce expert testimony as to causation in a medical malpractice action may result in the failure to make out a prima facie case, see Prete v Rafla-Demetrious, 224 AD2d 674, 638 NYS2d 700 (2d Dept 1996); Kennedy v Peninsula Hosp. Center, 135 AD2d 788, 522 NYS2d 671 (2d Dept 1987).

As a general rule, in a medical malpractice action against a doctor, the opinion of a witness who is not a doctor as to the proper course of treatment is not competent evidence on the issue of defendant's negligence, Parese v Shankman, 300 AD2d 1087, 752 NYS2d 503 (4th Dept 2002); Jordan v Glens Falls Hosp., 261 AD2d 666, 689 NYS2d 538 (3d Dept 1999); see Elliot v Long Island Home, Ltd., 12 AD3d 481, 784 NYS2d 615 (2d Dept 2004); LaMarque v North Shore University Hosp., 227 AD2d 594, 643 NYS2d 221 (2d Dept 1996). A medical expert need not be a specialist in a particular field in order to testify regarding accepted practices in that field, but the witness nonetheless should be possessed of the requisite skill, training, education, knowledge or experience from which it can be assumed that his or her opinion is reliable, Tsimbler v Fell, 123 AD3d 1009, 999 NYS2d 863 (2d Dept 2014); Mitrovic v Silverman, 104 AD3d 430, 961 NYS2d 75 (1st Dept 2013); Ozugowski v New York, 90 AD3d

875, 935 NYS2d 613 (2d Dept 2011); Mustello v Berg, 44 AD3d 1018, 845 NYS2d 86 (2d Dept 2007); Behar v Coren, 21 AD3d 1045, 803 NYS2d 629 (2d Dept 2005); Postlethwaite v United Health Services Hospitals, Inc., 5 AD3d 892, 773 NYS2d 480 (3d Dept 2004). Thus, where a physician opines outside his or her area of specialization, a foundation must be laid tending to support the reliability of the opinion rendered, DiLorenzo v Zaso, 148 AD3d 1111, 50 NYS3d 503 (2d Dept 2017) (pediatrician and neonatologist failed to lay proper foundation for opinion regarding rheumatology); Ozugowski v New York, supra (internist/cardiologist failed to establish foundation for opinion regarding psychiatric treatment); Bartolacci-Meir v Sassoon, 149 AD3d 567, 50 NYS3d 395 (1st Dept 2017) (general surgeon failed to lay proper foundation for opinion regarding gastroenterological treatment); Mustello v Berg, supra (same); Behar v Coren, supra (pathologist failed to establish proper foundation to opine on surgical and gastroenterological treatment); Postlethwaite v United Health Services Hospitals, Inc., supra (physician whose expertise confined to anesthesiology and pharmacology properly permitted to testify regarding certain accepted medical practices in internal medicine, gastroenterology, general surgery and nursing, but properly precluded from testifying as to whether surgeon and gastroenterologist correctly diagnosed and treated decedent based upon accepted diagnostic practices in their respective fields); see Escobar v Allen, 5 AD3d 242, 774 NYS2d 28 (1st Dept 2004) (podiatrist licensed to treat the type of injury sustained by plaintiff should not have been precluded from testifying against defendant physician without exploring information concerning his or her professional and educational experience); Parese v Shankman, supra.

Whether a duty is owed by a consulting physician to a treating physician and, ultimately to the patient, is a question of law and expert opinion on the subject is not permissible, Sawh v Schoen, 215 AD2d 291, 627 NYS2d 7 (1st Dept 1995); Lipton by Lipton v Kaye, 214 AD2d 319, 624 NYS2d 590 (1st Dept 1995); but see Cogswell by Cogswell v Chapman, 249 AD2d 865, 672 NYS2d 460 (3d Dept 1998) (question of fact as to whether doctor-patient relationship had arisen where there was evidence that defendant doctor had more than informal interest and involvement in plaintiff's condition and in light of defendant's expertise in area of treatment and emergency room doctor's lack of expertise in area).

C. Speed

The opinion evidence of a properly qualified police officer is admissible and sufficient to sustain a conviction for speeding even in the absence of a mechanical device to gauge a vehicle's speed, People v Olsen, 22 NY2d 230, 292 NYS2d 420, 239 NE2d 354 (1968). Additionally, where a proper foundation is laid, lay witnesses may properly be allowed to testify as to the speeds of automobiles and buses, Senecal v Drollette, 304 NY 446, 108 NE2d 602 (1952); Guthrie v Overmyer, 19 AD3d 1169, 797 NYS2d 203 (4th Dept 2005); Sweeney v Peterson, 1 AD3d 650, 766 NYS2d 255 (3d Dept 2003); Lo Faso v Jamaica Buses, Inc.,

63 AD2d 998, 406 NYS2d 131 (2d Dept 1978); Beechey v De Sorbo, 53 AD2d 727, 383 NYS2d 925 (3d Dept 1976); see Nikolov v Cheektowaga, 96 AD3d 1372, 946 NYS2d 734 (4th Dept 2012) (lay witness's testimony inadmissible where witness stated that she "was not a driver" and "can't tell speed"). In Soto v New York City Transit Authority, 6 NY3d 487, 813 NYS2d 701, 846 NE2d 1211 (2006), the Court of Appeals upheld the admission of a plaintiff's estimate of his own running speed where the plaintiff established a sufficient foundation by demonstrating that he had two years' experience running on a treadmill calibrated to measure miles per hour.

D. Accident Reconstruction

Cases in which testimony from accident reconstruction experts has been approved include: Wellington v New York City Transit Authority, 117 AD3d 592, 985 NYS2d 872 (1st Dept 2014) (explanation of how photographs demonstrated that accident was bus driver's fault); Hilton v Jones, 114 AD3d 1113, 981 NYS2d 223 (3d Dept 2014) (testimony based on accident reconstruction report); Felicia v Boro Crescent Corp., 105 AD3d 697, 964 NYS2d 158 (2d Dept 2013) (accident reconstruction testimony); Van Scooter v 450 Trabold Road, Inc., 206 AD2d 865, 616 NYS2d 129 (4th Dept 1994) (testimony that lack of bumper on truck contributed to injuries); Sullivan v Locastro, 178 AD2d 523, 577 NYS2d 631 (2d Dept 1991) (testimony as to how unusual configuration and traffic patterns of intersection affected plaintiff's conduct in his attempt to cross street); Sitaras v James Ricciardi & Sons, Inc., 154 AD2d 451, 545 NYS2d 937 (2d Dept 1989) (testimony that plaintiff's vehicle would have been more heavily damaged if accident had occurred as plaintiff described); Norfleet v New York City Transit Authority, 124 AD2d 715, 508 NYS2d 468 (2d Dept 1986) (accident-reconstruction evidence admissible even where there were certain dissimilarities between simulation and actual accident, at least where several variations more favorable to plaintiff than actual conditions).

In the following cases, accident-reconstruction evidence from experts was held inadmissible: Groninger v Mamaroneck, 17 NY3d 125, 927 NYS2d 304, 950 NE2d 908 (2011) (plaintiff's expert engineer's testimony speculative where premises inspection made and photographs taken over two years after accident); Feldsberg v Nitschke, 49 NY2d 636, 427 NYS2d 751, 404 NE2d 1293 (1980) (investigator properly precluded from testifying as to cause of skid marks, since he was not shown to have been familiar with circumstances of particular accident); Costanzo v Chautauqua, 110 AD3d 1473, 972 NYS2d 791 (4th Dept 2013) (accident reconstruction expert's affidavit speculative and of no probative worth where expert failed to submit data on which opinions based); Lopez v Yannotti, 24 AD2d 758, 263 NYS2d 523 (2d Dept 1965) (insufficient record evidence to support opinion of police officer's accident reconstruction testimony).

E. Biomechanical Engineers

In personal injury actions, the testimony of a biomechanical engineer is sometimes offered to establish the amount of force generated as a result of an event (such as an automobile accident), that the amount of force did or did not cause the plaintiff's injuries (i.e., the mechanics of injuries), or both, see Shillingford v New York City Transit Authority, 147 AD3d 465, 46 NYS3d 110 (1st Dept 2017); Vargas v Sabri, 115 AD3d 505, 981 NYS2d 914 (1st Dept 2014). Cases in which opinions from biomechanical engineers were allowed include: Shillingford v New York City Transit Authority, supra (opinion regarding maximum force that may have been applied to plaintiff and likelihood that it caused resulting injury); Vargas v Sabri, supra (opinion that force of accident could not have caused alleged injuries; biomechanical engineer's lack of medical training did not render him unqualified); Plate v Palisade Film Delivery Corp., 39 AD3d 835, 835 NYS2d 324 (2d Dept 2007) (opinion regarding whether force of impact in accident could have caused injury or exacerbated preexisting injury); Valentine v Grossman, 283 AD2d 571, 724 NYS2d 504 (2d Dept 2001) (opinion that force generated in accident was not sufficient to cause alleged injury); but see Gates v Longden, 120 AD3d 980, 991 NYS2d 229 (4th Dept 2014) (biomechanical engineer, who was not medical doctor, lacked requisite qualifications to render opinion regarding injury causation).

F. Miscellaneous Issues

Expert testimony may be used to establish the monetary value of the services of a homemaker in an action for her wrongful death, De Long v Erie, 60 NY2d 296, 469 NYS2d 611, 457 NE2d 717 (1983); see Smith v M.V. Woods Const. Co., 309 AD2d 1155, 764 NYS2d 749 (4th Dept 2003) (vocational rehabilitation expert not qualified to express opinion on past and future loss of earnings, past and future loss of household services and future medical expenses; such matters are generally the subject of expert testimony by an economist); see also PJI 2:320.3. As to the use of expert testimony to establish the extent of future lost business profits, see Wathne Imports, Ltd. v PRL USA, Inc., 101 AD3d 83, 953 NYS2d 7 (1st Dept 2012).

Value is not strictly a subject for expert testimony, S. Nicolia & Sons Realty Corp. v A.J.A. Concrete Ready Mix, Inc., 137 AD3d 994, 30 NYS3d 636 (2d Dept 2015). The opinion of a nonexpert witness may be received concerning the value of property where the witness is shown to be acquainted with the value of similar things, id. The amount of knowledge that a witness must be shown to possess in order to qualify to testify to an opinion as to value is largely discretionary with the judge, id.

VI. Pre-trial Procedure

A. Expert Disclosure Requirements Under CPLR 3101(d)(1)

CPLR 3101(d)(1)(i) provides that, upon request, each party must identify the experts he or she intends to call at trial and must also disclose in reasonable detail (a) the subject matter on which each expert is expected to testify, (b) the substance of the facts and opinions on which each expert is expected to testify, (c) the qualifications of each expert witness and (d) a summary of the grounds for each expert's opinion, see Carter v Isabella Geriatric Center, Inc., 71 AD3d 443, 896 NYS2d 332 (1st Dept 2010) (dismissing complaint where all of plaintiff's claims required expert testimony and expert disclosure statements contained a "sea of generalities"). CPLR 3101(d)(1)(i) only applies to expert witnesses, not fact witnesses, Sheppard v Blitman/Atlas Building Corp., 288 AD2d 33, 734 NYS2d 1 (1st Dept 2001). Expert disclosure need not be as detailed as the expert's report, which need not itself be disclosed, see Barrowman v Niagara Mohawk Power Corp., 252 AD2d 946, 675 NYS2d 734 (4th Dept 1998). Where a party for good cause shown has retained an expert too close to the time of trial to give the adversary appropriate notice, the party is not automatically precluded from introducing the expert's testimony at the trial. In fact, preclusion as a penalty for late disclosure is not permitted where "good cause" exists for a party's retention of an expert "an insufficient period of time before the commencement of trial to give appropriate notice," CPLR 3101(d)(1)(i); see Shopsin v Siben & Siben, 289 AD2d 220, 733 NYS2d 697 (2d Dept 2001) (preclusion improvident where delay not willful or intentional and prejudice could be obviated by adjournment); Carringi v International Paper Co., 184 AD2d 137, 591 NYS2d 600 (3d Dept 1992); see also Burbige v Siben & Ferber, 115 AD3d 632, 981 NYS2d 537 (2d Dept 2014) (preclusion of expert testimony not required where delay in disclosure not willful and no prejudice shown); Rowan v Cross County Ski & Skate, Inc., 42 AD3d 563, 840 NYS2d 414 (2d Dept 2007) (preclusion of expert testimony not required where delay in retaining expert not willful and disclosure occurred two weeks before scheduled trial date); Quinn v Artcraft Const., Inc., 203 AD2d 444, 610 NYS2d 598 (2d Dept 1994) (preclusion permitted where party failed to show good cause of late retention of expert). Instead, on motion of any party made before or at trial, or on its own initiative, the court may fashion an order in the interest of justice, CPLR 3101(d)(1)(i).

Moreover, CPLR 3212(b) provides, in relevant part, that "[w]here an expert affidavit is submitted in support of, or opposition to, a motion for summary judgment, the court shall not decline to consider the affidavit because an expert exchange pursuant to [CPLR 3101[d][1][i]] was not furnished prior to the submission of the affidavit." That provision took effect on December 11, 2015 and applies to all pending cases for which a summary judgment motion was made on or after that date and all cases commenced on or after it, L 2015, ch 529, § 2.

For motions made prior to the effective date, the fact that disclosure has occurred after the filing of a note of issue and certification of readiness does not, by itself, render the disclosure untimely or require that the expert's affidavit be disregarded on a motion for summary judgment, Rivers v Birnbaum, 102 AD3d 26, 953 NYS2d 232 (2d Dept 2012). In Rivers v Birnbaum, the Second Department clarified its view that "the fact that the disclosure of an expert pursuant to CPLR 3101(d)(1)(i) takes place after the filing of the note of issue and certificate of readiness does not, by itself, render the disclosure untimely," see Abreu v Metropolitan Transp. Authority, 117 AD3d 972, 986 NYS2d 557 (2d Dept 2014); Buchanan v Mack Trucks, Inc., 113 AD3d 716, 979 NYS2d 342 (2d Dept 2014); Begley v New York, 111 AD3d 5, 972 NYS2d 48 (2d Dept 2013).

Rather, that fact is but one factor for the trial court to use in determining whether disclosure was untimely and, if untimely, whether the court should nevertheless, in its discretion, impose a sanction short of preclusion, Rivers v Birnbaum, 102 AD3d 26, 953 NYS2d 232 (2d Dept 2012). At least one post-Rivers decision, however, indicates that a party's failure to disclose his or her expert pursuant to CPLR 3101(d)(1)(i) prior to the filing of a note of issue and certificate of readiness precludes a court, absent good cause, from considering an affidavit submitted by that party's expert in the context of a timely motion for summary judgment, see DeSimone v New York, 121 AD3d 420, 993 NYS2d 551 (1st Dept 2014).

1. Failure to Comply with Expert Disclosure Requirements

Trial courts possess broad discretion in their supervision of expert disclosure under CPLR 3101(d)(1)(i), Rivera v Montefiore Medical Center, 28 NY3d 999, 41 NYS3d 454, 64 NE3d 274 (2016). A determination regarding whether to preclude a party from introducing the testimony of an expert witness at trial based on the party's failure to comply with 3101(d)(1)(i) is left to the sound discretion of the trial court, id. Where a defendant's timely-served CPLR 3101(d)(1)(i) statement contained a purported deficiency that was readily apparent from the face of the statement and could have been raised before trial, but the plaintiff did not object to the alleged deficiency until mid-trial immediately prior to the expert's testimony, the trial court acted within its discretion in determining that the time to challenge the statement's content had passed, id. Supreme Court has broad discretion in determining whether to impose the sanction of preclusion for a failure of timely disclosure regarding expert testimony, see Hansel v Lamb, 257 AD2d 795, 684 NYS2d 20 (3d Dept 1999); Marra v Hensonville Frozen Food Lockers Inc., 189 AD2d 1004, 592 NYS2d 525 (3d Dept 1993). Where a party has failed to provide required disclosure, the court may preclude the testimony of the undisclosed expert, Donacik v Pool Mart, Inc., 270 AD2d 921, 705 NYS2d 784 (4th Dept 2000); Hudson v Manhattan and Bronx Surface Transit Operating Authority, 188 AD2d 355, 591 NYS2d 31 (1st Dept 1992); Olden v Bolton, 137 AD2d 878, 524 NYS2d 562 (3d Dept 1988). There is no specific time limit for disclosing information about a

party's experts, Mead v Dr. Rajadhyax' Dental Group, 34 AD3d 1139, 824 NYS2d 790 (3d Dept 2006); Gushlaw v Roll, 290 AD2d 667, 735 NYS2d 667 (3d Dept 2002); see Rivers v Birnbaum, 102 AD3d 26, 953 NYS2d 232 (2d Dept 2012). The Third Judicial District has adopted a local rule requiring an expert disclosure response to be served with or before the filing of the Note of Issue, but the Third Department has held that the courts have discretion to excuse untimely disclosure in the absence of prejudice or intentional misconduct, Washington v Albany Housing Authority, 297 AD2d 426, 746 NYS2d 99 (3d Dept 2002); Gushlaw v Roll, supra. Individual judges, local districts and particular parts (including the Commercial Division and the Matrimonial Parts) may have rules establishing deadlines for expert disclosures, see 22 NYCRR 202.70(g)(13)(c).

2. Medical, Dental and Podiatric Malpractice Actions

In an action for medical, dental or podiatric malpractice, a party responding to a request for disclosure under CPLR 3101(d)(1)(i) may omit the names of medical, dental or podiatric experts but is still required to disclose all of the other information about such experts required by the statute, CPLR 3101(d)(1)(i). The Fourth Department has held that if disclosure of the expert's qualifications would tend to reveal the expert's identity, the qualifications may be withheld, Thompson v Swiantek, 291 AD2d 884, 736 NYS2d 819 (4th Dept 2002). In contrast, the Second Department has held that a plaintiff in a medical malpractice action may avoid full disclosure of its expert's qualifications only when he or she can establish that there is a reasonable probability that such disclosure (a) would lead to the discovery of the actual identity of its expert and (b) would cause the expert to be subjected to unreasonable annoyance, expense, embarrassment, disadvantage or other prejudice, Thomas v Alleyne, 302 AD2d 36, 752 NYS2d 362 (2d Dept 2002); see Mattis v Keen, 54 AD3d 610, 864 NYS2d 6 (1st Dept 2008).

Despite efforts by parties to force disclosure of the names of their adversaries' expert by moving for summary judgment and thereby requiring the submission of the expert's affidavit, the courts have held that a party opposing a summary judgment motion in a medical, dental or podiatric malpractice action may do so without disclosing the identity of the party's medical experts, as long as an unredacted version of the physician's affidavit is provided in camera, Turi v Birk, 118 AD3d 979, 988 NYS2d 670 (2d Dept 2014); Rojas v McDonald, 267 AD2d 130, 701 NYS2d 21 (1st Dept 1999); Carrasquillo v Rosencrans, 208 AD2d 488, 617 NYS2d 51 (2d Dept 1994); see Napierski v Finn, 229 AD2d 869, 646 NYS2d 415 (3d Dept 1996). However, a party moving for summary judgment in a medical, dental or podiatric malpractice action must reveal the identity of any expert submitting an affidavit in support of the motion, Rivera v Albany Medical Center Hosp., 119 AD3d 1135, 990 NYS2d 310 (3d Dept 2014); Marano v Mercy Hosp., 241 AD2d 48, 670 NYS2d 570 (2d Dept 1998).

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CPLR 3101(d)(1) applies only to experts retained to give testimony at trial, and not to treating physicians, Mantuano v Mehale, 258 AD2d 566, 685 NYS2d 467 (2d Dept 1999), even where the treating physician is offering expert testimony at trial, Hamer v New York, 106 AD3d 504, 965 NYS2d 99 (1st Dept 2013); Malanga v New York, 300 AD2d 549, 752 NYS2d 391 (2d Dept 2002); Overeem v Neuhoff, 254 AD2d 398, 679 NYS2d 74 (2d Dept 1998); but see Norton v Nguyen, 49 AD3d 927, 853 NYS2d 671 (3d Dept 2008).

3. Commercial Division Rules

The Uniform Rules for Commercial Division cases, which may be found in 22 NYCRR § 202.70, contain provisions with respect to expert disclosure. Those Rules, along with the Individual Part Rules, should be consulted for a complete understanding of the current expert disclosure requirements in the Commercial Division.

B. Required Medical Disclosure in Personal Injury and Wrongful Death Actions—22 NYCRR § 202.17

Section 202.17 of the Uniform Rules for the Supreme and County Courts, 22 NYCRR § 202.17, provides for physical examinations and exchange of medical reports in personal injury and wrongful death actions. A party's obligation to provide a report under § 202.17 of the Uniform Rules may not be avoided by the failure of the medical expert to prepare a report after the examination, Kelly v Tarnowski, 213 AD2d 1054, 624 NYS2d 504 (4th Dept 1995). Under § 202.17(h), plaintiff may be precluded from offering in evidence any hospital record not made available for inspection pursuant to the rule unless the court orders otherwise. Further, no party may offer (a) evidence of injuries or conditions not set forth or challenged in the medical reports exchanged between the parties or (b) testimony of any treating or examining physician whose medical report has not been exchanged, see Stern v Calzado, 163 AD2d 299, 557 NYS2d 156 (2d Dept 1990). However, plaintiffs are not required to document or create medical evidence of every alleged injury. Thus, 202.17(b)(1) does not oblige plaintiffs to hire a medical provider to conduct an examination solely for purposes of litigation. Rather, plaintiffs are required only to produce reports from medical providers who have previously treated or examined them, Hamilton v Miller, 23 NY3d 592, 992 NYS2d 190, 15 NE3d 1199 (2014) (plaintiffs, who alleged childhood injuries from lead paint, may never have been contemporaneously treated for such injuries).

Notwithstanding 22 NYCRR § 202.17, a medical expert may testify regarding a party's injury without an exchange of medical reports if the expert's testimony is based solely upon the records already in evidence and not upon the expert's examination of the injured party, Putchlawski v Diaz, 192 AD2d 444, 597 NYS2d 10 (1st Dept 1993); Campoli v Lobmeyer, 183

AD2d 1049, 583 NYS2d 639 (3d Dept 1992); Markey v Eiseman, 114 AD2d 887, 495 NYS2d 61 (2d Dept 1985). The expert may be permitted to testify, even if he or she examined a party, where the testimony will be based solely upon other evidence in the case, Neils v Darmochwal, 6 AD3d 589, 774 NYS2d 809 (2d Dept 2004). However, if the opinion being offered is also based upon an examination, it will be precluded, Kelly v Tarnowski, 213 AD2d 1054, 624 NYS2d 504 (4th Dept 1995); Erena v Colavita Pasta & Olive Oil Corp., 199 AD2d 729, 605 NYS2d 475 (3d Dept 1993). Absent unfair surprise to the opposing party, a treating or examining physician is permitted to testify regarding causation notwithstanding any failure to provide an opinion regarding causation in disclosure under § 202.17, see Kowalsky v Suffolk, 139 AD3d 903, 34 NYS3d 75 (2d Dept 2016); Moreno v Roberts, 161 AD2d 1099, 557 NYS2d 657 (3d Dept 1990); see also Overeem v Neuhoff, 254 AD2d 398, 679 NYS2d 74 (2d Dept 1998) (CPLR 3101[d][1][i]); Holshek v Stokes, 122 AD2d 777, 505 NYS2d 664 (2d Dept 1986) (physician properly allowed to testify that plaintiff's condition permanent, since permanence not an "injury" or "condition" within § 202.17).

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Guide to NY Evidence Objective

The objective of this Guide, as set forth in Rule 1.01,"is to bring together in one document, for the benefit of the bench and bar, New York's existing rules of evidence, setting forth each rule with a note on the sources for that rule. Given that most of New York's evidentiary rules are not codified and that the New York Court of Appeals provides the controlling interpretation of the New York State constitution, statutes and common law, this Guide places particular emphasis on and adheres to the controlling precedents of the New York Court of Appeals. Finally, the rules of evidence set forth in this Guide are not intended to alter the existing law of New York evidence and shall not be construed as doing so or as precluding a change in the law."

This Guide is presently a work in progress. The Committee on the Guide to New York Evidence will publish additional rules as they are completed. The initial numbering of the rules skips every other number to allow the insertion of additional rules as necessary.

The Committee wishes to acknowledge, with thanks, the editorial assistance of the State Reporter, William J. Hooks, and the members of his office.

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FEDERAL RULES

OF

EVIDENCE

DECEMBER 1, 2016

Printed for the use
of
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OF

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FOREWORD

This document contains the Federal Rules of Evidence, as amended to December 1, 2016. The rules were enacted by Public Law 93-595 (approved January 2, 1975) and have been amended by Acts of Congress, and further amended by the United States Supreme Court. This document has been prepared by the Committee in response to the need for an official up-to-date document containing the latest amendments to the rules.

For the convenience of the user, where a rule has been amended a reference to the date the amendment was promulgated and the date the amendment became effective follows the text of the rule.

The Committee on Rules of Practice and Procedure and the Advisory Committee on the Federal Rules of Evidence, Judicial Conference of the United States, prepared notes explaining the purpose and intent of the amendments to the rules. The Committee Notes may be found in the Appendix to Title 28, United States Code, following the particular rule to which they relate.

Bob Goodlatte

Chairman, Committee on the Judiciary.

DECEMBER 1, 2016.

AUTHORITY FOR PROMULGATION OF RULES

TITLE 28, UNITED STATES CODE

§ 2072. Rules of procedure and evidence; power to prescribe

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrate judges thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect.

(c) Such rules may define when a ruling of a district court is final for the purposes of appeal under section 1291 of this title.

(Added Pub. L. 100–702, title IV, § 401(a), Nov. 19, 1988, 102 Stat. 4648, eff. Dec. 1, 1988; amended Pub. L. 101–650, title III, §§ 315, 321, Dec. 1, 1990, 104 Stat. 5115, 5117.)

§ 2073. Rules of procedure and evidence; method of prescribing

(a)(1) The Judicial Conference shall prescribe and publish the procedures for the consideration of proposed rules under this section.

(2) The Judicial Conference may authorize the appointment of committees to assist the Conference by recommending rules to be prescribed under sections 2072 and 2075 of this title. Each such committee shall consist of members of the bench and the professional bar, and trial and appellate judges.

(b) The Judicial Conference shall authorize the appointment of a standing committee on rules of practice, procedure, and evidence under subsection (a) of this section. Such standing committee shall review each recommendation of any other committees so appointed and recommend to the Judicial Conference rules of practice, procedure, and evidence and such changes in rules proposed by a committee appointed under subsection (a)(2) of this section as may be necessary to maintain consistency and otherwise promote the interest of justice.

(c)(1) Each meeting for the transaction of business under this chapter by any committee appointed under this section shall be open to the public, except when the committee so meeting, in open session and with a majority present, determines that it is in the public interest that all or part of the remainder of the meeting on that day shall be closed to the public, and states the reason for so closing the meeting. Minutes of each meeting for the transaction of business under this chapter shall be maintained by the committee and made available to the public, except that any portion of such minutes, relating to a closed meeting and made available to the public, may contain such deletions as may be necessary to avoid frustrating the purposes of closing the meeting.

(2) Any meeting for the transaction of business under this chapter, by a committee appointed under this section, shall be preceded by sufficient notice to enable all interested persons to attend.

(d) In making a recommendation under this section or under section 2072 or 2075, the body making that recommendation shall provide a proposed rule, an explanatory note on the rule, and a written report explaining the body's action, including any minority or other separate views.

(e) Failure to comply with this section does not invalidate a rule prescribed under section 2072 or 2075 of this title.

(Added Pub. L. 100–702, title IV, §401(a), Nov. 19, 1988, 102 Stat. 4649, eff. Dec. 1, 1988; amended Pub. L. 103–394, title I, §104(e), Oct. 22, 1994, 108 Stat. 4110.)

§2074. Rules of procedure and evidence; submission to Congress; effective date

(a) The Supreme Court shall transmit to the Congress not later than May 1 of the year in which a rule prescribed under section 2072 is to become effective a copy of the proposed rule. Such rule shall take effect no earlier than December 1 of the year in which such rule is so transmitted unless otherwise provided by law. The Supreme Court may fix the extent such rule shall apply to proceedings then pending, except that the Supreme Court shall not require the application of such rule to further proceedings then pending to the extent that, in the opinion of the court in which such proceedings are pending, the application of such rule in such proceedings would not be feasible or would work injustice, in which event the former rule applies.

(b) Any such rule creating, abolishing, or modifying an evidentiary privilege shall have no force or effect unless approved by Act of Congress.

(Added Pub. L. 100–702, title IV, §401(a), Nov. 19, 1988, 102 Stat. 4649, eff. Dec. 1, 1988.)

§2075. Bankruptcy rules

The Supreme Court shall have the power to prescribe by general rules, the forms of process, writs, pleadings, and motions, and the practice and procedure in cases under title 11.

Such rules shall not abridge, enlarge, or modify any substantive right.

The Supreme Court shall transmit to Congress not later than May 1 of the year in which a rule prescribed under this section is to become effective a copy of the proposed rule. The rule shall take effect no earlier than December 1 of the year in which it is transmitted to Congress unless otherwise provided by law.

The bankruptcy rules promulgated under this section shall prescribe a form for the statement required under section 707(b)(2)(C) of title 11 and may provide general rules on the content of such statement.

(Added Pub. L. 88–623, §1, Oct. 3, 1964, 78 Stat. 1001; amended Pub. L. 95–598, title II, §247, Nov. 6, 1978, 92 Stat. 2672; Pub. L. 103–394, title I, §104(f), Oct. 22, 1994, 108 Stat. 4110; Pub. L. 109–8, title XII, §1232, Apr. 20, 2005, 119 Stat. 202.)

HISTORICAL NOTE

The Supreme Court prescribes Federal Rules of Evidence pursuant to section 2072 of Title 28, United States Code, as enacted by Title IV "Rules Enabling Act" of Pub. L. 100–702 (approved November 19, 1988, 102 Stat. 4648), effective December 1, 1988, and section 2075 of Title 28. Pursuant to section 2074 of Title 28, the Supreme Court transmits to Congress (not later than May 1 of the year in which a rule prescribed under section 2072 is to become effective) a copy of the proposed rule. The rule takes effect no earlier than December 1 of the year in which the rule is transmitted unless otherwise provided by law.

Pursuant to sections 3402, 3771, and 3772 of Title 18, United States Code, and sections 2072 and 2075 of Title 28, United States Code, as then in effect, the Supreme Court through the Chief Justice submitted Federal Rules of Evidence to Congress on February 5, 1973 (409 U.S. 1132; Cong. Rec., vol. 119, pt. 3, p. 3247, Exec. Comm. 359, H. Doc. 93–46). To allow additional time for Congress to review the proposed rules, Public Law 93–12 (approved March 30, 1973, 87 Stat. 9) provided that the proposed rules "shall have no force or effect except to the extent, and with such amendments, as they may be expressly approved by Act of Congress".

Public Law 93–595[1] (approved January 2, 1975, 88 Stat. 1926) enacted the Federal Rules of Evidence proposed by the Supreme Court, with amendments made by Congress, to be effective July 1, 1975.

Section 1 of Public Law 94–113 (approved October 16, 1975, 89 Stat. 576) added clause (C) to Rule 801(d)(1), effective October 31, 1975.

Section 1 of Public Law 94–149 (approved December 12, 1975, 89 Stat. 805) enacted technical amendments which affected the Table of Contents and Rules 410, 606(b), 803(23), 804(b)(3), and 1101(e).

Section 2 of Public Law 95–540 (approved October 28, 1978, 92 Stat. 2046) added Rule 412 and inserted item 412 in the Table of Contents. The amendments apply to trials that begin more than thirty days after October 28, 1978.

Section 251 of Public Law 95–598 (approved November 6, 1978, 92 Stat. 2673) amended Rule 1101(a) and (b) by striking out ", referees in bankruptcy," and by substituting "title 11, United States

[1] LEGISLATIVE HISTORY:
HOUSE REPORTS: No. 93–650 (Comm. on the Judiciary) and No. 93–1597 (Comm. of Conference).
SENATE REPORT No. 93–1277 (Comm. on the Judiciary).
CONGRESSIONAL RECORD, Vol. 120 (1974):
Jan. 30, Feb. 6, considered and passed House.
Nov. 21, 22, considered and passed Senate, amended.
Dec. 16, Senate agreed to conference report.
Dec. 17, 18, House agreed to conference report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 11, No. 1:
Jan. 3, 1975, Presidential statement.

Code" for "the Bankruptcy Act", effective October 1, 1979, pursuant to section 402(c) of Public Law 95–598.

Section 252 of Public Law 95–598 would have amended Rule 1101(a) by inserting "the United States Bankruptcy Courts," immediately after "the United States district courts,", effective April 1, 1984, pursuant to section 402(b) of Public Law 95–598. However, following a series of amendments (extending the April 1, 1984, effective date) by Public Laws 98–249, §1(a), 98–271, §1(a), 98–299, §1(a), 98–325, §1(a), and 98–353, §121(a), section 402(b) of Public Law 95–598 was amended by section 113 of Public Law 98–353 to provide that the amendment "shall not be effective".

An amendment to Rule 410 was proposed by the Supreme Court by order dated April 30, 1979, transmitted to Congress by the Chief Justice on the same day (441 U.S. 970, 1007; Cong. Rec., vol. 125, pt. 8, p. 9366, Exec. Comm. 1456; H. Doc. 96–112), and was to be effective August 1, 1979. Public Law 96–42 (approved July 31, 1979, 93 Stat. 326) delayed the effective date of the amendment to Rule 410 until December 1, 1980, or until and to the extent approved by Act of Congress, whichever is earlier. In the absence of further action by Congress, the amendment to Rule 410 became effective December 1, 1980.

Sections 142 and 402 of Public Law 97–164 (approved April 2, 1982, 96 Stat. 45, 57) amended Rule 1101(a), effective October 1, 1982.

Section 406 of Public Law 98–473 (approved October 12, 1984, 98 Stat. 2067) amended Rule 704.

Additional amendments were adopted by the Court by order dated March 2, 1987, transmitted to Congress by the Chief Justice on the same day (480 U.S. 1023; Cong. Rec., vol. 133, pt. 4, p. 4484, Exec. Comm. 713; H. Doc. 100–41), and became effective October 1, 1987. The amendments affected Rules 101, 104(c), (d), 106, 404(a)(1), (b), 405(b), 411, 602 to 604, 606, 607, 608(b), 609(a), 610, 611(c), 612, 613, 615, 701, 703, 705, 706(a), 801(a), (d), 803(5), (18), (19), (21), (24), 804(a), (b)(2), (3), (5), 806, 902(2), (3), 1004(3), 1007, and 1101(a).

Additional amendments were adopted by the Court by order dated April 25, 1988, transmitted to Congress by the Chief Justice on the same day (485 U.S. 1049; Cong. Rec., vol. 134, pt. 7, p. 9154, Exec. Comm. 3517; H. Doc. 100–187), and became effective November 1, 1988. The amendments affected Rules 101, 602, 608(b), 613(b), 615, 902(3), and 1101(a), (e).

Sections 7046 and 7075 of Public Law 100–690 (approved November 18, 1988, 102 Stat. 4400, 4405) amended the Tables of Contents and Rules 412, 615, 804(a)(5), and 1101(a). Section 7075(a) of Public Law 100–690, which directed the amendment of Rule 615 by inserting "a" before "party which is not a natural person.", could not be executed because "party which is not a natural person." did not appear. However, the word "a" was inserted by the intervening amendment adopted by the Court by order dated April 25, 1988, effective November 1, 1988. Section 7075(c)(1) of Public Law 100–690, which directed the amendment of Rule 1101(a) by striking "Rules" and inserting "rules", could not be executed because of the intervening amendment adopted by the Court by order dated April 25, 1988, effective November 1, 1988.

An additional amendment was adopted by the Court by order dated January 26, 1990, transmitted to Congress by the Chief Justice on the same day (493 U.S. 1175; Cong. Rec., vol. 136, pt. 1, p.

662, Exec. Comm. 2370; H. Doc. 101–142), and became effective December 1, 1990. The amendment affected Rule 609(a).

Additional amendments were adopted by the Court by order dated April 30, 1991, transmitted to Congress by the Chief Justice on the same day (500 U.S. 1001; Cong. Rec., vol. 137, pt. 7, p. 9721, Ex. Comm. 1189; H. Doc. 102–76), and became effective December 1, 1991. The amendments affected Rules 404(b) and 1102.

Additional amendments were adopted by the Court by order dated April 22, 1993, transmitted to Congress by the Chief Justice on the same day (507 U.S. 1187; Cong. Rec., vol. 139, pt. 6, p. 8127, Ex. Comm. 1104; H. Doc. 103–76), and became effective December 1, 1993. The amendments affected Rules 101, 705, and 1101(a), (e).

An additional amendment was adopted by the Court by order dated April 29, 1994, and transmitted to Congress by the Chief Justice on the same day (511 U.S. 1187; Cong. Rec., vol. 140, pt. 7, p. 8903, Ex. Comm. 3085; H. Doc. 103–250). The amendment affected Rule 412 and was to become effective December 1, 1994. Section 40141(a) of Public Law 103–322 (approved September 13, 1994, 108 Stat. 1918) provided that such amendment would take effect on December 1, 1994, but with the general amendment of Rule 412 made by section 40141(b) of Public Law 103–322.

Section 320935(a) of Public Law 103–322 (approved September 13, 1994, 108 Stat. 2135) amended the Federal Rules of Evidence by adding Rules 413 to 415, with provisions in section 320935(b)–(e) of Public Law 103–322 relating to the effective date and application of such rules. Pursuant to Pub. L. 103–322, §320935(c), the Judicial Conference transmitted a report to Congress on February 9, 1995, containing recommendations different from the amendments made by Pub. L. 103–322, §320935(a). Congress did not adopt the recommendations submitted or provide otherwise by law. Accordingly, Rules 413 to 415, as so added, became effective on July 9, 1995.

Additional amendments were adopted by the Court by order dated April 11, 1997, transmitted to Congress by the Chief Justice on the same day (520 U.S. 1323; Cong. Rec., vol. 143, pt. 4, p. 5550, Ex. Comm. 2798; H. Doc. 105–69), and became effective December 1, 1997. The amendments affected Rules 407, 801, 803, 804, and 806 and added Rule 807.

Additional amendments were adopted by the Court by order dated April 24, 1998, transmitted to Congress by the Chief Justice on the same day (523 U.S. 1235; Cong. Rec., vol. 144, pt. 6, p. 8151, Ex. Comm. 8996 to Ex. Comm. 8998; H. Doc. 105–268), and became effective December 1, 1998. The amendments affected Rule 615.

Additional amendments were adopted by the Court by order dated April 17, 2000, transmitted to Congress by the Chief Justice on the same day (529 U.S. 1189; Cong. Rec., vol. 146, pt. 5, p. 6328, Ex. Comm. 7333; H. Doc. 106–225), and became effective December 1, 2000. The amendments affected Rules 103, 404, 701, 702, 703, 803, and 902.

An additional amendment was adopted by the Court by order dated March 27, 2003, transmitted to Congress by the Chief Justice on the same day (538 U.S. 1097; Cong. Rec., vol. 149, pt. 6, p. 7689, Ex. Comm. 1494; H. Doc. 108–57), and became effective December 1, 2003. The amendment affected Rule 608.

Additional amendments were adopted by the Court by order dated April 12, 2006, transmitted to Congress by the Chief Justice on the same day (547 U.S. 1281; Cong. Rec., vol. 152, pt. 6, p. 7213, Ex. Comm. 7320; H. Doc. 109–108), and became effective December 1, 2006. The amendments affected Rules 404, 408, 606, and 609.

Section 1 of Public Law 110–322 (approved September 19, 2008, 122 Stat. 3537) added Rule 502 and inserted item 502 in the Table of Contents. The amendments apply in all proceedings commenced after September 19, 2008, and, insofar as is just and practicable, in all proceedings pending on that date.

An additional amendment was adopted by the Court by order dated April 28, 2010, transmitted to Congress by the Chief Justice on the same day (559 U.S. 1157; Cong. Rec., vol. 156, pt. 6, p. 8139, Ex. Comm. 7475; H. Doc. 111–113), and became effective December 1, 2010. The amendment affected Rule 804.

Additional amendments were adopted by the Court by order dated April 26, 2011, transmitted to Congress by the Chief Justice on the same day (563 U.S. 1075; Cong. Rec., vol. 157, pt. 6, p. 7770, Ex. Comm. 1662; H. Doc. 112–28), and became effective December 1, 2011. The amendments affected Rules 101 to 1103.

An additional amendment was adopted by the Court by order dated April 13, 2013, transmitted to Congress by the Chief Justice on April 16, 2013 (569 U.S.——; Cong. Rec., vol. 159, p. H2652, Daily Issue, Ex. Comm. 1492; H. Doc. 113–26), and became effective December 1, 2013. The amendment affected Rule 803.

Additional amendments were adopted by the Court by order dated April 25, 2014, transmitted to Congress by the Chief Justice on the same day (572 U.S.——; Cong. Rec., vol. 160, p. H7933, Daily Issue, Ex. Comm. 7580; H. Doc. 113–164), and became effective December 1, 2014. The amendments affected Rules 801 and 803.

Committee Notes

Committee Notes prepared by the Committee on Rules of Practice and Procedure and the Advisory Committee on the Federal Rules of Evidence, Judicial Conference of the United States, explaining the purpose and intent of the amendments are set out in the Appendix to Title 28, United States Code, following the particular rule to which they relate. In addition, the notes are set out in the House documents listed above.

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FEDERAL RULES OF EVIDENCE

Effective July 1, 1975, as amended to December 1, 2016

ARTICLE I. GENERAL PROVISIONS

Rule 101. Scope; Definitions

(a) SCOPE. These rules apply to proceedings in United States courts. The specific courts and proceedings to which the rules apply, along with exceptions, are set out in Rule 1101.

(b) DEFINITIONS. In these rules:

(1) "civil case" means a civil action or proceeding;

(2) "criminal case" includes a criminal proceeding;

(3) "public office" includes a public agency;

(4) "record" includes a memorandum, report, or data compilation;

(5) a "rule prescribed by the Supreme Court" means a rule adopted by the Supreme Court under statutory authority; and

(6) a reference to any kind of written material or any other medium includes electronically stored information.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Apr. 22, 1993, eff. Dec. 1, 1993; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 102. Purpose

These rules should be construed so as to administer every proceeding fairly, eliminate unjustifiable expense and delay, and promote the development of evidence law, to the end of ascertaining the truth and securing a just determination.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 103. Rulings on Evidence

(a) PRESERVING A CLAIM OF ERROR. A party may claim error in a ruling to admit or exclude evidence only if the error affects a substantial right of the party and:

(1) if the ruling admits evidence, a party, on the record:

(A) timely objects or moves to strike; and

(B) states the specific ground, unless it was apparent from the context; or

(2) if the ruling excludes evidence, a party informs the court of its substance by an offer of proof, unless the substance was apparent from the context.

(b) NOT NEEDING TO RENEW AN OBJECTION OR OFFER OF PROOF. Once the court rules definitively on the record—either before or at trial—a party need not renew an objection or offer of proof to preserve a claim of error for appeal.

(c) COURT'S STATEMENT ABOUT THE RULING; DIRECTING AN OFFER OF PROOF. The court may make any statement about the character or form of the evidence, the objection made, and the ruling.

The court may direct that an offer of proof be made in question-and-answer form.

(d) PREVENTING THE JURY FROM HEARING INADMISSIBLE EVIDENCE. To the extent practicable, the court must conduct a jury trial so that inadmissible evidence is not suggested to the jury by any means.

(e) TAKING NOTICE OF PLAIN ERROR. A court may take notice of a plain error affecting a substantial right, even if the claim of error was not properly preserved.

(As amended Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 104. Preliminary Questions

(a) IN GENERAL. The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege.

(b) RELEVANCE THAT DEPENDS ON A FACT. When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist. The court may admit the proposed evidence on the condition that the proof be introduced later.

(c) CONDUCTING A HEARING SO THAT THE JURY CANNOT HEAR IT. The court must conduct any hearing on a preliminary question so that the jury cannot hear it if:

(1) the hearing involves the admissibility of a confession;

(2) a defendant in a criminal case is a witness and so requests; or

(3) justice so requires.

(d) CROSS-EXAMINING A DEFENDANT IN A CRIMINAL CASE. By testifying on a preliminary question, a defendant in a criminal case does not become subject to cross-examination on other issues in the case.

(e) EVIDENCE RELEVANT TO WEIGHT AND CREDIBILITY. This rule does not limit a party's right to introduce before the jury evidence that is relevant to the weight or credibility of other evidence.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 105. Limiting Evidence That Is Not Admissible Against Other Parties or for Other Purposes

If the court admits evidence that is admissible against a party or for a purpose—but not against another party or for another purpose—the court, on timely request, must restrict the evidence to its proper scope and instruct the jury accordingly.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 106. Remainder of or Related Writings or Recorded Statements

If a party introduces all or part of a writing or recorded statement, an adverse party may require the introduction, at that time, of any other part—or any other writing or recorded statement—that in fairness ought to be considered at the same time.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE II. JUDICIAL NOTICE

Rule 201. Judicial Notice of Adjudicative Facts

(a) SCOPE. This rule governs judicial notice of an adjudicative fact only, not a legislative fact.

(b) KINDS OF FACTS THAT MAY BE JUDICIALLY NOTICED. The court may judicially notice a fact that is not subject to reasonable dispute because it:

(1) is generally known within the trial court's territorial jurisdiction; or

(2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.

(c) TAKING NOTICE. The court:

(1) may take judicial notice on its own; or

(2) must take judicial notice if a party requests it and the court is supplied with the necessary information.

(d) TIMING. The court may take judicial notice at any stage of the proceeding.

(e) OPPORTUNITY TO BE HEARD. On timely request, a party is entitled to be heard on the propriety of taking judicial notice and the nature of the fact to be noticed. If the court takes judicial notice before notifying a party, the party, on request, is still entitled to be heard.

(f) INSTRUCTING THE JURY. In a civil case, the court must instruct the jury to accept the noticed fact as conclusive. In a criminal case, the court must instruct the jury that it may or may not accept the noticed fact as conclusive.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE III. PRESUMPTIONS IN CIVIL CASES

Rule 301. Presumptions in Civil Cases Generally

In a civil case, unless a federal statute or these rules provide otherwise, the party against whom a presumption is directed has the burden of producing evidence to rebut the presumption. But this rule does not shift the burden of persuasion, which remains on the party who had it originally.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 302. Applying State Law to Presumptions in Civil Cases

In a civil case, state law governs the effect of a presumption regarding a claim or defense for which state law supplies the rule of decision.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE IV. RELEVANCE AND ITS LIMITS

Rule 401. Test for Relevant Evidence

Evidence is relevant if:

(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and

(b) the fact is of consequence in determining the action.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 402. General Admissibility of Relevant Evidence

Relevant evidence is admissible unless any of the following provides otherwise:

- the United States Constitution;
- a federal statute;
- these rules; or
- other rules prescribed by the Supreme Court.

Irrelevant evidence is not admissible.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 403. Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons

The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 404. Character Evidence; Crimes or Other Acts

(a) CHARACTER EVIDENCE.

(1) *Prohibited Uses.* Evidence of a person's character or character trait is not admissible to prove that on a particular occasion the person acted in accordance with the character or trait.

(2) *Exceptions for a Defendant or Victim in a Criminal Case.* The following exceptions apply in a criminal case:

(A) a defendant may offer evidence of the defendant's pertinent trait, and if the evidence is admitted, the prosecutor may offer evidence to rebut it;

(B) subject to the limitations in Rule 412, a defendant may offer evidence of an alleged victim's pertinent trait, and if the evidence is admitted, the prosecutor may:

(i) offer evidence to rebut it; and

(ii) offer evidence of the defendant's same trait; and

(C) in a homicide case, the prosecutor may offer evidence of the alleged victim's trait of peacefulness to rebut evidence that the victim was the first aggressor.

(3) *Exceptions for a Witness.* Evidence of a witness's character may be admitted under Rules 607, 608, and 609.

(b) CRIMES, WRONGS, OR OTHER ACTS.

(1) *Prohibited Uses.* Evidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character.

(2) *Permitted Uses; Notice in a Criminal Case.* This evidence may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident. On request by a defendant in a criminal case, the prosecutor must:

(A) provide reasonable notice of the general nature of any such evidence that the prosecutor intends to offer at trial; and

(B) do so before trial—or during trial if the court, for good cause, excuses lack of pretrial notice.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 30, 1991, eff. Dec. 1, 1991; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 12, 2006, eff. Dec. 1, 2006; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 405. Methods of Proving Character

(a) BY REPUTATION OR OPINION. When evidence of a person's character or character trait is admissible, it may be proved by testimony about the person's reputation or by testimony in the form of an opinion. On cross-examination of the character witness, the court may allow an inquiry into relevant specific instances of the person's conduct.

(b) BY SPECIFIC INSTANCES OF CONDUCT. When a person's character or character trait is an essential element of a charge, claim, or defense, the character or trait may also be proved by relevant specific instances of the person's conduct.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 406. Habit; Routine Practice

Evidence of a person's habit or an organization's routine practice may be admitted to prove that on a particular occasion the person or organization acted in accordance with the habit or routine practice. The court may admit this evidence regardless of whether it is corroborated or whether there was an eyewitness.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 407. Subsequent Remedial Measures

When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:

- negligence;
- culpable conduct;
- a defect in a product or its design; or
- a need for a warning or instruction.

But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

(As amended Apr. 11, 1997, eff. Dec. 1, 1997; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 408. Compromise Offers and Negotiations

(a) PROHIBITED USES. Evidence of the following is not admissible—on behalf of any party—either to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction:

(1) furnishing, promising, or offering—or accepting, promising to accept, or offering to accept—a valuable consideration in compromising or attempting to compromise the claim; and

(2) conduct or a statement made during compromise negotiations about the claim—except when offered in a criminal case and when the negotiations related to a claim by a public office in the exercise of its regulatory, investigative, or enforcement authority.

(b) EXCEPTIONS. The court may admit this evidence for another purpose, such as proving a witness's bias or prejudice, negating a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution.

(As amended Apr. 12, 2006, eff. Dec. 1, 2006; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 409. Offers to Pay Medical and Similar Expenses

Evidence of furnishing, promising to pay, or offering to pay medical, hospital, or similar expenses resulting from an injury is not admissible to prove liability for the injury.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 410. Pleas, Plea Discussions, and Related Statements

(a) PROHIBITED USES. In a civil or criminal case, evidence of the following is not admissible against the defendant who made the plea or participated in the plea discussions:

(1) a guilty plea that was later withdrawn;

(2) a nolo contendere plea;

(3) a statement made during a proceeding on either of those pleas under Federal Rule of Criminal Procedure 11 or a comparable state procedure; or

(4) a statement made during plea discussions with an attorney for the prosecuting authority if the discussions did not result in a guilty plea or they resulted in a later-withdrawn guilty plea.

(b) EXCEPTIONS. The court may admit a statement described in Rule 410(a)(3) or (4):

(1) in any proceeding in which another statement made during the same plea or plea discussions has been introduced, if in fairness the statements ought to be considered together; or

(2) in a criminal proceeding for perjury or false statement, if the defendant made the statement under oath, on the record, and with counsel present.

(As amended Pub. L. 94–149, §1(9), Dec. 12, 1975, 89 Stat. 805; Apr. 30, 1979, eff. Dec. 1, 1980; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 411. Liability Insurance

Evidence that a person was or was not insured against liability is not admissible to prove whether the person acted negligently or otherwise wrongfully. But the court may admit this evidence for another purpose, such as proving a witness's bias or prejudice or proving agency, ownership, or control.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 412. Sex-Offense Cases: The Victim's Sexual Behavior or Predisposition

(a) PROHIBITED USES. The following evidence is not admissible in a civil or criminal proceeding involving alleged sexual misconduct:

(1) evidence offered to prove that a victim engaged in other sexual behavior; or

(2) evidence offered to prove a victim's sexual predisposition.

(b) EXCEPTIONS.

(1) *Criminal Cases.* The court may admit the following evidence in a criminal case:

(A) evidence of specific instances of a victim's sexual behavior, if offered to prove that someone other than the defendant was the source of semen, injury, or other physical evidence;

(B) evidence of specific instances of a victim's sexual behavior with respect to the person accused of the sexual misconduct, if offered by the defendant to prove consent or if offered by the prosecutor; and

(C) evidence whose exclusion would violate the defendant's constitutional rights.

(2) *Civil Cases.* In a civil case, the court may admit evidence offered to prove a victim's sexual behavior or sexual predisposition if its probative value substantially outweighs the danger of harm to any victim and of unfair prejudice to any party. The court may admit evidence of a victim's reputation only if the victim has placed it in controversy.

(c) PROCEDURE TO DETERMINE ADMISSIBILITY.

(1) *Motion.* If a party intends to offer evidence under Rule 412(b), the party must:

(A) file a motion that specifically describes the evidence and states the purpose for which it is to be offered;

(B) do so at least 14 days before trial unless the court, for good cause, sets a different time;

(C) serve the motion on all parties; and

(D) notify the victim or, when appropriate, the victim's guardian or representative.

(2) *Hearing.* Before admitting evidence under this rule, the court must conduct an in camera hearing and give the victim and parties a right to attend and be heard. Unless the court orders otherwise, the motion, related materials, and the record of the hearing must be and remain sealed.

(d) DEFINITION OF "VICTIM." In this rule, "victim" includes an alleged victim.

(As added Pub. L. 95–540, §2(a), Oct. 28, 1978, 92 Stat. 2046, eff. Nov. 28, 1978; amended Pub. L. 100–690, title VII, §7046(a), Nov. 18, 1988, 102 Stat. 4400; Apr. 29, 1994, eff. Dec. 1, 1994; Sept. 13, 1994, eff. Dec. 1, 1994; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 413. Similar Crimes in Sexual-Assault Cases

(a) PERMITTED USES. In a criminal case in which a defendant is accused of a sexual assault, the court may admit evidence that the defendant committed any other sexual assault. The evidence may be considered on any matter to which it is relevant.

(b) DISCLOSURE TO THE DEFENDANT. If the prosecutor intends to offer this evidence, the prosecutor must disclose it to the defendant, including witnesses' statements or a summary of the expected testimony. The prosecutor must do so at least 15 days before trial or at a later time that the court allows for good cause.

(c) EFFECT ON OTHER RULES. This rule does not limit the admission or consideration of evidence under any other rule.

(d) DEFINITION OF "SEXUAL ASSAULT." In this rule and Rule 415, "sexual assault" means a crime under federal law or under state law (as "state" is defined in 18 U.S.C. §513) involving:

(1) any conduct prohibited by 18 U.S.C. chapter 109A;

(2) contact, without consent, between any part of the defendant's body—or an object—and another person's genitals or anus;

(3) contact, without consent, between the defendant's genitals or anus and any part of another person's body;

(4) deriving sexual pleasure or gratification from inflicting death, bodily injury, or physical pain on another person; or

(5) an attempt or conspiracy to engage in conduct described in subparagraphs (1)–(4).

(As added Pub. L. 103–322, title XXXII, §320935(a), Sept. 13, 1994, 108 Stat. 2136, eff. July 9, 1995; amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 414. Similar Crimes in Child-Molestation Cases

(a) PERMITTED USES. In a criminal case in which a defendant is accused of child molestation, the court may admit evidence that the defendant committed any other child molestation. The evidence may be considered on any matter to which it is relevant.

(b) DISCLOSURE TO THE DEFENDANT. If the prosecutor intends to offer this evidence, the prosecutor must disclose it to the defendant, including witnesses' statements or a summary of the expected testimony. The prosecutor must do so at least 15 days before trial or at a later time that the court allows for good cause.

(c) EFFECT ON OTHER RULES. This rule does not limit the admission or consideration of evidence under any other rule.

(d) DEFINITION OF "CHILD" AND "CHILD MOLESTATION." In this rule and Rule 415:

(1) "child" means a person below the age of 14; and

(2) "child molestation" means a crime under federal law or under state law (as "state" is defined in 18 U.S.C. §513) involving:

(A) any conduct prohibited by 18 U.S.C. chapter 109A and committed with a child;

(B) any conduct prohibited by 18 U.S.C. chapter 110;

(C) contact between any part of the defendant's body—or an object—and a child's genitals or anus;

(D) contact between the defendant's genitals or anus and any part of a child's body;

(E) deriving sexual pleasure or gratification from inflicting death, bodily injury, or physical pain on a child; or

(F) an attempt or conspiracy to engage in conduct described in subparagraphs (A)–(E).

(As added Pub. L. 103–322, title XXXII, §320935(a), Sept. 13, 1994, 108 Stat. 2136, eff. July 9, 1995; amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 415. Similar Acts in Civil Cases Involving Sexual Assault or Child Molestation

(a) PERMITTED USES. In a civil case involving a claim for relief based on a party's alleged sexual assault or child molestation, the court may admit evidence that the party committed any other sexual assault or child molestation. The evidence may be considered as provided in Rules 413 and 414.

(b) DISCLOSURE TO THE OPPONENT. If a party intends to offer this evidence, the party must disclose it to the party against whom it will be offered, including witnesses' statements or a summary of the expected testimony. The party must do so at least 15 days before trial or at a later time that the court allows for good cause.

(c) EFFECT ON OTHER RULES. This rule does not limit the admission or consideration of evidence under any other rule.

(As added Pub. L. 103-322, title XXXII, §320935(a), Sept. 13, 1994, 108 Stat. 2137, eff. July 9, 1995; amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE V. PRIVILEGES

Rule 501. Privilege in General

The common law—as interpreted by United States courts in the light of reason and experience—governs a claim of privilege unless any of the following provides otherwise:

- the United States Constitution;
- a federal statute; or
- rules prescribed by the Supreme Court.

But in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 502. Attorney-Client Privilege and Work Product; Limitations on Waiver

The following provisions apply, in the circumstances set out, to disclosure of a communication or information covered by the attorney-client privilege or work-product protection.

(a) DISCLOSURE MADE IN A FEDERAL PROCEEDING OR TO A FEDERAL OFFICE OR AGENCY; SCOPE OF A WAIVER. When the disclosure is made in a federal proceeding or to a federal office or agency and waives the attorney-client privilege or work-product protection, the waiver extends to an undisclosed communication or information in a federal or state proceeding only if:

(1) the waiver is intentional;

(2) the disclosed and undisclosed communications or information concern the same subject matter; and

(3) they ought in fairness to be considered together.

(b) INADVERTENT DISCLOSURE. When made in a federal proceeding or to a federal office or agency, the disclosure does not operate as a waiver in a federal or state proceeding if:

(1) the disclosure is inadvertent;

(2) the holder of the privilege or protection took reasonable steps to prevent disclosure; and

(3) the holder promptly took reasonable steps to rectify the error, including (if applicable) following Federal Rule of Civil Procedure 26(b)(5)(B).

(c) DISCLOSURE MADE IN A STATE PROCEEDING. When the disclosure is made in a state proceeding and is not the subject of a state-court order concerning waiver, the disclosure does not operate as a waiver in a federal proceeding if the disclosure:

(1) would not be a waiver under this rule if it had been made in a federal proceeding; or

(2) is not a waiver under the law of the state where the disclosure occurred.

(d) CONTROLLING EFFECT OF A COURT ORDER. A federal court may order that the privilege or protection is not waived by disclosure connected with the litigation pending before the court—in which event the disclosure is also not a waiver in any other federal or state proceeding.

(e) CONTROLLING EFFECT OF A PARTY AGREEMENT. An agreement on the effect of disclosure in a federal proceeding is binding only on the parties to the agreement, unless it is incorporated into a court order.

(f) CONTROLLING EFFECT OF THIS RULE. Notwithstanding Rules 101 and 1101, this rule applies to state proceedings and to federal court-annexed and federal court-mandated arbitration proceedings, in the circumstances set out in the rule. And notwithstanding Rule 501, this rule applies even if state law provides the rule of decision.

(g) DEFINITIONS. In this rule:

(1) "attorney-client privilege" means the protection that applicable law provides for confidential attorney-client communications; and

(2) "work-product protection" means the protection that applicable law provides for tangible material (or its intangible equivalent) prepared in anticipation of litigation or for trial.

(As added Pub. L. 110–322, §1(a), Sept. 19, 2008, 122 Stat. 3537; amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE VI. WITNESSES

Rule 601. Competency to Testify in General

Every person is competent to be a witness unless these rules provide otherwise. But in a civil case, state law governs the witness's competency regarding a claim or defense for which state law supplies the rule of decision.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 602. Need for Personal Knowledge

A witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may consist of the witness's own testimony. This rule does not apply to a witness's expert testimony under Rule 703.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 603. Oath or Affirmation to Testify Truthfully

Before testifying, a witness must give an oath or affirmation to testify truthfully. It must be in a form designed to impress that duty on the witness's conscience.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 604. Interpreter

An interpreter must be qualified and must give an oath or affirmation to make a true translation.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 605. Judge's Competency as a Witness

The presiding judge may not testify as a witness at the trial. A party need not object to preserve the issue.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 606. Juror's Competency as a Witness

(a) AT THE TRIAL. A juror may not testify as a witness before the other jurors at the trial. If a juror is called to testify, the court must give a party an opportunity to object outside the jury's presence.

(b) DURING AN INQUIRY INTO THE VALIDITY OF A VERDICT OR INDICTMENT.

(1) *Prohibited Testimony or Other Evidence.* During an inquiry into the validity of a verdict or indictment, a juror may not testify about any statement made or incident that occurred during the jury's deliberations; the effect of anything on that juror's or another juror's vote; or any juror's mental processes concerning the verdict or indictment. The court may not receive a juror's affidavit or evidence of a juror's statement on these matters.

(2) *Exceptions.* A juror may testify about whether:

(A) extraneous prejudicial information was improperly brought to the jury's attention;

(B) an outside influence was improperly brought to bear on any juror; or

(C) a mistake was made in entering the verdict on the verdict form.

(As amended Pub. L. 94–149, §1(10), Dec. 12, 1975, 89 Stat. 805; Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 12, 2006, eff. Dec. 1, 2006; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 607. Who May Impeach a Witness

Any party, including the party that called the witness, may attack the witness's credibility.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 608. A Witness's Character for Truthfulness or Untruthfulness

(a) REPUTATION OR OPINION EVIDENCE. A witness's credibility may be attacked or supported by testimony about the witness's reputation for having a character for truthfulness or untruthfulness, or by testimony in the form of an opinion about that character. But evidence of truthful character is admissible only after the witness's character for truthfulness has been attacked.

(b) SPECIFIC INSTANCES OF CONDUCT. Except for a criminal conviction under Rule 609, extrinsic evidence is not admissible to prove specific instances of a witness's conduct in order to attack or support the witness's character for truthfulness. But the court may, on cross-examination, allow them to be inquired into if they are probative of the character for truthfulness or untruthfulness of:

(1) the witness; or

(2) another witness whose character the witness being cross-examined has testified about.

By testifying on another matter, a witness does not waive any privilege against self-incrimination for testimony that relates only to the witness's character for truthfulness.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Mar. 27, 2003, eff. Dec. 1, 2003; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 609. Impeachment by Evidence of a Criminal Conviction

(a) IN GENERAL. The following rules apply to attacking a witness's character for truthfulness by evidence of a criminal conviction:

(1) for a crime that, in the convicting jurisdiction, was punishable by death or by imprisonment for more than one year, the evidence:

(A) must be admitted, subject to Rule 403, in a civil case or in a criminal case in which the witness is not a defendant; and

(B) must be admitted in a criminal case in which the witness is a defendant, if the probative value of the evidence outweighs its prejudicial effect to that defendant; and

(2) for any crime regardless of the punishment, the evidence must be admitted if the court can readily determine that establishing the elements of the crime required proving—or the witness's admitting—a dishonest act or false statement.

(b) LIMIT ON USING THE EVIDENCE AFTER 10 Years. This subdivision (b) applies if more than 10 years have passed since the witness's conviction or release from confinement for it, whichever is later. Evidence of the conviction is admissible only if:

(1) its probative value, supported by specific facts and circumstances, substantially outweighs its prejudicial effect; and

(2) the proponent gives an adverse party reasonable written notice of the intent to use it so that the party has a fair opportunity to contest its use.

(c) EFFECT OF A PARDON, ANNULMENT, OR CERTIFICATE OF REHABILITATION. Evidence of a conviction is not admissible if:

(1) the conviction has been the subject of a pardon, annulment, certificate of rehabilitation, or other equivalent procedure based on a finding that the person has been rehabilitated, and the person has not been convicted of a later crime punishable by death or by imprisonment for more than one year; or

(2) the conviction has been the subject of a pardon, annulment, or other equivalent procedure based on a finding of innocence.

(d) JUVENILE ADJUDICATIONS. Evidence of a juvenile adjudication is admissible under this rule only if:

(1) it is offered in a criminal case;

(2) the adjudication was of a witness other than the defendant;

(3) an adult's conviction for that offense would be admissible to attack the adult's credibility; and

(4) admitting the evidence is necessary to fairly determine guilt or innocence.

(e) PENDENCY OF AN APPEAL. A conviction that satisfies this rule is admissible even if an appeal is pending. Evidence of the pendency is also admissible.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Jan. 26, 1990, eff. Dec. 1, 1990; Apr. 12, 2006, eff. Dec. 1, 2006; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 610. Religious Beliefs or Opinions

Evidence of a witness's religious beliefs or opinions is not admissible to attack or support the witness's credibility.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 611. Mode and Order of Examining Witnesses and Presenting Evidence

(a) CONTROL BY THE COURT; PURPOSES. The court should exercise reasonable control over the mode and order of examining witnesses and presenting evidence so as to:

(1) make those procedures effective for determining the truth;

(2) avoid wasting time; and

(3) protect witnesses from harassment or undue embarrassment.

(b) SCOPE OF CROSS-EXAMINATION. Cross-examination should not go beyond the subject matter of the direct examination and matters affecting the witness's credibility. The court may allow inquiry into additional matters as if on direct examination.

(c) LEADING QUESTIONS. Leading questions should not be used on direct examination except as necessary to develop the witness's testimony. Ordinarily, the court should allow leading questions:

(1) on cross-examination; and

(2) when a party calls a hostile witness, an adverse party, or a witness identified with an adverse party.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 612. Writing Used to Refresh a Witness's Memory

(a) SCOPE. This rule gives an adverse party certain options when a witness uses a writing to refresh memory:

(1) while testifying; or

(2) before testifying, if the court decides that justice requires the party to have those options.

(b) ADVERSE PARTY'S OPTIONS; DELETING UNRELATED MATTER. Unless 18 U.S.C. §3500 provides otherwise in a criminal case, an adverse party is entitled to have the writing produced at the hearing, to inspect it, to cross-examine the witness about it, and to introduce in evidence any portion that relates to the witness's testimony. If the producing party claims that the writing includes unrelated matter, the court must examine the writing in camera, delete any unrelated portion, and order that the rest be delivered to the adverse party. Any portion deleted over objection must be preserved for the record.

(c) FAILURE TO PRODUCE OR DELIVER THE WRITING. If a writing is not produced or is not delivered as ordered, the court may issue any appropriate order. But if the prosecution does not comply in a criminal case, the court must strike the witness's testimony or—if justice so requires—declare a mistrial.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 613. Witness's Prior Statement

(a) SHOWING OR DISCLOSING THE STATEMENT DURING EXAMINATION. When examining a witness about the witness's prior statement, a party need not show it or disclose its contents to the witness. But the party must, on request, show it or disclose its contents to an adverse party's attorney.

(b) EXTRINSIC EVIDENCE OF A PRIOR INCONSISTENT STATEMENT. Extrinsic evidence of a witness's prior inconsistent statement is admissible only if the witness is given an opportunity to explain or deny the statement and an adverse party is given an opportunity to examine the witness about it, or if justice so requires. This subdivision (b) does not apply to an opposing party's statement under Rule 801(d)(2).

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 614. Court's Calling or Examining a Witness

(a) CALLING. The court may call a witness on its own or at a party's request. Each party is entitled to cross-examine the witness.

(b) EXAMINING. The court may examine a witness regardless of who calls the witness.

(c) OBJECTIONS. A party may object to the court's calling or examining a witness either at that time or at the next opportunity when the jury is not present.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 615. Excluding Witnesses

At a party's request, the court must order witnesses excluded so that they cannot hear other witnesses' testimony. Or the court may do so on its own. But this rule does not authorize excluding:

(a) a party who is a natural person;

(b) an officer or employee of a party that is not a natural person, after being designated as the party's representative by its attorney;

(c) a person whose presence a party shows to be essential to presenting the party's claim or defense; or

(d) a person authorized by statute to be present.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Pub. L. 100–690, title VII, §7075(a), Nov. 18, 1988, 102 Stat. 4405; Apr. 24, 1998, eff. Dec. 1, 1998; Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE VII. OPINIONS AND EXPERT TESTIMONY

Rule 701. Opinion Testimony by Lay Witnesses

If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:

(a) rationally based on the witness's perception;

(b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and

(c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 702. Testimony by Expert Witnesses

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.

(As amended Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 703. Bases of an Expert's Opinion Testimony

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 704. Opinion on an Ultimate Issue

(a) IN GENERAL—NOT AUTOMATICALLY OBJECTIONABLE. An opinion is not objectionable just because it embraces an ultimate issue.

(b) EXCEPTION. In a criminal case, an expert witness must not state an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the

crime charged or of a defense. Those matters are for the trier of fact alone.

(As amended Pub. L. 98–473, title II, §406, Oct. 12, 1984, 98 Stat. 2067; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 705. Disclosing the Facts or Data Underlying an Expert's Opinion

Unless the court orders otherwise, an expert may state an opinion—and give the reasons for it—without first testifying to the underlying facts or data. But the expert may be required to disclose those facts or data on cross-examination.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 22, 1993, eff. Dec. 1, 1993; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 706. Court-Appointed Expert Witnesses

(a) APPOINTMENT PROCESS. On a party's motion or on its own, the court may order the parties to show cause why expert witnesses should not be appointed and may ask the parties to submit nominations. The court may appoint any expert that the parties agree on and any of its own choosing. But the court may only appoint someone who consents to act.

(b) EXPERT'S ROLE. The court must inform the expert of the expert's duties. The court may do so in writing and have a copy filed with the clerk or may do so orally at a conference in which the parties have an opportunity to participate. The expert:

(1) must advise the parties of any findings the expert makes;

(2) may be deposed by any party;

(3) may be called to testify by the court or any party; and

(4) may be cross-examined by any party, including the party that called the expert.

(c) COMPENSATION. The expert is entitled to a reasonable compensation, as set by the court. The compensation is payable as follows:

(1) in a criminal case or in a civil case involving just compensation under the Fifth Amendment, from any funds that are provided by law; and

(2) in any other civil case, by the parties in the proportion and at the time that the court directs—and the compensation is then charged like other costs.

(d) DISCLOSING THE APPOINTMENT TO THE JURY. The court may authorize disclosure to the jury that the court appointed the expert.

(e) PARTIES' CHOICE OF THEIR OWN EXPERTS. This rule does not limit a party in calling its own experts.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE VIII. HEARSAY

Rule 801. Definitions That Apply to This Article; Exclusions from Hearsay

(a) STATEMENT. "Statement" means a person's oral assertion, written assertion, or nonverbal conduct, if the person intended it as an assertion.

(b) DECLARANT. "Declarant" means the person who made the statement.

(c) HEARSAY. "Hearsay" means a statement that:

(1) the declarant does not make while testifying at the current trial or hearing; and

(2) a party offers in evidence to prove the truth of the matter asserted in the statement.

(d) STATEMENTS THAT ARE NOT HEARSAY. A statement that meets the following conditions is not hearsay:

(1) *A Declarant-Witness's Prior Statement.* The declarant testifies and is subject to cross-examination about a prior statement, and the statement:

(A) is inconsistent with the declarant's testimony and was given under penalty of perjury at a trial, hearing, or other proceeding or in a deposition;

(B) is consistent with the declarant's testimony and is offered:

(i) to rebut an express or implied charge that the declarant recently fabricated it or acted from a recent improper influence or motive in so testifying; or

(ii) to rehabilitate the declarant's credibility as a witness when attacked on another ground; or

(C) identifies a person as someone the declarant perceived earlier.

(2) *An Opposing Party's Statement.* The statement is offered against an opposing party and:

(A) was made by the party in an individual or representative capacity;

(B) is one the party manifested that it adopted or believed to be true;

(C) was made by a person whom the party authorized to make a statement on the subject;

(D) was made by the party's agent or employee on a matter within the scope of that relationship and while it existed; or

(E) was made by the party's coconspirator during and in furtherance of the conspiracy.

The statement must be considered but does not by itself establish the declarant's authority under (C); the existence or scope of the relationship under (D); or the existence of the conspiracy or participation in it under (E).

(As amended Pub. L. 94–113, §1, Oct. 16, 1975, 89 Stat. 576, eff. Oct. 31, 1975; Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 11, 1997, eff. Dec. 1, 1997; Apr. 26, 2011, eff. Dec. 1, 2011; Apr. 25, 2014, eff. Dec. 1, 2014.)

Rule 802. The Rule Against Hearsay

Hearsay is not admissible unless any of the following provides otherwise:

- a federal statute;
- these rules; or
- other rules prescribed by the Supreme Court.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 803. Exceptions to the Rule Against Hearsay—Regardless of Whether the Declarant Is Available as a Witness

The following are not excluded by the rule against hearsay, regardless of whether the declarant is available as a witness:

(1) *Present Sense Impression.* A statement describing or explaining an event or condition, made while or immediately after the declarant perceived it.

(2) *Excited Utterance.* A statement relating to a startling event or condition, made while the declarant was under the stress of excitement that it caused.

(3) *Then-Existing Mental, Emotional, or Physical Condition.* A statement of the declarant's then-existing state of mind (such as motive, intent, or plan) or emotional, sensory, or physical condition (such as mental feeling, pain, or bodily health), but not including a statement of memory or belief to prove the fact remembered or believed unless it relates to the validity or terms of the declarant's will.

(4) *Statement Made for Medical Diagnosis or Treatment.* A statement that:

(A) is made for—and is reasonably pertinent to—medical diagnosis or treatment; and

(B) describes medical history; past or present symptoms or sensations; their inception; or their general cause.

(5) *Recorded Recollection.* A record that:

(A) is on a matter the witness once knew about but now cannot recall well enough to testify fully and accurately;

(B) was made or adopted by the witness when the matter was fresh in the witness's memory; and

(C) accurately reflects the witness's knowledge.

If admitted, the record may be read into evidence but may be received as an exhibit only if offered by an adverse party.

(6) *Records of a Regularly Conducted Activity.* A record of an act, event, condition, opinion, or diagnosis if:

(A) the record was made at or near the time by—or from information transmitted by—someone with knowledge;

(B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;

(C) making the record was a regular practice of that activity;

(D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and

(E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

(7) *Absence of a Record of a Regularly Conducted Activity.* Evidence that a matter is not included in a record described in paragraph (6) if:

(A) the evidence is admitted to prove that the matter did not occur or exist;

(B) a record was regularly kept for a matter of that kind; and

(C) the opponent does not show that the possible source of the information or other circumstances indicate a lack of trustworthiness.

(8) *Public Records.* A record or statement of a public office if:

(A) it sets out:

(i) the office's activities;

(ii) a matter observed while under a legal duty to report, but not including, in a criminal case, a matter observed by law-enforcement personnel; or

(iii) in a civil case or against the government in a criminal case, factual findings from a legally authorized investigation; and

(B) the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness.

(9) *Public Records of Vital Statistics.* A record of a birth, death, or marriage, if reported to a public office in accordance with a legal duty.

(10) *Absence of a Public Record.* Testimony—or a certification under Rule 902—that a diligent search failed to disclose a public record or statement if:

(A) the testimony or certification is admitted to prove that

(i) the record or statement does not exist; or

(ii) a matter did not occur or exist, if a public office regularly kept a record or statement for a matter of that kind; and

(B) in a criminal case, a prosecutor who intends to offer a certification provides written notice of that intent at least 14 days before trial, and the defendant does not object in writing within 7 days of receiving the notice—unless the court sets a different time for the notice or the objection.

(11) *Records of Religious Organizations Concerning Personal or Family History.* A statement of birth, legitimacy, ancestry, marriage, divorce, death, relationship by blood or marriage, or similar facts of personal or family history, contained in a regularly kept record of a religious organization.

(12) *Certificates of Marriage, Baptism, and Similar Ceremonies.* A statement of fact contained in a certificate:

(A) made by a person who is authorized by a religious organization or by law to perform the act certified;

(B) attesting that the person performed a marriage or similar ceremony or administered a sacrament; and

(C) purporting to have been issued at the time of the act or within a reasonable time after it.

(13) *Family Records.* A statement of fact about personal or family history contained in a family record, such as a Bible, genealogy, chart, engraving on a ring, inscription on a portrait, or engraving on an urn or burial marker.

(14) *Records of Documents That Affect an Interest in Property.* The record of a document that purports to establish or affect an interest in property if:

(A) the record is admitted to prove the content of the original recorded document, along with its signing and its delivery by each person who purports to have signed it;

(B) the record is kept in a public office; and

(C) a statute authorizes recording documents of that kind in that office.

(15) *Statements in Documents That Affect an Interest in Property.* A statement contained in a document that purports to establish or affect an interest in property if the matter stated was relevant to the document's purpose—unless later dealings with the property are inconsistent with the truth of the statement or the purport of the document.

(16) *Statements in Ancient Documents.* A statement in a document that is at least 20 years old and whose authenticity is established.

(17) *Market Reports and Similar Commercial Publications.* Market quotations, lists, directories, or other compilations that are generally relied on by the public or by persons in particular occupations.

(18) *Statements in Learned Treatises, Periodicals, or Pamphlets.* A statement contained in a treatise, periodical, or pamphlet if:

(A) the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination; and

(B) the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice.

If admitted, the statement may be read into evidence but not received as an exhibit.

(19) *Reputation Concerning Personal or Family History.* A reputation among a person's family by blood, adoption, or marriage—or among a person's associates or in the community—concerning the person's birth, adoption, legitimacy, ancestry, marriage, divorce, death, relationship by blood, adoption, or marriage, or similar facts of personal or family history.

(20) *Reputation Concerning Boundaries or General History.* A reputation in a community—arising before the controversy—concerning boundaries of land in the community or customs that affect the land, or concerning general historical events important to that community, state, or nation.

(21) *Reputation Concerning Character.* A reputation among a person's associates or in the community concerning the person's character.

(22) *Judgment of a Previous Conviction.* Evidence of a final judgment of conviction if:

(A) the judgment was entered after a trial or guilty plea, but not a nolo contendere plea;

(B) the conviction was for a crime punishable by death or by imprisonment for more than a year;

(C) the evidence is admitted to prove any fact essential to the judgment; and

(D) when offered by the prosecutor in a criminal case for a purpose other than impeachment, the judgment was against the defendant.

The pendency of an appeal may be shown but does not affect admissibility.

(23) *Judgments Involving Personal, Family, or General History, or a Boundary.* A judgment that is admitted to prove a matter

of personal, family, or general history, or boundaries, if the matter:

(A) was essential to the judgment; and

(B) could be proved by evidence of reputation.

(24) [*Other Exceptions.*] [Transferred to Rule 807.]

(As amended Pub. L. 94–149, §1(11), Dec. 12, 1975, 89 Stat. 805; Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 11, 1997, eff. Dec. 1, 1997; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011; Apr. 13, 2013, eff. Dec. 1, 2013; Apr. 25, 2014, eff. Dec. 1, 2014.)

Rule 804. Exceptions to the Rule Against Hearsay—When the Declarant Is Unavailable as a Witness

(a) CRITERIA FOR BEING UNAVAILABLE. A declarant is considered to be unavailable as a witness if the declarant:

(1) is exempted from testifying about the subject matter of the declarant's statement because the court rules that a privilege applies;

(2) refuses to testify about the subject matter despite a court order to do so;

(3) testifies to not remembering the subject matter;

(4) cannot be present or testify at the trial or hearing because of death or a then-existing infirmity, physical illness, or mental illness; or

(5) is absent from the trial or hearing and the statement's proponent has not been able, by process or other reasonable means, to procure:

(A) the declarant's attendance, in the case of a hearsay exception under Rule 804(b)(1) or (6); or

(B) the declarant's attendance or testimony, in the case of a hearsay exception under Rule 804(b)(2), (3), or (4).

But this subdivision (a) does not apply if the statement's proponent procured or wrongfully caused the declarant's unavailability as a witness in order to prevent the declarant from attending or testifying.

(b) THE EXCEPTIONS. The following are not excluded by the rule against hearsay if the declarant is unavailable as a witness:

(1) *Former Testimony.* Testimony that:

(A) was given as a witness at a trial, hearing, or lawful deposition, whether given during the current proceeding or a different one; and

(B) is now offered against a party who had—or, in a civil case, whose predecessor in interest had—an opportunity and similar motive to develop it by direct, cross-, or redirect examination.

(2) *Statement Under the Belief of Imminent Death.* In a prosecution for homicide or in a civil case, a statement that the declarant, while believing the declarant's death to be imminent, made about its cause or circumstances.

(3) *Statement Against Interest.* A statement that:

(A) a reasonable person in the declarant's position would have made only if the person believed it to be true because, when made, it was so contrary to the declarant's proprietary or pecuniary interest or had so great a tendency to invalidate the declarant's claim against someone

else or to expose the declarant to civil or criminal liability; and

(B) is supported by corroborating circumstances that clearly indicate its trustworthiness, if it is offered in a criminal case as one that tends to expose the declarant to criminal liability.

(4) *Statement of Personal or Family History.* A statement about:

(A) the declarant's own birth, adoption, legitimacy, ancestry, marriage, divorce, relationship by blood, adoption, or marriage, or similar facts of personal or family history, even though the declarant had no way of acquiring personal knowledge about that fact; or

(B) another person concerning any of these facts, as well as death, if the declarant was related to the person by blood, adoption, or marriage or was so intimately associated with the person's family that the declarant's information is likely to be accurate.

(5) [*Other Exceptions.*] [Transferred to Rule 807.]

(6) *Statement Offered Against a Party That Wrongfully Caused the Declarant's Unavailability.* A statement offered against a party that wrongfully caused—or acquiesced in wrongfully causing—the declarant's unavailability as a witness, and did so intending that result.

(As amended Dec. 12, 1975; Mar. 2, 1987, eff. Oct. 1, 1987; Nov. 18, 1988; Apr. 11, 1997, eff. Dec. 1, 1997; Apr. 28, 2010, eff. Dec. 1, 2010; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 805. Hearsay Within Hearsay

Hearsay within hearsay is not excluded by the rule against hearsay if each part of the combined statements conforms with an exception to the rule.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 806. Attacking and Supporting the Declarant's Credibility

When a hearsay statement—or a statement described in Rule 801(d)(2)(C), (D), or (E)—has been admitted in evidence, the declarant's credibility may be attacked, and then supported, by any evidence that would be admissible for those purposes if the declarant had testified as a witness. The court may admit evidence of the declarant's inconsistent statement or conduct, regardless of when it occurred or whether the declarant had an opportunity to explain or deny it. If the party against whom the statement was admitted calls the declarant as a witness, the party may examine the declarant on the statement as if on cross-examination.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 11, 1997, eff. Dec. 1, 1997; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 807. Residual Exception

(a) IN GENERAL. Under the following circumstances, a hearsay statement is not excluded by the rule against hearsay even if the statement is not specifically covered by a hearsay exception in Rule 803 or 804:

(1) the statement has equivalent circumstantial guarantees of trustworthiness;

(2) it is offered as evidence of a material fact;

(3) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts; and

(4) admitting it will best serve the purposes of these rules and the interests of justice.

(b) NOTICE. The statement is admissible only if, before the trial or hearing, the proponent gives an adverse party reasonable notice of the intent to offer the statement and its particulars, including the declarant's name and address, so that the party has a fair opportunity to meet it.

(Added Apr. 11, 1997, eff. Dec. 1, 1997; amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE IX. AUTHENTICATION AND IDENTIFICATION

Rule 901. Authenticating or Identifying Evidence

(a) IN GENERAL. To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.

(b) EXAMPLES. The following are examples only—not a complete list—of evidence that satisfies the requirement:

(1) *Testimony of a Witness with Knowledge.* Testimony that an item is what it is claimed to be.

(2) *Nonexpert Opinion About Handwriting.* A nonexpert's opinion that handwriting is genuine, based on a familiarity with it that was not acquired for the current litigation.

(3) *Comparison by an Expert Witness or the Trier of Fact.* A comparison with an authenticated specimen by an expert witness or the trier of fact.

(4) *Distinctive Characteristics and the Like.* The appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances.

(5) *Opinion About a Voice.* An opinion identifying a person's voice—whether heard firsthand or through mechanical or electronic transmission or recording—based on hearing the voice at any time under circumstances that connect it with the alleged speaker.

(6) *Evidence About a Telephone Conversation.* For a telephone conversation, evidence that a call was made to the number assigned at the time to:

(A) a particular person, if circumstances, including self-identification, show that the person answering was the one called; or

(B) a particular business, if the call was made to a business and the call related to business reasonably transacted over the telephone.

(7) *Evidence About Public Records.* Evidence that:

(A) a document was recorded or filed in a public office as authorized by law; or

(B) a purported public record or statement is from the office where items of this kind are kept.

(8) *Evidence About Ancient Documents or Data Compilations.* For a document or data compilation, evidence that it:

(A) is in a condition that creates no suspicion about its authenticity;

(B) was in a place where, if authentic, it would likely be; and

(C) is at least 20 years old when offered.

(9) *Evidence About a Process or System.* Evidence describing a process or system and showing that it produces an accurate result.

(10) *Methods Provided by a Statute or Rule.* Any method of authentication or identification allowed by a federal statute or a rule prescribed by the Supreme Court.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 902. Evidence That Is Self-Authenticating

The following items of evidence are self-authenticating; they require no extrinsic evidence of authenticity in order to be admitted:

(1) *Domestic Public Documents That Are Sealed and Signed.* A document that bears:

(A) a seal purporting to be that of the United States; any state, district, commonwealth, territory, or insular possession of the United States; the former Panama Canal Zone; the Trust Territory of the Pacific Islands; a political subdivision of any of these entities; or a department, agency, or officer of any entity named above; and

(B) a signature purporting to be an execution or attestation.

(2) *Domestic Public Documents That Are Not Sealed but Are Signed and Certified.* A document that bears no seal if:

(A) it bears the signature of an officer or employee of an entity named in Rule 902(1)(A); and

(B) another public officer who has a seal and official duties within that same entity certifies under seal—or its equivalent—that the signer has the official capacity and that the signature is genuine.

(3) *Foreign Public Documents.* A document that purports to be signed or attested by a person who is authorized by a foreign country's law to do so. The document must be accompanied by a final certification that certifies the genuineness of the signature and official position of the signer or attester—or of any foreign official whose certificate of genuineness relates to the signature or attestation or is in a chain of certificates of genuineness relating to the signature or attestation. The certification may be made by a secretary of a United States embassy or legation; by a consul general, vice consul, or consular agent of the United States; or by a diplomatic or consular official of the foreign country assigned or accredited to the United States. If all parties have been given a reasonable opportunity to investigate the document's authenticity and accuracy, the court may, for good cause, either:

(A) order that it be treated as presumptively authentic without final certification; or

(B) allow it to be evidenced by an attested summary with or without final certification.

(4) *Certified Copies of Public Records.* A copy of an official record—or a copy of a document that was recorded or filed in a public office as authorized by law—if the copy is certified as correct by:

(A) the custodian or another person authorized to make the certification; or

(B) a certificate that complies with Rule 902(1), (2), or (3), a federal statute, or a rule prescribed by the Supreme Court.

(5) *Official Publications.* A book, pamphlet, or other publication purporting to be issued by a public authority.

(6) *Newspapers and Periodicals.* Printed material purporting to be a newspaper or periodical.

(7) *Trade Inscriptions and the Like.* An inscription, sign, tag, or label purporting to have been affixed in the course of business and indicating origin, ownership, or control.

(8) *Acknowledged Documents.* A document accompanied by a certificate of acknowledgment that is lawfully executed by a notary public or another officer who is authorized to take acknowledgments.

(9) *Commercial Paper and Related Documents.* Commercial paper, a signature on it, and related documents, to the extent allowed by general commercial law.

(10) *Presumptions Under a Federal Statute.* A signature, document, or anything else that a federal statute declares to be presumptively or prima facie genuine or authentic.

(11) *Certified Domestic Records of a Regularly Conducted Activity.* The original or a copy of a domestic record that meets the requirements of Rule 803(6)(A)–(C), as shown by a certification of the custodian or another qualified person that complies with a federal statute or a rule prescribed by the Supreme Court. Before the trial or hearing, the proponent must give an adverse party reasonable written notice of the intent to offer the record—and must make the record and certification available for inspection—so that the party has a fair opportunity to challenge them.

(12) *Certified Foreign Records of a Regularly Conducted Activity.* In a civil case, the original or a copy of a foreign record that meets the requirements of Rule 902(11), modified as follows: the certification, rather than complying with a federal statute or Supreme Court rule, must be signed in a manner that, if falsely made, would subject the maker to a criminal penalty in the country where the certification is signed. The proponent must also meet the notice requirements of Rule 902(11).

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 903. Subscribing Witness's Testimony

A subscribing witness's testimony is necessary to authenticate a writing only if required by the law of the jurisdiction that governs its validity.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE X. CONTENTS OF WRITINGS, RECORDINGS, AND PHOTOGRAPHS

Rule 1001. Definitions That Apply to This Article

In this article:

(a) A "writing" consists of letters, words, numbers, or their equivalent set down in any form.

(b) A "recording" consists of letters, words, numbers, or their equivalent recorded in any manner.

(c) A "photograph" means a photographic image or its equivalent stored in any form.

(d) An "original" of a writing or recording means the writing or recording itself or any counterpart intended to have the same effect by the person who executed or issued it. For electronically stored information, "original" means any printout—or other output readable by sight—if it accurately reflects the information. An "original" of a photograph includes the negative or a print from it.

(e) A "duplicate" means a counterpart produced by a mechanical, photographic, chemical, electronic, or other equivalent process or technique that accurately reproduces the original.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1002. Requirement of the Original

An original writing, recording, or photograph is required in order to prove its content unless these rules or a federal statute provides otherwise.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1003. Admissibility of Duplicates

A duplicate is admissible to the same extent as the original unless a genuine question is raised about the original's authenticity or the circumstances make it unfair to admit the duplicate.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1004. Admissibility of Other Evidence of Content

An original is not required and other evidence of the content of a writing, recording, or photograph is admissible if:

(a) all the originals are lost or destroyed, and not by the proponent acting in bad faith;

(b) an original cannot be obtained by any available judicial process;

(c) the party against whom the original would be offered had control of the original; was at that time put on notice, by pleadings or otherwise, that the original would be a subject of proof at the trial or hearing; and fails to produce it at the trial or hearing; or

(d) the writing, recording, or photograph is not closely related to a controlling issue.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1005. Copies of Public Records to Prove Content

The proponent may use a copy to prove the content of an official record—or of a document that was recorded or filed in a public office as authorized by law—if these conditions are met: the record or document is otherwise admissible; and the copy is certified as correct in accordance with Rule 902(4) or is testified to be correct by a witness who has compared it with the original. If no such copy can be obtained by reasonable diligence, then the proponent may use other evidence to prove the content.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1006. Summaries to Prove Content

The proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court. The proponent must make the originals or duplicates available for examination or copying, or both, by other parties at a reasonable time and place. And the court may order the proponent to produce them in court.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1007. Testimony or Statement of a Party to Prove Content

The proponent may prove the content of a writing, recording, or photograph by the testimony, deposition, or written statement of the party against whom the evidence is offered. The proponent need not account for the original.

(As amended Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1008. Functions of the Court and Jury

Ordinarily, the court determines whether the proponent has fulfilled the factual conditions for admitting other evidence of the content of a writing, recording, or photograph under Rule 1004 or 1005. But in a jury trial, the jury determines—in accordance with Rule 104(b)—any issue about whether:

(a) an asserted writing, recording, or photograph ever existed;

(b) another one produced at the trial or hearing is the original; or

(c) other evidence of content accurately reflects the content.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

ARTICLE XI. MISCELLANEOUS RULES

Rule 1101. Applicability of the Rules

(a) TO COURTS AND JUDGES. These rules apply to proceedings before:

- United States district courts;
- United States bankruptcy and magistrate judges;
- United States courts of appeals;
- the United States Court of Federal Claims; and
- the district courts of Guam, the Virgin Islands, and the Northern Mariana Islands.

(b) TO CASES AND PROCEEDINGS. These rules apply in:

- civil cases and proceedings, including bankruptcy, admiralty, and maritime cases;
- criminal cases and proceedings; and
- contempt proceedings, except those in which the court may act summarily.

(c) RULES ON PRIVILEGE. The rules on privilege apply to all stages of a case or proceeding.

(d) EXCEPTIONS. These rules—except for those on privilege—do not apply to the following:

(1) the court's determination, under Rule 104(a), on a preliminary question of fact governing admissibility;

(2) grand-jury proceedings; and

(3) miscellaneous proceedings such as:

- extradition or rendition;
- issuing an arrest warrant, criminal summons, or search warrant;
- a preliminary examination in a criminal case;
- sentencing;
- granting or revoking probation or supervised release; and
- considering whether to release on bail or otherwise.

(e) OTHER STATUTES AND RULES. A federal statute or a rule prescribed by the Supreme Court may provide for admitting or excluding evidence independently from these rules.

(As amended Pub. L. 94–149, §1(14), Dec. 12, 1975, 89 Stat. 806; Pub. L. 95–598, title II, §§251, 252, Nov. 6, 1978, 92 Stat. 2673, eff. Oct. 1, 1979; Pub. L. 97–164, title I, §142, Apr. 2, 1982, 96 Stat. 45, eff. Oct. 1, 1982; Mar. 2, 1987, eff. Oct. 1, 1987; Apr. 25, 1988, eff. Nov. 1, 1988; Pub. L. 100–690, title VII, §7075(c), Nov. 18, 1988, 102 Stat. 4405; Apr. 22, 1993, eff. Dec. 1, 1993; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1102. Amendments

These rules may be amended as provided in 28 U.S.C. §2072.

(As amended Apr. 30, 1991, eff. Dec. 1, 1991; Apr. 26, 2011, eff. Dec. 1, 2011.)

Rule 1103. Title

These rules may be cited as the Federal Rules of Evidence.

(As amended Apr. 26, 2011, eff. Dec. 1, 2011.)

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USCS Fed Rules Evid R 702, Part 1 of 3

Current through changes received August 9, 2018.

Rule 702. Testimony by Expert Witnesses

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.

History

Jan. 2, 1975, P. L. 93-595, § 1, *88 Stat. 1937*; April 17, 2000, eff. Dec. 1, 2000; April 26, 2011, eff. Dec. 1, 2011.

Annotations

Notes

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Other provisions:

Notes of Advisory Committee on Rules. An intelligent evaluation of facts is often difficult or impossible without the application of some scientific, technical, or other specialized knowledge. The most common source of this knowledge is the expert witness, although there are other techniques for supplying it.

Most of the literature assumes that experts testify only in the form of opinions. The assumption is logically unfounded. The rule accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts. Since much of the criticism of expert testimony has centered upon the hypothetical question, it seems wise to recognize that opinions are not indispensable and to encourage the use of expert testimony in non-opinion form when counsel believes the trier can itself draw the requisite inference. The use of opinions is not abolished by the rule, however. It will continue to be permissible for the experts to take the further step of suggesting the inference which should be drawn from applying the specialized knowledge to the facts. See Rules 703 to 705.

Whether the situation is a proper one for the use of expert testimony is to be determined on the basis of assisting the trier. "There is no more certain test for determining when experts may be used than the common sense inquiry whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the

dispute." Ladd, Expert Testimony, 5 Vand.L.Rev. 414, 418 (1952). When opinions are excluded, it is because they are unhelpful and therefore superfluous and a waste of time. 7 Wigmore § 1918.

The rule is broadly phrased. The fields of knowledge which may be drawn upon are not limited merely to the "scientific" and "technical" but extend to all "specialized" knowledge. Similarly, the expert is viewed, not in a narrow sense, but as a person qualified by "knowledge, skill, experience, training or education." Thus within the scope of the rule are not only experts in the strictest sense of the word, e.g., physicians, physicists, and architects, but also the large group sometimes called "skilled" witnesses, such as bankers or landowners testifying to land values.

Committee notes on proposed revision. This revision is intended to limit the use, but increase the utility and reliability, of party-initiated opinion testimony bearing on scientific and technical issues.

The use of such testimony has greatly increased since enactment of the Federal Rules of Evidence. This result was intended by the drafters of the rule, who were responding to concerns that the restraints previously imposed on expert testimony were artificial and an impediment to the illumination of technical issues in dispute. See, e.g., McCormick on Evidence, § 203 (3d ed., 1984). While much expert testimony now presented is illuminating and useful, much is not. Virtually all is expensive, if not to the proponent then to adversaries. Particularly in civil litigation with high financial stakes, large expenditures for marginally useful expert testimony has become commonplace. Procurement of expert testimony is occasionally used as a trial technique to wear down adversaries. In short, while testimony from experts may be desirable if not crucial in many cases, excesses cannot be doubted and should be curtailed.

While concern for the quality and even integrity of hired testimony is not new, *Winans v. New York & Erie R.R., 62 U.S. 88, 101 (1858)*; Hand, Historical and Practical Considerations Regarding Expert Testimony, 15 Harv. L. Rev. 40 (1901), the hazards to the judicial process have increased as more technical evidence is presented:

When the evidence relates to highly technical matters and each side has shopped for experts favorable to its position, it is naive to expect the jury to be capable of assessing the validity of dramatically opposed testimony.

3J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE, § 706[01] at 706–07 (1985).

While the admissibility of such evidence is, and remains, subject to the general principles of Rule 403, the revision requires that expert testimony be "reasonably reliable" and "substantially assist" the fact-finder. The rule does not mandate a return to the strictures of *Frye v. United States, 293 F.2d 1013* (D.C. Cir., 1923) (requiring general acceptance of the scientific premises on which the testimony is based). However, the court is called upon to reject testimony that is based upon premises lacking any significant support and acceptance within the scientific community, or that otherwise would be only marginally helpful to the fact-finder. In civil cases the court is authorized and expected under revised *Rule 26(c)(4) of the Federal Rules of Civil Procedure* to impose in advance of trial appropriate restrictions on the use of expert testimony. In exercising this responsibility, the court should not only consider the potential admissibility of the testimony under Rule 702 but also weigh the need and utility of the testimony against the time and expense involved.

In deciding whether the opinion evidence is reasonably reliable and will substantially assist the trier of fact, as well as in deciding whether the proposed witness has sufficient expertise to express such opinions, the court, as under present Rule 702, is governed by Rule 104(a).

The rule is also revised to complement changes in the Federal Rules of Civil Procedure requiring pretrial disclosure of the expert testimony to be presented at trial. The rule precludes the offering on direct examination in civil actions of expert opinions, or the reasons or bases for opinions, that have not been adequately and timely disclosed in advance of trial. It has not been unusual for the testimony given at trial by an expert to vary substantially from that provided under former *Fed. R. Civ. P. 26(b)(4)(A)(i)* or at a deposition of the expert. At a minimum, any significant changes in an expert's expected testimony should be disclosed before trial, and this revision of Rule 702 provides an appropriate incentive for such disclosure in addition to those contained in the Rules of Civil Procedure.

Additions or other changes to an expert's opinions must, under *Fed. R. Civ. P. 26(e)(1)*, be disclosed no later than the time the proponent is required to disclose its witnesses and exhibits that are to be used at trial. Unless the court has specified another time, these revisions must be disclosed at least 30 days before trial.

Of course, a witness should not be required to testify contrary to the person's oath or affirmation. If the witness is unable, consistent with the oath or affirmation, to testify in a manner consistent with the earlier disclosure, then—unless the court grants leave to deviate from the earlier testimony—the witness should not testify.

By its terms the new sentence applies only in civil cases. The consequences of the failure to make disclosures of expert testimony which may be required under new *Fed. R. Crim. P. 16(a)(1)(E)* and *16(b)(1)(C)* will be determined in accordance with the principles that govern enforcement of the requirements of *Fed. R. Crim. P. 16*.

Notes of Advisory Committee on 2000 amendments. Rule 702 has been amended in response to *Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 [125 L. Ed. 2d 469] (1993)*, and to the many cases applying *Daubert*, including *Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167 (1999)*. In *Daubert* the Court charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony, and the Court in *Kumho* clarified that this gatekeeper function applies to all expert testimony, not just testimony based in science. *See also Kumho, 119 S.Ct. at 1178* (citing the Committee Note to the proposed amendment to Rule 702, which had been released for public comment before the date of the *Kumho* decision). The amendment affirms the trial court's role as gatekeeper and provides some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony. Consistently with Kumho, the Rule as amended provides that all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful. Consequently, the admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence. *See Bourjaily v. United States, 483 U.S. 171 [97 L. Ed. 2d 144]* (1987).

Daubert set forth a non-exclusive checklist for trial courts to use in assessing the reliability of scientific expert testimony. The specific factors explicated by the *Daubert* Court are (1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community. The Court in *Kumho* held that these factors might also be applicable in assessing the reliability of non-scientific expert testimony, depending upon "the particular circumstances of the particular case at issue." *119 S.Ct. at 1175*.

No attempt has been made to "codify" these specific factors. Daubert itself emphasized that the factors were neither exclusive nor dispositive. Other cases have recognized that not all of the specific Daubert factors can apply to every type of expert testimony. In addition to *Kumho, 119 S.Ct. at 1175*, *see Tyus v. Urban Search Management, 102 F.3d 256* (7th Cir. 1996) (noting that the factors mentioned by the Court in *Daubert* do not neatly apply to expert testimony from a sociologist). *See also Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 809* (3d Cir. 1997) (holding that lack of peer review or publication was not dispositive where the expert's opinion was supported by "widely accepted scientific knowledge"). The standards set forth in the amendment are broad enough to require consideration of any or all of the specific Daubert factors where appropriate.

Courts both before and after *Daubert* have found other factors relevant in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact. These factors include:

(1) Whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317* (9th Cir. 1995).

(2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion. *See General Elec. Co. v. Joiner, 522 U.S. 136 [139 L. Ed. 2d 508], 146 (1997)* (noting that in some cases a trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

(3) Whether the expert has adequately accounted for obvious alternative explanations. *See Claar v. Burlington N.R.R., 29 F.3d 499* (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiffs condition). *Compare Ambrosini v. Labarraque, 101 F.3d 129* (D.C.Cir. 1996) (the possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert).

(4) Whether the expert "is being as careful as he would be in his regular professional work outside his paid litigation consulting." *Sheehan v. Daily Racing Form, Inc., 104 F.3d 940, 942* (7th Cir. 1997). *See Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1176 (1999)* (*Daubert* requires the trial court to assure itself that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

(5) Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give. *See Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1175 (1999)* (Daubert's general acceptance factor does not "help show that an expert's testimony is reliable where the discipline itself lacks reliability, as, for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy."); *Moore v. Ashland Chemical, Inc., 151 F.3d 269* (5th Cir. 1998) (en banc) (clinical doctor was properly precluded from testifying to the toxicological cause of the plaintiffs respiratory problem, where the opinion was not sufficiently grounded in scientific methodology); *Sterling v. Velsicol Chem. Corp., 855 F.2d 1188* (6th Cir. 1988) (rejecting testimony based on "clinical ecology" as unfounded and unreliable).

All of these factors remain relevant to the determination of the reliability of expert testimony under the Rule as amended. Other factors may also be relevant. *See Kumho, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1176* ("[W]e conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). Yet no single factor is necessarily dispositive of the reliability of a particular expert's testimony. *See, e.g., Heller v. Shaw Industries, Inc., 167 F.3d 146, 155* (3d Cir. 1999) ("not only must each stage of the expert's testimony be reliable, but each stage must be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules."); *Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317*, n.5 (9th Cir. 1995) (noting that some expert disciplines "have the courtroom as a principal theatre of operations" and as to these disciplines "the fact that the expert has developed an expertise principally for purposes of litigation will obviously not be a substantial consideration.").

A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule. *Daubert* did not work a "seachange over federal evidence law," and "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. 14.38 Acres of Land Situated in Leflore County, Mississippi, 80 F.3d 1074, 1078* (5th Cir. 1996). As the Court in Daubert stated: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *509 U.S. at 595*. Likewise, this amendment is not intended to provide an excuse for an automatic challenge to the testimony of every expert. *See Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1176 (1999)* (noting that the trial judge has the discretion "both to avoid unnecessary 'reliability' proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises.").

When a trial court, applying this amendment, rules that an expert's testimony is reliable, this does not necessarily mean that contradictory expert testimony is unreliable. The amendment is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise. *See, e.g., Heller v. Shaw Industries, Inc., 167 F.3d 146, 160* (3d Cir. 1999) (expert testimony cannot be excluded simply because the expert uses one test rather than another, when both tests are accepted in the field and both reach reliable results). As the court stated in *In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 744* (3d Cir. 1994), proponents "do not have to

demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable. . . . The evidentiary requirement of reliability is lower than the merits standard of correctness." *See also* Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1318 (9th Cir. 1995) (scientific experts might be permitted to testify if they could show that the methods they used were also employed by "a recognized minority of scientists in their field."); Ruiz-Troche v. Pepsi Cola, 161 F.3d 77, 85 (1st Cir. 1998) ("*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.").

The Court in *Daubert* declared that the "focus, of course, must be solely on principles and methodology, not on the conclusions they generate." 509 U.S. at 595. Yet as the Court later recognized, "conclusions and methodology are not entirely distinct from one another." General Elec. Co. v. Joiner, 522 U.S. 136 [139 L. Ed. 2d 508], 146 (1997). Under the amendment, as under *Daubert,* when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied. *See* Lust v. Merrell Dow Pharmaceuticals, Inc., 89 F.3d 594, 598 (9th Cir. 1996). The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case. As the court noted in In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994), "any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology."*

If the expert purports to apply principles and methods to the facts of the case, it is important that this application be conducted reliably. Yet it might also be important in some cases for an expert to educate the factfinder about general principles, without ever attempting to apply these principles to the specific facts of the case. For example, experts might instruct the factfinder on the principles of thermodynamics, or bloodclotting, or on how financial markets respond to corporate reports, without ever knowing about or trying to tie their testimony into the facts of the case. The amendment does not alter the venerable practice of using expert testimony to educate the factfinder on general principles. For this kind of generalized testimony, Rule 702 simply requires that: (1) the expert be qualified; (2) the testimony address a subject matter on which the factfinder can be assisted by an expert; (3) the testimony be reliable; and (4) the testimony "fit" the facts of the case.

As stated earlier, the amendment does not distinguish between scientific and other forms of expert testimony. The trial court's gatekeeping function applies to testimony by any expert. *See* Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1171 (1999) ("We conclude that Daubert's general holding—setting forth the trial judge's general 'gatekeeping' obligation—applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge."). While the relevant factors for determining reliability will vary from expertise to expertise, the amendment rejects the premise that an expert's testimony should be treated more permissively simply because it is outside the realm of science. An opinion from an expert who is not a scientist should receive the same degree of scrutiny for reliability as an opinion from an expert who purports to be a scientist. *See* Watkins v. Telsmith, Inc., 121 F.3d 984, 991 (5th Cir. 1997) ("[I]t seems exactly backwards that experts who purport to rely on general engineering principles and practical experience might escape screening by the district court simply by stating that their conclusions were not reached by any particular method or technique."). Some types of expert testimony will be more objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication, than others. Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise. The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted. The expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded. See, e.g., American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Testimony after* Daubert, 157 F.R.D. 571, 579 (1994) ("[W]hether the testimony concerns economic principles, accounting standards, property valuation or other non-scientific subjects, it should be evaluated by reference to the 'knowledge and experience' of that particular field.").

The amendment requires that the testimony must be the product of reliable principles and methods that are reliably applied to the facts of the case. While the terms "principles" and "methods" may convey a certain impression when applied to scientific knowledge, they remain relevant when applied to testimony based on technical or other specialized knowledge. For example, when a law enforcement agent testifies regarding the use of code words in a drug transaction, the principle used by the agent is that participants in such transactions regularly use code words to conceal the nature of their activities. The method used by the agent is the application of extensive experience to analyze the meaning of the conversations. So long as the principles and methods are reliable and applied reliably to the facts of the case, this type of testimony should be admitted.

Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony. *See, e.g., United States v. Jones, 107 F.3d 1147* (6th Cir. 1997) (no abuse of discretion in admitting the testimony of a handwriting examiner who had years of practical experience and extensive training, and who explained his methodology in detail); *Tassin v. Sears Roebuck, 946 F.Supp. 1241, 1248 (M.D.La. 1996)* (design engineer's testimony can be admissible when the expert's opinions "are based on facts, a reasonable investigation, and traditional technical/mechanical expertise, and he provides a reasonable link between the information and procedures he uses and the conclusions he reaches"). See also *Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1178 (1999)* (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it." *See Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1319* (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable. *See O'Conner v. Commonwealth Edison Co., 13 F.3d 1090* (7th Cir. 1994) (expert testimony based on a completely subjective methodology held properly excluded). *See also Kumho Tire Co. v. Carmichael, [143 L. Ed. 2d 238,] 119 S.Ct. 1167, 1176 (1999)* ("[I] will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable.").

Subpart (1) of Rule 702 calls for a quantitative rather than qualitative analysis. The amendment requires that expert testimony be based on sufficient underlying "facts or data." The term "data" is intended to encompass the reliable opinions of other experts. See the original Advisory Committee Note to Rule 703. The language "facts or data" is broad enough to allow an expert to rely on hypothetical facts that are supported by the evidence. *Id.*

When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on "sufficient facts or data" is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.

There has been some confusion over the relationship between Rules 702 and 703. The amendment makes clear that the sufficiency of the basis of an expert's testimony is to be decided under Rule 702. Rule 702 sets forth the overarching requirement of reliability, and an analysis of the sufficiency of the expert's basis cannot be divorced from the ultimate reliability of the expert's opinion. In contrast, the "reasonable reliance" requirement of Rule 703 is a relatively narrow inquiry. When an expert relies on inadmissible information, Rule 703 requires the trial court to determine whether that information is of a type reasonably relied on by other experts in the field. If so, the expert can rely on the information in reaching an opinion. However, the question whether the expert is relying on a sufficient basis of information—whether admissible information or not—is governed by the requirements of Rule 702.

The amendment makes no attempt to set forth procedural requirements for exercising the trial court's gatekeeping function over expert testimony. *See* Daniel J. Capra, *The Daubert Puzzle*, *38 Ga.L.Rev. 699, 766 (1998)* ("Trial courts should be allowed substantial discretion in dealing with Daubert questions; any attempt to codify procedures will likely give rise to unnecessary changes in practice and create difficult questions for appellate review."). Courts have shown considerable ingenuity and flexibility in considering challenges to expert testimony under Daubert, and it is contemplated that this will continue under the amended Rule. *See, e.g., Cortes-Irizarry v. Corporacion Insular, 111 F.3d 184* (1st Cir. 1997) (discussing the application of Daubert in ruling on a motion for summary judgment); *In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 736, 739* (3d Cir. 1994) (discussing the use of in limine hearings); *Claar v. Burlington N.R.R., 29 F.3d 499, 502-05* (9th Cir. 1994) (discussing the trial court's technique of ordering experts to submit serial affidavits explaining the reasoning and methods underlying their conclusions).

The amendment continues the practice of the original Rule in referring to a qualified witness as an "expert." This was done to provide continuity and to minimize change. The use of the term "expert" in the Rule does not, however, mean that a jury should actually be informed that a qualified witness is testifying as an "expert." Indeed, there is much to be said for a practice that prohibits the use of the term "expert" by both the parties and the court at trial. Such a practice "ensures that trial courts do not inadvertently put their stamp of authority" on a witness's opinion, and protects against the jury's being "overwhelmed by the so-called 'experts'." *Hon. Charles Richey, Proposals to Eliminate the Prejudicial Effect of the Use of the Word "Expert" Under the Federal Rules of Evidence in Criminal and Civil Jury Trials, 154 F.R.D. 537, 559 (1994)* (setting forth limiting instructions and a standing order employed to prohibit the use of the term "expert" in jury trials).

Notes of Advisory Committee on 2011 amendments. The language of Rule 702 has been amended as part of the restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to be stylistic only. There is no intent to change any result in any ruling on evidence admissibility.

INTERPRETIVE NOTES AND DECISIONS

I.IN GENERAL

1.Generally

2.Relationship to other rules and laws

3.—*FRE 403*—Excludable evidence

4.—*FRE 701*—Lay opinions

5.Discretion of court, generally

6.Factors in determining admissibility, generally

7.Reliability and relevancy of testimony, generally

8.Helpfulness to trier of fact

9.Weight vs. admissibility of testimony

10.—Particular cases

11.Opinion of expert

12.Legal conclusions or opinions

Supreme Court of the United States
William DAUBERT, et ux., etc., et al., Petitioners,
v.
MERRELL DOW PHARMACEUTICALS, INC.

No. 92–102.
Argued March 30, 1993
Decided June 28, 1993.

Infants and their guardians ad litem sued pharmaceutical company to recover for limb reduction birth defects allegedly sustained as result of mothers' ingestion of antinausea drug Bendectin. The United States District Court for the Southern District of California, 727 F.Supp. 570, granted company's motion for summary judgment, and plaintiffs appealed. The Court of Appeals, 951 F.2d 1128, affirmed. Plaintiffs filed petition for writ of certiorari, which was granted. The Supreme Court, Justice Blackmun, held that: (1) "general acceptance" is not necessary precondition to admissibility of scientific evidence under Federal Rules of Evidence, and (2) Rules assign to trial judge the task of ensuring that expert's testimony both rests on reliable foundation and is relevant to task at hand.

Vacated and remanded.

Chief Justice Rehnquist filed opinion concurring in part and dissenting in part in which Justice Stevens joined.

West Headnotes

[1] Evidence 157 150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Federal Rules of Evidence superseded *Frye* "general acceptance" test for admissibility of scientific evidence. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[2] Federal Civil Procedure 170A 21

170A Federal Civil Procedure
170AI In General
170AI(B) Rules of Court in General
170AI(B)1 In General
170Ak21 k. In general. Most Cited Cases

Supreme Court interprets legislatively enacted Federal Rules of Evidence as it would any statute.

[3] Evidence 157 99

157 Evidence
157IV Admissibility in General
157IV(A) Facts in Issue and Relevant to Issues
157k99 k. Relevancy in general. Most Cited Cases

Basic standard of relevance under Federal Rules of Evidence is liberal one. Fed.Rules Evid.Rules 401, 402, 28 U.S.C.A.

[4] Evidence 157 150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Rigid "general acceptance" requirement for admission of scientific evidence would be at odds with "liberal thrust" of Federal Rules of Evidence and their general approach of relaxing traditional barriers to "opinion" testimony. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[5] Evidence 157 150

157 Evidence
157IV Admissibility in General

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157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Trial judge is not disabled under Federal Rules of Evidence from screening purportedly scientific evidence. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[6] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Under Federal Rules of Evidence, trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[7] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

"Scientific," within meaning of Federal Rule of Evidence stating that if "scientific," technical, or other specialized knowledge will assist trier of fact to understand evidence or to determine fact in issue an expert may testify thereto, implies grounding in methods and procedures of science. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[8] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

"Knowledge," within meaning of Federal Rule of Evidence stating that if scientific, technical, or other specialized "knowledge" will assist trier of fact to understand evidence or to determine fact in issue an expert may testify thereto, connotes more than subjective belief or unsupported speculation. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[9] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Subject of scientific knowledge need not be "known" to certainty to permit expert testimony, since, arguably, there are not certainties in science. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[10] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Inference or assertion must be derived by scientific method to qualify as "scientific knowledge," within meaning of Federal Rule of Evidence stating that if scientific, technical, or other specialized knowledge will assist trier of fact to understand evidence or to determine fact in issue an expert may testify thereto. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[11] Evidence 157 ⚿555.1

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.1 k. In general. Most Cited Cases

For scientific testimony to be admitted, proposed testimony must be supported by appropriate validation, in other words, "good grounds" based on what is known. Fed.Rules

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Evid.Rule 702, 28 U.S.C.A.

[12] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Requirement under Federal Rule of Evidence that expert's testimony pertain to "scientific knowledge" establishes standard of evidentiary reliability. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[13] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

In case involving scientific evidence, evidentiary reliability will be based upon scientific reliability. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[14] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Condition for admission of scientific evidence or testimony under Federal Rule of Evidence, that evidence or testimony assist trier of fact to understand evidence or to determine fact in issue, goes primarily to relevance. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[15] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

In determining admissibility of scientific evidence or testimony, scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[16] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

"Helpfulness" standard under Federal Rule of Evidence for admissibility of scientific evidence or testimony requires valid scientific connection to pertinent inquiry as precondition to admissibility. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[17] Evidence 157 ⚿505

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k505 k. Matters of opinion or facts. Most Cited Cases

Unlike ordinary witness, expert is permitted wide latitude to offer opinions, including those that are not based on first-hand knowledge or observation. Fed.Rules Evid.Rules 701 – 703, 28 U.S.C.A.

[18] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Presumably, relaxation under Federal Rules of Evidence of usual requirement of first-hand knowledge when there is testimony by expert is premised on assumption that expert's opinion will have reliable basis in knowledge and experience of his discipline. Fed.Rules Evid.Rules 701 – 703, 28

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[19] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Faced with proffer of expert scientific testimony, trial judge must determine at outset whether expert is proposing to testify to (1) scientific knowledge that (2) will assist trier of fact to understand or determine fact in issue; preliminary assessment must be made of whether reasoning or methodology underlying testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to facts in issue. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[20] Evidence 157 ⚿546

157 Evidence
157XII Opinion Evidence
157XII(C) Competency of Experts
157k546 k. Determination of question of competency. Most Cited Cases

Preliminary questions concerning qualification of person to be witness, existence of privilege, or admissibility of evidence should be established by preponderance of proof. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[21] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Requirements for admissibility of scientific testimony or opinion under Federal Rule of Evidence do not apply specially or exclusively to unconventional evidence. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[22] Evidence 157 ⚿9

157 Evidence
157I Judicial Notice
157k9 k. Scientific facts and principles. Most Cited Cases

Scientific theories that are so firmly established as to have obtained status of scientific law, such as laws of thermodynamics, properly are subject to judicial notice. Fed.Rules Evid.Rule 201, 28 U.S.C.A.

[23] Evidence 157 ⚿555.1

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.1 k. In general. Most Cited Cases

Definitive checklist or test does not exist in making preliminary assessment of whether reasoning or methodology underlying expert testimony is scientifically valid and whether that reasoning or methodology properly can be applied to facts in issue. Fed.Rules Evid.Rule 104(a), 28 U.S.C.A.

[24] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Ordinarily, key question to be answered in determining whether theory or technique is scientific knowledge that will assist trier of fact, and, thus, whether expert testimony is admissible, will be whether theory or technique can be, and has been, tested. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[25] Evidence 157 ⚿508

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157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

In determining whether theory or technique is scientific knowledge that will assist trier of fact, and, thus, whether expert testimony is admissible, is whether theory or technique has been subjected to peer review and publication. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[26] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Publication of theory or technique, which is but one element of peer review, is not sine qua non of admissibility of expert testimony; publication does not necessarily correlate with reliability, and, in some instances, well-grounded but innovative theories will not have been published. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[27] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Fact of publication of theory or technique, or lack thereof, in peer-review journal will be relevant, though not dispositive, consideration in assessing scientific validity of particular technique or methodology on which expert opinion is premised; submission to scrutiny of scientific community is component of “good science,” in part because it increases likelihood that substantive flaws in methodology will be detected. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[28] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

In determining admissibility of expert opinion regarding particular scientific technique, court ordinarily should consider known or potential rate of error, and existence and maintenance of standards controlling technique's operation. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[29] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

“General acceptance” of scientific theory or technique can have bearing in determining admissibility of expert testimony. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[30] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Widespread acceptance of scientific theory or technique can be important factor in ruling particular evidence admissible, and known technique that has been able to draw only minimal support within community may properly be viewed with skepticism. Fed.Rules Evid.Rules 104(a), 702, 28 U.S.C.A.

[31] Evidence 157 ⚿150

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157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Inquiry envisioned by Federal Rule of Evidence pertaining to admission of scientific testimony and evidence is flexible one. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[32] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Overarching subject of Federal Rule of Evidence on admission of scientific testimony and evidence is scientific validity, and, thus, evidentiary relevance and reliability, of principles that underlie proposed submission. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[33] Evidence 157 ⚿150

157 Evidence
157IV Admissibility in General
157IV(E) Competency
157k150 k. Results of experiments. Most Cited Cases

Focus of Federal Rule of Evidence on admission of scientific testimony and evidence must be solely on principles and methodology, not on conclusions that they generate. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[34] Evidence 157 ⚿546

157 Evidence
157XII Opinion Evidence
157XII(C) Competency of Experts
157k546 k. Determination of question of competency. Most Cited Cases

Judge assessing proffer of expert's scientific testimony under Federal Rule of Evidence on testimony by experts should also be mindful of other applicable rules, including rule on expert opinions based on otherwise inadmissible hearsay, rule allowing court to procure assistance of expert of its own choosing, and rule permitting exclusion of relevant evidence if its probative value is substantially outweighed by danger of unfair prejudice, confusion of issues, or misleading jury. Fed.Rules Evid.Rules 403, 702, 703, 706, 28 U.S.C.A.

[35] Federal Civil Procedure 170A ⚿2146

170A Federal Civil Procedure
170AXV Trial
170AXV(F) Taking Case or Question from Jury; Preverdict Motion for Judgment as Matter of Law
170AXV(F)2 Questions for Jury
170Ak2142 Weight and Sufficiency of Evidence
170Ak2146 k. Scintilla of evidence. Most Cited Cases

Federal Civil Procedure 170A ⚿2546

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(C) Summary Judgment
170AXVII(C)3 Proceedings
170Ak2542 Evidence
170Ak2546 k. Weight and sufficiency. Most Cited Cases

In event that trial court concludes that scintilla of scientific evidence presented supporting a position is insufficient to allow reasonable juror to conclude that position more likely than not is true, court remains free to direct verdict, and likewise to grant summary judgment. Fed.Rules Civ.Proc.Rules 50(a), 56, 28 U.S.C.A.; Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[36] Federal Civil Procedure 170A ⚿21

170A Federal Civil Procedure
170AI In General

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170AI(B) Rules of Court in General
170AI(B)1 In General
170Ak21 k. In general. Most Cited Cases

Federal Rules of Evidence are designed not for exhaustive search for cosmic understanding but for particularized resolution of legal disputes.

****2789** *Syllabus* FN*

FN* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Lumber Co.*, 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

***579** Petitioners, two minor children and their parents, alleged in their suit against respondent that the children's serious birth defects had been caused by the mothers' prenatal ingestion of Bendectin, a prescription drug marketed by respondent. The District Court granted respondent summary judgment based on a well-credentialed expert's affidavit concluding, upon reviewing the extensive published scientific literature on the subject, that maternal use of Bendectin has not been shown to be a risk factor for human birth defects. Although petitioners had responded with the testimony of eight other well-credentialed experts, who based their conclusion ****2790** that Bendectin can cause birth defects on animal studies, chemical structure analyses, and the unpublished "reanalysis" of previously published human statistical studies, the court determined that this evidence did not meet the applicable "general acceptance" standard for the admission of expert testimony. The Court of Appeals agreed and affirmed, citing *Frye v. United States*, 54 App.D.C. 46, 47, 293 F. 1013, 1014, for the rule that expert opinion based on a scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community.

Held: The Federal Rules of Evidence, not *Frye*, provide the standard for admitting expert scientific testimony in a federal trial. Pp. 2792–99.

(a) *Frye's* "general acceptance" test was superseded by the Rules' adoption. The Rules occupy the field, *United States v. Abel*, 469 U.S. 45, 49, 105 S.Ct. 465, 467, 83 L.Ed.2d 450, and, although the common law of evidence may serve as an aid to their application, *id.*, at 51–52, 105 S.Ct., at 468–469, respondent's assertion that they somehow assimilated *Frye* is unconvincing. Nothing in the Rules as a whole or in the text and drafting history of Rule 702, which specifically governs expert testimony, gives any indication that "general acceptance" is a necessary precondition to the admissibility of scientific evidence. Moreover, such a rigid standard would be at odds with the Rules' liberal thrust and their general approach of relaxing the traditional barriers to "opinion" testimony. Pp. 2792–94.

(b) The Rules—especially Rule 702 —place appropriate limits on the admissibility of purportedly scientific evidence by assigning to the trial 580***580** judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. The reliability standard is established by Rule 702's requirement that an expert's testimony pertain to "scientific ... knowledge," since the adjective "scientific" implies a grounding in science's methods and procedures, while the word " knowledge" connotes a body of known facts or of ideas inferred from such facts or accepted as true on good grounds. The Rule's requirement that the testimony "assist the trier of fact to understand the evidence or to determine a fact in issue" goes primarily to relevance by demanding a valid scientific connection to the pertinent inquiry as a precondition to admissibility. Pp. 2794–96.

(c) Faced with a proffer of expert scientific testimony under Rule 702, the trial judge, pursuant to Rule 104(a), must make a preliminary assessment of whether the testimony's underlying reasoning or methodology is scientifically valid and properly can be applied to the facts at issue. Many

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considerations will bear on the inquiry, including whether the theory or technique in question can be (and has been) tested, whether it has been subjected to peer review and publication, its known or potential error rate and the existence and maintenance of standards controlling its operation, and whether it has attracted widespread acceptance within a relevant scientific community. The inquiry is a flexible one, and its focus must be solely on principles and methodology, not on the conclusions that they generate. Throughout, the judge should also be mindful of other applicable Rules. Pp. 2796–98.

(d) Cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof, rather than wholesale exclusion under an uncompromising "general acceptance" standard, is the appropriate means by which evidence based on valid principles may be challenged. That even limited screening by the trial judge, on occasion, will prevent the jury from hearing of authentic scientific breakthroughs is simply a consequence of the fact that the Rules are not designed to seek cosmic understanding but, rather, to resolve legal disputes. Pp. 2798–99.

951 F.2d 1128 (CA9 1991), vacated and remanded.

****2791** BLACKMUN, J., delivered the opinion for a unanimous Court with respect to Parts I and II–A, and the opinion of the Court with respect to Parts II–B, II–C, III, and IV, in which WHITE, O'CONNOR, SCALIA, KENNEDY, SOUTER, and THOMAS, JJ., joined. REHNQUIST, C.J., filed an opinion concurring in part and dissenting in part, in which STEVENS, J., joined, *post*, p. ——.
***581** Michael H. Gottesman, Washington, DC, for petitioners.

Charles Fried, Cambridge, MA, for respondent.

582***582** Justice BLACKMUN delivered the opinion of the Court.

In this case we are called upon to determine the standard for admitting expert scientific testimony in a federal trial.

I

Petitioners Jason Daubert and Eric Schuller are minor children born with serious birth defects. They and their parents sued respondent in California state court, alleging that the birth defects had been caused by the mothers' ingestion of Bendectin, a prescription antinausea drug marketed by respondent. Respondent removed the suits to federal court on diversity grounds.

After extensive discovery, respondent moved for summary judgment, contending that Bendectin does not cause birth defects in humans and that petitioners would be unable to come forward with any admissible evidence that it does. In support of its motion, respondent submitted an affidavit of Steven H. Lamm, physician and epidemiologist, who is a well-credentialed expert on the risks from exposure to various chemical substances.[FN1] Doctor Lamm stated that he had reviewed all the literature on Bendectin and human birth defects —more than 30 published studies involving over 130,000 patients. No study had found Bendectin to be a human teratogen (*i.e.*, a substance capable of causing malformations in fetuses). On the basis of this review, Doctor Lamm concluded that maternal use of Bendectin during the first trimester of pregnancy has not been shown to be a risk factor for human birth defects.

FN1. Doctor Lamm received his master's and doctor of medicine degrees from the University of Southern California. He has served as a consultant in birth-defect epidemiology for the National Center for Health Statistics and has published numerous articles on the magnitude of risk from exposure to various chemical and biological substances. App. 34–44.

583***583** Petitioners did not (and do not) contest this characterization of the published record

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regarding Bendectin. Instead, they responded to respondent's motion with the testimony of eight experts of their own, each of whom also possessed impressive credentials.[FN2] These experts had concluded that Bendectin can cause birth defects. Their conclusions were based upon "in vitro" (test tube) and "in vivo" (live) animal studies that found a link between Bendectin and malformations; pharmacological studies of the chemical structure of Bendectin that purported to show similarities between the structure of the drug and that of other substances known to cause birth defects; and the "reanalysis" of previously ****2792** published epidemiological (human statistical) studies.

> FN2. For example, Shanna Helen Swan, who received a master's degree in biostatistics from Columbia University and a doctorate in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Services that determines causes of birth defects and has served as a consultant to the World Health Organization, the Food and Drug Administration, and the National Institutes of Health. *Id.*, at 113–114, 131–132. Stuart A. Newman, who received his bachelor's degree in chemistry from Columbia University and his master's and doctorate in chemistry from the University of Chicago, is a professor at New York Medical College and has spent over a decade studying the effect of chemicals on limb development. *Id.*, at 54–56. The credentials of the others are similarly impressive. See *Id.*, at 61–66, 73–80, 148–153, 187–192, and Attachments 12, 20, 21, 26, 31, and 32 to Petitioners' Opposition to Summary Judgment in No. 84–2013–G(I) (SD Cal.).

The District Court granted respondent's motion for summary judgment. The court stated that scientific evidence is admissible only if the principle upon which it is based is " 'sufficiently established to have general acceptance in the field to which it belongs.' " 727 F.Supp. 570, 572 (S.D.Cal.1989), quoting *United States v. Kilgus*, 571 F.2d 508, 510 (CA9 1978). The court concluded that petitioners' evidence did not meet this standard. Given the vast body of epidemiological data concerning Bendectin, the court held, expert opinion which is not based on epidemiological evidence 584***584** is not admissible to establish causation. 727 F.Supp., at 575. Thus, the animal-cell studies, live-animal studies, and chemical-structure analyses on which petitioners had relied could not raise by themselves a reasonably disputable jury issue regarding causation. *Ibid.* Petitioners' epidemiological analyses, based as they were on recalculations of data in previously published studies that had found no causal link between the drug and birth defects, were ruled to be inadmissible because they had not been published or subjected to peer review. *Ibid.*

The United States Court of Appeals for the Ninth Circuit affirmed. 951 F.2d 1128 (1991). Citing *Frye v. United States*, 54 App.D.C. 46, 47, 293 F. 1013, 1014 (1923), the court stated that expert opinion based on a scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community. 951 F.2d, at 1129–1130. The court declared that expert opinion based on a methodology that diverges "significantly from the procedures accepted by recognized authorities in the field ... cannot be shown to be 'generally accepted as a reliable technique.' " *Id.*, at 1130, quoting *United States v. Solomon*, 753 F.2d 1522, 1526 (CA9 1985).

The court emphasized that other Courts of Appeals considering the risks of Bendectin had refused to admit reanalyses of epidemiological studies that had been neither published nor subjected to peer review. 951 F.2d, at 1130–1131. Those courts had found unpublished reanalyses "particularly problematic in light of the massive

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weight of the original published studies supporting [respondent's] position, all of which had undergone full scrutiny from the scientific community." *Id.*, at 1130. Contending that reanalysis is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field, the Court of Appeals rejected petitioners' reanalyses as "unpublished, not subjected to the normal peer review process and generated solely for use in litigation." *Id.*, at 1131. The 585***585** court concluded that petitioners' evidence provided an insufficient foundation to allow admission of expert testimony that Bendectin caused their injuries and, accordingly, that petitioners could not satisfy their burden of proving causation at trial.

We granted certiorari, 506 U.S. 914, 113 S.Ct. 320, 121 L.Ed.2d 240 (1992), in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony. Compare, *e.g.*, *United States v. Shorter*, 257 U.S.App.D.C. 358, 363–364, 809 F.2d 54, 59–60 (applying the "general acceptance" standard), cert. denied, 484 U.S. 817, 108 S.Ct. 71, 98 L.Ed.2d 35 (1987), with *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (CA3 1990) (rejecting the "general acceptance" standard).

II

A

In the 70 years since its formulation in the *Frye* case, the "general acceptance" test has been the dominant standard for determining the admissibility of novel scientific evidence at trial. See E. Green & C. Nesson, Problems, Cases, and Materials on Evidence 649 (1983). Although under increasing attack of late, the rule continues to be followed by a ****2793** majority of courts, including the Ninth Circuit.[FN3]

FN3. For a catalog of the many cases on either side of this controversy, see P. Giannelli & E. Imwinkelried, Scientific Evidence § 1–5, pp. 10–14 (1986 and Supp.1991).

The *Frye* test has its origin in a short and citation-free 1923 decision concerning the admissibility of evidence derived from a systolic blood pressure deception test, a crude precursor to the polygraph machine. In what has become a famous (perhaps infamous) passage, the then Court of Appeals for the District of Columbia described the device and its operation and declared:

> "Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages 586***586** is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.*" 54 App.D.C., at 47, 293 F., at 1014 (emphasis added).

Because the deception test had "not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made," evidence of its results was ruled inadmissible. *Ibid.*

[1] The merits of the *Frye* test have been much debated, and scholarship on its proper scope and application is legion.[FN4] 587***587** Petitioners' primary attack, however, is not on the content but on the continuing authority of the rule. They contend that the *Frye* test was superseded by the adoption of the Federal Rules of Evidence.[FN5] We agree.

FN4. See, *e.g.*, Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of *Agent Orange* and Bendectin Litigation, 86 Nw.U.L.Rev. 643 (1992) (hereinafter Green); Becker & Orenstein, The Federal

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Rules of Evidence After Sixteen Years—the Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules, 60 Geo.Wash.L.Rev. 857, 876–885 (1992); Hanson, James Alphonzo Frye is Sixty–Five Years Old; Should He Retire?," 16 West.St.U.L.Rev. 357 (1989); Black, A Unified Theory of Scientific Evidence, 56 Ford.L.Rev. 595 (1988); Imwinkelried, The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony, 67 N.C.L.Rev. 1 (1988); Proposals for a Model Rule on the Admissibility of Scientific Evidence, 26 Jurimetrics J. 235 (1986); Giannelli, The Admissibility of Novel Scientific Evidence: *Frye v. United States*, a Half–Century Later, 80 Colum.L.Rev. 1197 (1980); The Supreme Court, 1986 Term, 101 Harv.L.Rev. 7, 119, 125–127 (1987).

> Indeed, the debates over *Frye* are such a well-established part of the academic landscape that a distinct term—" *Frye* –ologist"—has been advanced to describe those who take part. See Behringer, Introduction, Proposals for a Model Rule on the Admissibility of Scientific Evidence, 26 Jurimetrics J. 237, 239 (1986), quoting Lacey, Scientific Evidence, 24 Jurimetrics J. 254, 264 (1984).

FN5. Like the question of *Frye'* s merit, the dispute over its survival has divided courts and commentators. Compare, *e.g.*, *United States v. Williams*, 583 F.2d 1194 (CA2 1978) (*Frye* is superseded by the Rules of Evidence), cert. denied, 439 U.S. 1117, 99 S.Ct. 1025, 59 L.Ed.2d 77 (1979) with *Christophersen v. Allied–Signal Corp.*, 939 F.2d 1106, 1111, 1115–1116 (CA5 1991) (en banc) (*Frye* and the Rules coexist), cert. denied, 503 U.S. 912, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992), 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[03], pp. 702–36 to 702–37 (1988) (hereinafter Weinstein & Berger) (*Frye* is dead), and M. Graham, Handbook of Federal Evidence § 703.2 (3d ed. 1991) (*Frye* lives). See generally P. Giannelli & E. Imwinkelried, Scientific Evidence § 1–5, at 28–29 (citing authorities).

[2][3] We interpret the legislatively enacted Federal Rules of Evidence as we would any statute. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163, 109 S.Ct. 439, 446, 102 L.Ed.2d 445 (1988). Rule 402 provides the baseline:

> "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, ****2794** by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible."

"Relevant evidence" is defined as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Rule 401. The Rule's basic standard of relevance thus is a liberal one.

Frye, of course, predated the Rules by half a century. In *United States v. Abel*, 469 U.S. 45, 105 S.Ct. 465, 83 L.Ed.2d 450 (1984), we considered the pertinence of background common law in interpreting the Rules of Evidence. We noted that the Rules occupy the field, *id.*, at 49, 105 S.Ct., at 467, but, quoting Professor Cleary, the Reporter, 588***588** explained that the common law nevertheless could serve as an aid to their application:

> " 'In principle, under the Federal Rules no common law of evidence remains. "All relevant

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> evidence is admissible, except as otherwise provided....” In reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers.’ ” *Id.*, at 51–52, 105 S.Ct., at 469.

We found the common-law precept at issue in the *Abel* case entirely consistent with Rule 402's general requirement of admissibility, and considered it unlikely that the drafters had intended to change the rule. *Id.*, at 50–51, 105 S.Ct., at 468–469. In *Bourjaily v. United States*, 483 U.S. 171, 107 S.Ct. 2775, 97 L.Ed.2d 144 (1987), on the other hand, the Court was unable to find a particular common-law doctrine in the Rules, and so held it superseded.

[4] Here there is a specific Rule that speaks to the contested issue. Rule 702, governing expert testimony, provides:

> “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.”

Nothing in the text of this Rule establishes “general acceptance” as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that Rule 702 or the Rules as a whole were intended to incorporate a “general acceptance” standard. The drafting history makes no mention of *Frye*, and a rigid “general acceptance” requirement would be at odds with the “liberal thrust” of the Federal Rules and their “general approach of relaxing the traditional barriers to ‘opinion’ testimony.” *Beech Aircraft Corp. v. Rainey*, 488 U.S., at 169, 109 S.Ct., at 450 (citing Rules 701 to 705). See also Weinstein, Rule 702 of the Federal Rules of Evidence is 589***589** Sound; It Should Not Be Amended, 138 F.R.D. 631 (1991) (“The Rules were designed to depend primarily upon lawyer-adversaries and sensible triers of fact to evaluate conflicts”). Given the Rules' permissive backdrop and their inclusion of a specific rule on expert testimony that does not mention “ ‘general acceptance,’ ” the assertion that the Rules somehow assimilated *Frye* is unconvincing. *Frye* made “general acceptance” the exclusive test for admitting expert scientific testimony. That austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials.[FN6]

> FN6. Because we hold that *Frye* has been superseded and base the discussion that follows on the content of the congressionally enacted Federal Rules of Evidence, we do not address petitioners' argument that application of the *Frye* rule in this diversity case, as the application of a judge-made rule affecting substantive rights, would violate the doctrine of *Erie R. Co. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938).

B

[5][6] That the *Frye* test was displaced by the Rules of Evidence does not mean, ****2795** however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence.[FN7] Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.

> FN7. THE CHIEF JUSTICE “do[es] not doubt that Rule 702 confides to the judge some gatekeeping responsibility,” *post*, at 2800, but would neither say how it does so nor explain what that role entails. We believe the better course is to note the nature and source of the duty.

[7][8][9][10][11][12][13] The primary locus of this obligation is Rule 702, which clearly contemplates some degree of regulation of the

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subjects and theories about which an expert may testify. "*If scientific,* technical, or other specialized *knowledge will assist the trier of fact* to understand the evidence or to determine a fact in issue" an expert "may testify *thereto.* " (Emphasis added.) The subject of an expert's testimony must 590***590** be "scientific ... knowledge." FN8 The adjective " scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Webster's Third New International Dictionary 1252 (1986). Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. See, *e.g.,* Brief for Nicolaas Bloembergen et al. as *Amici Curiae* 9 ("Indeed, scientists do not assert that they know what is immutably 'true'—they are committed to searching for new, temporary, theories to explain, as best they can, phenomena"); Brief for American Association for the Advancement of Science et al. as *Amici Curiae* 7–8 ("Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement" (emphasis in original)). But, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—*i.e.,* "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to " scientific knowledge" establishes a standard of evidentiary reliability. FN9

FN8. Rule 702 also applies to "technical, or other specialized knowledge." Our discussion is limited to the scientific context because that is the nature of the expertise offered here.

FN9. We note that scientists typically distinguish between "validity" (does the principle support what it purports to show?) and "reliability" (does application of the principle produce consistent results?). See Black, 56 Ford.L.Rev., at 599. Although "the difference between accuracy, validity, and reliability may be such that each is distinct from the other by no more than a hen's kick," Starrs, *Frye v. United States* Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702, 26 Jurimetrics J. 249, 256 (1986), our reference here is to *evidentiary* reliability—that is, trustworthiness. Cf., *e.g.,* Advisory Committee's Notes on Fed.Rule Evid. 602, 28 U.S.C.App., p. 755 (" '[T]he rule requiring that a witness who testifies to a fact which can be perceived by the senses must have had an opportunity to observe, and must have actually observed the fact' is a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information' " (citation omitted)); Advisory Committee's Notes on Art. VIII of Rules of Evidence, 28 U.S.C.App., p. 770 (hearsay exceptions will be recognized only "under circumstances supposed to furnish guarantees of trustworthiness"). In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity.*

[14][15][16] 591***591** Rule 702 further requires that the evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This condition goes primarily to relevance. " Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." 3 Weinstein & Berger ¶ 702[02], p. 702–18. See also *United States v. Downing,* 753 F.2d 1224, 1242 (CA3 1985) ("An additional consideration****2796** under Rule 702—and another

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aspect of relevancy—is whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute"). The consideration has been aptly described by Judge Becker as one of "fit." *Ibid.* "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. See Starrs, *Frye v. United States* Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702, 26 Jurimetrics J. 249, 258 (1986). The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent creditable grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night. Rule 702's "helpfulness" 592***592** standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

[17][18] That these requirements are embodied in Rule 702 is not surprising. Unlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. See Rules 702 and 703. Presumably, this relaxation of the usual requirement of firsthand knowledge—a rule which represents "a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information,' " Advisory Committee's Notes on Fed.Rule Evid. 602, 28 U.S.C.App., p. 755 (citation omitted)—is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

[19][20][21][22][23] Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a),[FN10] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.[FN11] This entails a preliminary assessment of whether the reasoning or methodology***593** underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. We are confident that federal judges possess the capacity to undertake this review. Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.

FN10. Rule 104(a) provides:

> "Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining to conditional admissions]. In making its determination it is not bound by the rules of evidence except those with respect to privileges." These matters should be established by a preponderance of proof. See *Bourjaily v. United States*, 483 U.S. 171, 175–176, 107 S.Ct. 2775, 2778–2779, 97 L.Ed.2d 144 (1987).

FN11. Although the *Frye* decision itself focused exclusively on "novel" scientific techniques, we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence. Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended. Indeed, theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under Federal Rule of Evidence 201.

[24] Ordinarily, a key question to be answered in determining whether a theory or technique is

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scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." Green 645. See also C. Hempel, Philosophy of Natural Science 49 (1966) ****2797** ("[T]he statements constituting a scientific explanation must be capable of empirical test"); K. Popper, Conjectures and Refutations: The Growth of Scientific Knowledge 37 (5th ed. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability") (emphasis deleted).

[25][26][27] Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, see S. Jasanoff, The Fifth Branch: Science Advisors as Policymakers 61–76 (1990), and in some instances well-grounded but innovative theories will not have been published, see Horrobin, The Philosophical Basis of Peer Review and the Suppression of Innovation, 263 JAMA 1438 (1990). Some propositions, moreover, are too particular, too new, or of too limited interest to be published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. See J. Ziman, Reliable Knowledge: An Exploration 594***594** of the Grounds for Belief in Science 130–133 (1978); Relman & Angell, How Good Is Peer Review?, 321 New Eng.J.Med. 827 (1989). The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

[28] Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error, see, *e.g.*, *United States v. Smith*, 869 F.2d 348, 353–354 (CA7 1989) (surveying studies of the error rate of spectrographic voice identification technique), and the existence and maintenance of standards controlling the technique's operation, see *United States v. Williams*, 583 F.2d 1194, 1198 (CA2 1978) (noting professional organization's standard governing spectrographic analysis), cert. denied, 439 U.S. 1117, 99 S.Ct. 1025, 59 L.Ed.2d 77 (1979).

[29][30] Finally, "general acceptance" can yet have a bearing on the inquiry. A "reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." *United States v. Downing*, 753 F.2d, at 1238. See also 3 Weinstein & Berger ¶ 702[03], pp. 702–41 to 702–42. Widespread acceptance can be an important factor in ruling particular evidence admissible, and "a known technique which has been able to attract only minimal support within the community," *Downing*, 753 F.2d, at 1238, may properly be viewed with skepticism.

[31][32][33] The inquiry envisioned by Rule 702 is, we emphasize, a flexible one.[FN12] Its overarching subject is the scientific validity***595** and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

> FN12. A number of authorities have presented variations on the reliability approach, each with its own slightly different set of factors. See, *e.g.*, *Downing*, 753 F.2d, at 1238–1239 (on which our discussion draws in part); 3 Weinstein & Berger ¶ 702[03], pp. 702–41 to 702–42 (on which the *Downing* court in turn partially relied); McCormick, Scientific Evidence: Defining a New Approach to

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Admissibility, 67 Iowa L.Rev. 879, 911–912 (1982); and Symposium on Science and the Rules of Evidence, 99 F.R.D. 187, 231 (1983) (statement by Margaret Berger). To the extent that they focus on the reliability of evidence as ensured by the scientific validity of its underlying principles, all these versions may well have merit, although we express no opinion regarding any of their particular details.

[34] Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules. Rule 703 provides that expert opinions based on otherwise inadmissible****2798** hearsay are to be admitted only if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 706 allows the court at its discretion to procure the assistance of an expert of its own choosing. Finally, Rule 403 permits the exclusion of relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury...." Judge Weinstein has explained: "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." Weinstein, 138 F.R.D., at 632.

III

[35] We conclude by briefly addressing what appear to be two underlying concerns of the parties and *amici* in this case. Respondent expresses apprehension that abandonment of "general acceptance" as the exclusive requirement for admission will result in a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions.***596** In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. See *Rock v. Arkansas*, 483 U.S. 44, 61, 107 S.Ct. 2704, 2714, 97 L.Ed.2d 37 (1987). Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, Fed.Rule Civ.Proc. 50(a), and likewise to grant summary judgment, Fed.Rule Civ.Proc. 56. Cf., *e.g.*, *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (CA6) (holding that scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff's injury), cert. denied, 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (CA5 1989) (reversing judgment entered on jury verdict for plaintiffs because evidence regarding causation was insufficient), modified, 884 F.2d 166 (CA5 1989), cert. denied, 494 U.S. 1046, 110 S.Ct. 1511, 108 L.Ed.2d 646 (1990); Green 680–681. These conventional devices, rather than wholesale exclusion under an uncompromising "general acceptance" test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.

[36] Petitioners and, to a greater extent, their *amici* exhibit a different concern. They suggest that recognition of a screening role for the judge that allows for the exclusion of "invalid" evidence will sanction a stifling and repressive scientific orthodoxy and will be inimical to the search for truth. See, *e.g.*, Brief for Ronald Bayer et al. as *Amici Curiae*. It is true that open debate is an essential part of both legal and scientific analyses. Yet there are important differences between the quest for truth in the courtroom and the quest 597

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597** for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic*2799** insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.[FN13]

FN13. This is not to say that judicial interpretation, as opposed to adjudicative factfinding, does not share basic characteristics of the scientific endeavor: "The work of a judge is in one sense enduring and in another ephemeral.... In the endless process of testing and retesting, there is a constant rejection of the dross and a constant retention of whatever is pure and sound and fine." B. Cardozo, The Nature of the Judicial Process 178, 179 (1921).

IV

To summarize: "General acceptance" is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence, but the Rules of Evidence—especially Rule 702—do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands.

The inquiries of the District Court and the Court of Appeals focused almost exclusively on "general acceptance," as gauged by publication and the decisions of other courts. Accordingly,***598** the judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

Chief Justice REHNQUIST, with whom Justice STEVENS joins, concurring in part and dissenting in part.

The petition for certiorari in this case presents two questions: first, whether the rule of *Frye v. United States*, 54 App.D.C. 46, 293 F. 1013 (1923), remains good law after the enactment of the Federal Rules of Evidence; and second, if *Frye* remains valid, whether it requires expert scientific testimony to have been subjected to a peer review process in order to be admissible. The Court concludes, correctly in my view, that the *Frye* rule did not survive the enactment of the Federal Rules of Evidence, and I therefore join Parts I and II–A of its opinion. The second question presented in the petition for certiorari necessarily is mooted by this holding, but the Court nonetheless proceeds to construe Rules 702 and 703 very much in the abstract, and then offers some "general observations." *Ante*, at 2796.

"General observations" by this Court customarily carry great weight with lower federal courts, but the ones offered here suffer from the flaw common to most such observations—they are not applied to deciding whether particular testimony was or was not admissible, and therefore they tend to be not only general, but vague and abstract. This is particularly unfortunate in a case such as this, where the ultimate legal question depends on an appreciation of one or more bodies of knowledge not judicially noticeable, and subject to different interpretations in the briefs of the parties and their *amici*. Twenty-two *amicus* briefs have been filed in the case, and indeed the Court's opinion contains no fewer than 37 citations to *amicus* briefs and other secondary sources.

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599***599** The various briefs filed in this case are markedly different from typical briefs, in that large parts of them do not deal with decided cases or statutory language—the sort of material we customarily interpret. Instead, they deal with definitions of scientific knowledge, scientific method, scientific validity, and peer review—in short, matters far afield from the expertise of judges. This is not to say that such materials are not useful or even necessary in deciding how Rule 703 should be applied; but it is to say that the unusual subject matter should cause us to proceed with great caution in deciding more than we have to, because our reach can so easily exceed our grasp.

But even if it were desirable to make "general observations" not necessary to decide****2800** the questions presented, I cannot subscribe to some of the observations made by the Court. In Part II–B, the Court concludes that reliability and relevancy are the touchstones of the admissibility of expert testimony. *Ante*, at 2794–95. Federal Rule of Evidence 402 provides, as the Court points out, that "[e]vidence which is not relevant is not admissible." But there is no similar reference in the Rule to "reliability." The Court constructs its argument by parsing the language "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, ... an expert ... may testify thereto...." Fed.Rule Evid. 702. It stresses that the subject of the expert's testimony must be "scientific ... knowledge," and points out that "scientific" "implies a grounding in the methods and procedures of science" and that the word "knowledge" "connotes more than subjective belief or unsupported speculation." *Ante*, at 2794–95. From this it concludes that "scientific knowledge" must be "derived by the scientific method." *Ante*, at 2795. Proposed testimony, we are told, must be supported by "appropriate validation." *Ante*, at 2795. Indeed, in footnote 9, the Court decides that "[i]n a case involving scientific evidence, evidentiary***600** reliability will be based upon *scientific validity.*" *Ante*, at 2795, n. 9 (emphasis inoriginal).

Questions arise simply from reading this part of the Court's opinion, and countless more questions will surely arise when hundreds of district judges try to apply its teaching to particular offers of expert testimony. Does all of this *dicta* apply to an expert seeking to testify on the basis of "technical or other specialized knowledge"—the other types of expert knowledge to which Rule 702 applies—or are the "general observations" limited only to "scientific knowledge"? What is the difference between scientific knowledge and technical knowledge; does Rule 702 actually contemplate that the phrase "scientific, technical, or other specialized knowledge" be broken down into numerous subspecies of expertise, or did its authors simply pick general descriptive language covering the sort of expert testimony which courts have customarily received? The Court speaks of its confidence that federal judges can make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Ante*, at 2796. The Court then states that a "key question" to be answered in deciding whether something is "scientific knowledge" "will be whether it can be (and has been) tested." *Ante*, at 2796. Following this sentence are three quotations from treatises, which not only speak of empirical testing, but one of which states that the " 'criterion of the scientific status of a theory is its falsifiability, or refutability, or testability,' " *Ante*, at 2796–97.

I defer to no one in my confidence in federal judges; but I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its "falsifiability," and I suspect some of them will be, too.

I do not doubt that Rule 702 confides to the judge some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony. But I do not think 601***601** it imposes

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on them either the obligation or the authority to become amateur scientists in order to perform that role. I think the Court would be far better advised in this case to decide only the questions presented, and to leave the further development of this important area of the law to future cases.

U.S.Cal.,1993.
Daubert v. Merrell Dow Pharmaceuticals, Inc.
509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469, 61 USLW 4805, 27 U.S.P.Q.2d 1200, 23 Envtl. L. Rep. 20,979, 37 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 13,494

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In re Bextra and Celebrex

KeyCite Yellow Flag - Negative Treatment
Declined to Follow by In re Zicam Cold Remedy Marketing, Sales Practices, and Products Liability Litigation, D.Ariz., July 15, 2011

524 F.Supp.2d 1166
United States District Court,
N.D. California.

In re BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION.

This Order Relates to: all Cases.

No. M:05-CV-01699-CRB.
|
MDL No. 1699.
|
Nov. 19, 2007.

Synopsis

Background: Consumers, among others, sued manufacturer of arthritis pain medication, alleging that they had suffered serious cardiovascular injury due to their ingestion of medication. After actions were consolidated in multi-district litigation, manufacturer moved to exclude expert testimony to the effect that medication was capable of causing heart attack or stroke when ingested at 200 milligrams a day (mg/d) or 400 mg/d, and plaintiffs moved to exclude expert testimony offered by manufacturer.

Holdings: The District Court, Charles R. Breyer, J., held that:

[1] proffered testimony of plaintiffs' cardiology expert on issue of whether medication was capable of causing heart attack at dose of 200 mg/d was inadmissible;

[2] neurologist's testimony on issue of whether medication was capable of causing stroke at dose of 200 mg/d was inadmissible;

[3] cardiologist's extrapolation opinion was inadmissible;

[4] exclusion of plaintiffs' expert testimony on issue of whether medication could cause heart attacks when used at dose of 400 mg/d was not warranted;

[5] neurologist's expert testimony that medication was capable of causing strokes was admissible; and

[6] exclusion of manufacturer's meta-analyses was not warranted.

Motions granted in part and denied in part.

West Headnotes (13)

[1] **Evidence**
Necessity and sufficiency

When evaluating the admissibility of expert testimony, the trial court must first determine nothing less than whether the experts' testimony reflects scientific knowledge, whether their findings are derived by the scientific method, and whether their work product amounts to good science. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

2 Cases that cite this headnote

[2] **Evidence**
Necessity and sufficiency

In evaluating reliability of proffered expert testimony, trial judge's obligation is to make certain that an expert employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

1 Cases that cite this headnote

[3] **Evidence**
Necessity and sufficiency

Many factors may be relevant to the inquiry into reliability of proffered expert testimony, including (1) whether the proffered theory or technique has been tested, (2) whether the

theory or technique has been subjected to peer review and publication, (3) the known or potential rate of error of the technique or theory when applied, and (4) the general acceptance of the theory or technique in the scientific community. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

Cases that cite this headnote

[4] **Evidence**
Matters involving scientific or other special knowledge in general

In addition to determining reliability of proffered expert testimony, court must ensure that the proposed testimony is relevant to the task at hand, in that it logically advances a material aspect of the proposing party's case; this is known as the "fit" requirement. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

1 Cases that cite this headnote

[5] **Negligence**
Dangerous instrumentalities and substances
Products Liability
Proximate Cause
Products Liability
Chemicals in general
Products Liability
Drugs in general

To prevail in toxic tort or pharmaceutical personal injury lawsuit, plaintiff must show both general causation, pertaining to whether substance had capacity to cause harm alleged, and individual or specific causation, referring to whether a particular individual suffers from a particular ailment as a result of exposure to a substance.

6 Cases that cite this headnote

[6] **Evidence**
Medical testimony

Proffered testimony of cardiology expert, which asserted to a reasonable degree of medical probability that 200 milligram-per-day dose of manufacturer's arthritis pain medication could increase consumers' risk of heart attacks, did not reflect scientific knowledge, was not derived by scientific method, and was not good science, and thus was inadmissible in multi-district litigation addressing consumers' pharmaceutical personal injury claims against manufacturer, inasmuch as expert, who lacked relevant experience and training, reached opinion by first identifying conclusion and then cherry-picking observational studies that supported his conclusion, including one study the results of which expert testified did not make "biological sense" and which expert fundamentally misunderstood, and rejected or ignored great weight of evidence that contradicted his conclusion. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

10 Cases that cite this headnote

[7] **Evidence**
Medical testimony

Doctor was not qualified to favor certain observational studies over great weight of epidemiologic evidence to give opinion on whether 200 milligram-per-day dose of arthritis pain medication could increase consumers' risk of heart attacks in multi-district litigation of pharmaceutical personal injury claims against drug manufacturer, in that doctor was clinical cardiologist who saw patients 95 percent of his physician time, did not have specialized epidemiology training, had not published any research for more than 10 years, and had not participated in observational study of any kind. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

2 Cases that cite this headnote

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[8] **Evidence**
Medical testimony

Neurologist offered as stroke expert by plaintiffs in multi-district litigation addressing consumers' pharmaceutical personal injury claims against manufacturer of arthritis pain medication ignored vast majority of evidence on issue of whether 200 milligram-per-day dose of medication could increase consumers' risk of cardiovascular injury in favor of few studies that supported her conclusion, including unpublished, non-peer-reviewed study that combined all doses of medication and failed to adjust for critical compounding factors, and therefore neurologist's testimony was unreliable and inadmissible to establish general causation. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

4 Cases that cite this headnote

[9] **Evidence**
Medical testimony
Evidence
Experiments and results thereof

Cardiology expert's extrapolation of studies addressing risk of cardiovascular injury stemming from use of arthritis pain medication at dose of 400 milligrams per day (mg/d) did not support proffered opinion that medication could cause heart attack when taken in doses of 200 mg/d, and therefore extrapolation evidence was inadmissible in multi-district litigation addressing consumers' pharmaceutical personal injury claims against medication's manufacturer, given that expert's method of extrapolation, in which he simply took relative risk point established for 400 mg/d dosage and cut it in half, while ignoring confidence interval, lacked support in scientific literature, that expert admitted that there was no way of knowing what confidence interval was for 200 mg/d dosage under his unique methodology, and that expert agreed that there was dose effect with medication. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

7 Cases that cite this headnote

[10] **Evidence**
Experiments and results thereof

Exclusion of expert testimony that arthritis pain medication was capable of causing heart attacks and strokes when used at dose of 400 milligrams per day (mg/d) was not warranted in multi-district litigation addressing consumers' pharmaceutical personal injury claims against medication's manufacturer, even though large, long-term, randomized, placebo-controlled clinical trial on which testimony was based was terminated early and its results had not been replicated by two other randomized controlled studies, given that trial was halted early because evidence of harm was so significant, that other studies also were halted early due to results of challenged trial, and that one of other studies was not designed to detect differences in cardiovascular and cerebrovascular risks and involved study participants with risk factors which possibly differed from general population. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

2 Cases that cite this headnote

[11] **Evidence**
Medical testimony

Although, in multi-district litigation addressing consumers' pharmaceutical personal injury claims against manufacturer of arthritis pain medication, there was some epidemiologic evidence to dispute neurologist's expert testimony that medication was capable of causing strokes, by suggesting that even though heart attacks and certain strokes were caused by same mechanism, manufacturer's medication did not cause both, there also was some evidence to support neurologist's mechanism testimony, and therefore such testimony was not scientifically invalid and was admissible. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

Cases that cite this headnote

[12] **Evidence**
Medical testimony

Consumers could present expert testimony that arthritis pain medication caused heart attacks or strokes at durations of less than 33 months of continuous daily use, in multi-district litigation on consumers' pharmaceutical personal injury claims against medication's manufacturer, even though statistically significant association did not appear until after 33 months in one clinical trial. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

Cases that cite this headnote

[13] **Evidence**
Experiments and results thereof

Plaintiffs' challenges to meta-analyses performed by experts for manufacturer of arthritis pain medication went to weight of meta-analyses, and not their validity, and thus did not warrant exclusion of meta-analyses in multi-district litigation addressing pharmaceutical personal injury claims against manufacturer. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

1 Cases that cite this headnote

Named Expert: Dr. Neil Doherty, Dr. Maryilyn Rymer

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*1169 MEMORANDUM AND ORDER RE: MOTIONS TO EXCLUDE EXPERT TESTIMONY

CHARLES R. BREYER, District Judge.

In this Multi-District Litigation ("MDL") proceeding, over 3000 plaintiffs allege that they or their loved ones suffered a heart attack, stroke or other adverse cardiovascular event as a result of taking Celebrex, a pain medication manufactured by defendant Pfizer, Inc. ("Pfizer"). Pfizer has moved to exclude any expert testimony to the effect that Celebrex is capable of causing a heart attack or stroke when ingested at 200 milligrams a day or 400 milligrams a day. Plaintiffs have also moved to exclude certain expert testimony offered by Pfizer. The Court held three days of hearings which included direct and cross examination of certain experts. After carefully considering the parties' memoranda and evidence, and the testimony offered at the hearing, the Court concludes that plaintiffs have not presented scientifically reliable evidence that Celebrex causes heart attacks or strokes when ingested at the 200 milligram a day dose. In all other respects the parties' motions are denied.

BACKGROUND

Non-steroidal anti-inflammatory drugs ("NSAIDs") have been widely used for pain relief for several years. NSAIDs, however, have certain side effects, including gastrointestinal toxicity which results in thousands of deaths every year. The pharmaceutical company Merck & Co., Inc. ("Merck") developed Vioxx, and Pfizer (or, more precisely, its predecessors) developed Celebrex and Bextra, NSAIDs known as COX-2 inhibitors, with the expectation that they would have fewer gastrointestinal side effects than traditional NSAIDs. The Food and Drug Administration ("FDA") approved Celebrex for adult

arthritis in 1998, Vioxx in 1999, and Bextra in late 2001. The recommended dose of Celebrex was and is 200 milligrams a day ("mg/d") for arthritis and 400 mg/d for rheumatoid arthritis.

In 2000 the results of a long-term randomized study of Celebrex known as CLASS ("Celecoxib Long-Term Arthritis Safety Study") were published. The study was designed to evaluate the gastrointestinal side effects of taking Celebrex at 800 mg/d. Based on investigator reported cardiovascular events, the study showed no increased risk of heart attack or stroke by taking Celebrex over diclofenac or ibuprofen. Around the same time, a similar study of Vioxx, known as VIGOR, showed a four-fold increase in cardiovascular ("cv") risk for patients taking Vioxx versus Aleve (naproxen). The FDA subsequently revised the labels of Celebrex and Vioxx to reflect the cv risk results of these studies.

Another Vioxx randomized clinical study, known as APPROVe, was published in 2004. This study demonstrated a two-fold increased risk of cv adverse events for patients taking Vioxx versus a placebo. This study contributed to Merck's voluntary removal of Vioxx from the market on September 30, 2004.

The preliminary results of APC, a randomized, placebo-controlled study of Celebrex at 200 mg twice daily (400 mg/d) and 400 mg twice daily (800 mg/d) to evaluate whether Celebrex prevents the development of colon polyps, became available in late 2004. APC showed dose-related increased cv risk for patients taking Celebrex compared to placebo: more than doubling the risk for 200 mg twice daily and tripling the risk for 400 mg twice daily. The APC steering committee discontinued the study in December 2004 because of these preliminary results.

In February 2005 the FDA convened an Advisory Committee to review the data on ***1170** cv risk and NSAIDs, including COX-2 inhibitors. The Committee concluded that all COX-2 inhibitors increase cv risk versus placebo, but it did not make any findings as to what dose is required to increase the risk. It also concluded that the data was insufficient to determine if traditional NSAIDs also increase cv risk. With respect to Celebrex, the FDA found that APC is the "strongest data in support of an increased risk of serious adverse CV events." FDA Decision Memorandum, April 6, 2005, at 4, Declaration of Loren Brown ("Brown Decl.") Exh. 16. The FDA also noted that APC's results had not been replicated by preliminary data from two other randomized controlled clinical studies: (1) PreSAP, a colon polyp prevention trial of Celebrex at 400 mg/d; and (2) ADAPT, an Alzheimer's trial of Celebrex at 200 twice daily (400 mg/d). Both studies showed no increased cv risk for Celebrex versus placebo.

The FDA subsequently asked Pfizer to remove Bextra from the market, which Pfizer did in April 2005. The FDA also determined that the benefits of Celebrex outweigh its risks and therefore it allowed Celebrex to remain on the market. Celebrex is the only COX-2 inhibitor currently on the market.

The FDA also directed all NSAIDs, including Celebrex, to include a black box warning on their labels. The black box warns of cv risk as follows:

> **Cardiovascular Risk**
>
> • CELEBREX may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk ....

Celebrex 2007 Label, Brown Decl. Exh. 3.

As a result of these developments, thousands of patients and patient representatives filed lawsuits against Merck and Pfizer alleging that the patient had suffered a serious cardiovascular injury, such as a heart attack or stroke, due to their ingestion of Vioxx, and/or Celebrex and/or Bextra. All of the federal court claims against Merck were consolidated in a MDL action in New Orleans. All of the federal court claims against Pfizer were consolidated into this MDL proceeding.

THE DAUBERT MOTIONS

Pursuant to Federal Rule of Evidence 702, Pfizer moves to exclude plaintiffs' experts from offering the following six opinions:

1. That 200 mg/d of Celebrex causes heart attacks and strokes;

2. That 400 mg/d of Celebrex causes heart attacks and strokes;

3. That Celebrex causes heart attacks or strokes more than three days after a patient stops taking it;

4. That Celebrex causes strokes; and;

5. That Celebrex causes heart attacks or stokes at durations of less than 33 months of continuous daily use.

Pfizer also asks the Court to exclude any expert opinion that Celebrex caused any individual plaintiff's heart or stroke absent epidemiology evidence that demonstrates a relative risk greater than 2.0, that is, that Celebrex doubles the risk. Plaintiffs have moved to exclude certain expert testimony offered by Pfizer; specifically, they seek to exclude admission of the meta-analyses performed by plaintiffs' experts.

In connection with these motions, the parties submitted direct written testimony of their respective experts as well as legal ***1171** memoranda. The Court then held three days of hearings, which were conducted jointly with the New York Justice presiding over the New York State Celebrex and Bextra cases. Plaintiffs' experts Dr. Neil Doherty, Dr. Joel Bennett, Dr. Nicholas Jewell and Dr. Maryilyn Rymer testified on direct and cross-examination, along with defendant's expert Dr. Milton Packer. The parties also submitted post-hearing memoranda. The motions are now ripe for decision.

LEGAL STANDARD

A. Admissibility of Expert Testimony

[1] [2] When evaluating the admissibility of expert testimony, the trial judge "must engage in a difficult, two-part analysis." *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1315 (9th Cir.1995) (*Daubert II*). First, the court must "determine nothing less than whether the experts' testimony reflects 'scientific knowledge,' whether their findings are 'derived by the scientific method,' and whether their work product amounts to 'good science.' " *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 589-90, 593, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993)); *see also In re Silicone Gel Breast Impl. Products Liab. Lit.,* 318 F.Supp.2d 879, 890 (C.D.Cal.2004) (" '[T]he trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted.' ") (quoting Fed.R.Evid. 702 Advisory Committee's Notes). The trial judge's obligation "is to make certain that an expert ... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

[3] Many factors may be relevant to the reliability inquiry, including: (1) whether the proffered theory or technique has been tested, (2) whether the theory or technique has been subjected to peer review and publication, (3) the known or potential rate of error of the technique or theory when applied, and (4) the "general acceptance" of the theory or technique in the scientific community. *Daubert,* 509 U.S. at 593-94, 113 S.Ct. 2786.

> [C]ourts have also found the following factors relevant in assessing the reliability of expert testimony: (1) whether the expert is proposing to testify about matters growing directly out of independent research he or she has conducted or whether the opinion was developed expressly for purposes of testifying; (2) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (3) whether the expert has adequately accounted for obvious alternative explanations; (4) whether the expert is being as careful as he would be in his regular professional work; and (5) whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion offered.

In re Silicone Gel Breast Impl. Products Liab. Lit., 318 F.Supp.2d at 890 (citing Fed.R.Evid. 702 Advisory Committee's Notes).

[4] In addition to determining reliability, the court "must ensure that the proposed expert testimony is 'relevant to the task at hand,' i.e., that it logically advances a material aspect of the proposing party's case." *Daubert II,* 43 F.3d at 1315 (quoting *Daubert,* 509 U.S. at 597, 113 S.Ct. 2786). This is known as the "fit" requirement. *Id.* Here, the pertinent fit inquiry is "causation." The parties' motions address expert testimony on the causation inquiry.

B. Causation

Causation in toxic tort or pharmaceutical personal injury cases "is typically discussed ***1172** in terms of generic and specific causation." *In Re Hanford Nuclear Reservation Lit.,* 292 F.3d 1124, 1133 (9th Cir.2002). General or generic causation means "whether the substance at issue had the capacity to cause the harm alleged." *Id.* In *Hanford,* for example, the Ninth Circuit explained that the general causation inquiry was "whether exposure to a substance for which a defendant is responsible, such as radiation at the level of exposure alleged by plaintiffs, is capable of causing a particular injury or condition in the general population." *Id.*

[5] To ultimately prevail in such a lawsuit, however, a plaintiff must show both general and "individual" or "specific" causation. *Id.* Specific causation refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance. *Id.* That is, that the challenged conduct, here, the taking of Celebrex at a certain dose for a particular amount of time, was "the cause-in-fact" of the particular plaintiff's injury. *Id.*

The parties' motions involve the use of epidemiology to prove causation. "The field of epidemiology addresses the incidence, distribution and etiology (causation) of disease in human populations by comparing individuals exposed to a particular agent to unexposed individuals to determine whether exposure increases the risk of disease." *In re Silicone Gel Breast Implants Products Liab. Lit.,* 318 F.Supp.2d at 892. Scientists use "relative risk" to identify an association between, for example, the ingestion of a drug and a disease.

> For example, if a study found that 10 out of 1000 women with breast implants were diagnosed with breast cancer and 5 out of 1000 women without implants (the "control" group) were diagnosed with breast cancer, the relative risk of implants is 2.0, or twice as great as the risk of breast cancer without implants. This is so, because the proportion of women in the implant group with breast cancer is 0.1 (10/1000) and the proportion of women in the non-implant group with breast cancer is 0.05 (5/1000). And 0.1 divided by 0.05 is 2.0.

Id. A relative risk of 1.0 suggests that there is no association between the product and the disease, that is, the same numbers of people using the product are diagnosed with the disease as those not using the product. Similarly, a relative risk of less than 1.0 suggests that the product is actually "protective" of the disease: fewer people using the product contract the disease than those not taking the product. *Id.* at n. 5.

In general, epidemiology studies are probative of general causation: a relative risk greater than 1.0 means the product has the capacity to cause the disease. "Where the study properly accounts for potential confounding factors and concludes that exposure to the agent is what increases the probability of contracting the disease, the study has demonstrated *general* causation-that exposure to the agent is capable of causing [the illness at issue] in the general population." *Id.* at 893 (internal quotation marks and citation omitted).

Such studies can also be probative of specific causation, but only if the relative risk is greater than 2.0, that is, the product more than doubles the risk of getting the disease.

> When the relative risk is 2.0, the alleged cause is responsible for an equal number of cases of the disease as all other background causes present in the control group. Thus, a relative risk of 2.0 implies a 50% probability that the agent at issue was responsible for a particular individual's disease. This means that a relative risk that is greater than 2.0 permits the conclusion that the agent ***1173** was more likely than not responsible for a particular individual's disease.

Id. at 893. The issue on these motions, however, is not specific causation; there is no particular plaintiff before the Court. Rather, the primary issue is whether the Court should permit plaintiffs' experts to testify that Celebrex is capable of causing heart attacks or strokes at certain doses.

EPIDEMIOLOGY STUDIES AND TERMS

Before discussing the parties' motions, it is important to identify the different epidemiology studies relied upon by the experts. There are generally three types of clinical epidemiology studies at issue on the parties' motions: (1)

randomized controlled clinical trials, (2) observational studies, and (3) meta-analyses.

The "gold standard" for determining whether a drug is related to the risk of developing an adverse health outcome is a "randomized clinical trial" in which the subjects are randomly assigned to one of two groups: one group exposed to the drug of interest and the other not exposed. After a period of time the study participants in both groups are evaluated for an adverse health outcome. Federal Judicial Center, Reference Manual on Scientific Evidence 338 (2d ed.2000). "Randomization minimizes the likelihood that there are differences in relevant characteristics between those exposed to the agent and those not exposed," such as smoking, obesity, aspirin use and so on that could account for any difference in outcomes between the two groups. *Id.*

An "observational study" evaluates causation by comparing the risk of disease between patients exposed to a given substance and patients who were not exposed. The study may be prospective, identifying patients and then following them for a period of time, or restrospective, identifying patients and then performing a medical chart review to determine what happened during the period they did or did not take the drug. The downside to observational studies is that because the investigators do not control who participates in the study, it is more difficult to control for confounding factors such as smoking, obesity and the like. The investigator attempts to address the possible role of confounding factors "by considering them in the design of the study and in the analysis and interpretation of the study results." *Id.* at 339.

There are two types of observational studies: a cohort study and a case control study. A cohort study identifies patients who are taking the drug (exposed) and follows them for a certain amount of time to determine if they have the alleged bad outcome, here, such outcome is heart attack or stroke. The cohort study also identifies people not taking the drug and follows them (unexposed). The study then compares the rate of the alleged bad outcomes in group one with the rate in group two to compute the "relative risk." *Id.* at 339-40.

A case control study identifies persons who had a bad outcome (the cases), for example, patients in the United Kingdom database that had a heart attack within the last three years, and reviews their medical records to determine how many of those persons were taking the studied drug around the time of their heart attack. The study then identifies an equal number of people who did not have a heart attack (the controls) and determines how many of them were taking the drug. *Id.* From those figures an "odds ratio" is computed. For example, if the percentage of people taking Celebrex in both groups is the same, the odds ratio is 1.0; that is, taking Celebrex did not increase the risk of heart attack.

Sometimes randomized controlled studies and observational studies of the same ***1174** drug will have conflicting results; some will show a statistically significant association while others will not. A meta-analysis pools the results of various studies to arrive at a single figure to represent the totality of the studies reviewed. "In a meta-analysis, studies are given different weights in proportion to the sizes of their study populations and other characteristics." *Id.* at 380. Meta-analysis has the advantage of pooling more data so that the results are less likely to be misleading solely due to chance. On the other hand, one problem with meta-analysis, particularly in meta-analysis of observational studies, is that the pooled studies often use disparate methodologies.

When reviewing the results of a study, whether it is a randomized clinical trial, observational trial, or a meta-analysis of such trials, it is important to consider the confidence interval. The confidence interval is, in simple terms, the "margin of error." So, for example, if a given study showed a relative risk of 1.40 (a 40 percent increased risk of adverse events), but the 95 percent confidence interval is .8 to 1.9, we would say that we are 95 percent confident that the true value, that is, the actual relative risk, is between .8 and 1.9. Because the confidence interval includes results which do not show any increased risk, and indeed, show a decreased risk, that is, it includes values less than 1.0, we would say the study does not demonstrate a "statistically significant" increased risk of an adverse outcome. Confidence intervals are calculated, in part, based on the number of people and events included in the study. "The larger the sample size in a study (all other things being equal), the narrower the confidence boundaries will be (indicating greater statistical stability), thereby reflecting the decreased likelihood that the association found in the study would occur if the true association is 1.0 [no increased or decreased risk]." *Id.* at 361.

With these terms in mind, the Court now turns to the parties' motions.

DISCUSSION

I. Pfizer's Motion

A threshold question raised by Pfizer's motion is whether a particular dose of Celebrex is relevant to the general causation inquiry. Pfizer seeks to exclude any opinion that Celebrex is capable of causing heart attacks and strokes at 200 mg/d as well as any opinion that Celebrex is capable of causing heart attacks and strokes at 400 mg/d. It does not move to exclude expert testimony that Celebrex is capable of causing heart attacks and strokes when a patient ingests 800 mg/d, at least when taken over many months. Thus, Pfizer's motion assumes that Celebrex at different doses can have different cardiovascular effects.

The Court finds that dose matters. All of plaintiffs' experts, with perhaps a single exception, agree that there is a dose effect with Celebrex; that is, that it is more toxic, and is therefore more likely to cause an adverse side effect, when taken at greater doses. *See* Reference Manual on Scientific Evidence at 403 ("There are three central tenets of toxicology. First, 'the dose makes the poison'; this implies that all chemical agents are intrinsically hazardous-whether they cause harm is only a question of dose. Even water, if consumed in large quantities, can be toxic."); *see also Mitchell v. Gencorp,* 165 F.3d 778, 781 (10th Cir.1999) (noting that to prevail in a toxic tort case a "a plaintiff must demonstrate 'the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover") (internal quotation marks and citation omitted); *Allen v. Penn. Eng'g Corp.,* 102 F.3d 194, 199 (5th Cir.1996) (explaining ***1175** that in toxic tort cases, "[s]cientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden"); *see also Hanford Nuclear Reservation Lit.,* 292 F.3d at 1133 (explaining that the general causation inquiry is whether exposure to the challenged substance *"at the level of exposure alleged by the plaintiffs* is capable of causing the alleged injuries") (emphasis added). As plaintiffs' cardiology expert, Dr. Neil Doherty, testified: it is a "fundamental principal of medicine" and "medical causality" that the risk of adverse cardiovascular events with Celebrex is dose-related. Transcript of October 10, 2007 Hearing ("Oct. 10 TR") at 328. Thus, the Court must analyze plaintiffs' experts' opinions as to causation at 200 mg/d separate from their opinions as to 400 mg/d.

A. 200 mg/d

Celebrex at 200 mg/d and the risk of adverse cv events has not been studied in published, large, long-term randomized controlled trials. Nonetheless, included in the record are approximately 30 unpublished randomized controlled trials, albeit of short duration and small size. These studies do not demonstrate any association between Celebrex and adverse cv outcomes. A meta-analysis of all available published and unpublished randomized clinical trials of all COX-2 inhibitors as well as traditional NSAIDs found that while COX-2 inhibitors as a whole are associated with a moderate increase in the risk of adverse cv events, no such association is found with the available data for Celebrex at 200 mg/d or less.[1]

The record also includes observational studies with Celebrex data, mostly at 200 mg/d. These observational studies together include more than 8,000 adverse cv events, and all of the studies with the most events demonstrate no statistically significant association between Celebrex at 200 mg/d and adverse cv events. A meta-analysis performed by an independent researcher unaffiliated with Pfizer ("McGettigan") concluded that while Vioxx does increase the risk of adverse cv events, "[i]n doses of around 200 mg/d, [Celebrex] was not associated with an increased risk ...."[2] Another meta-analysis of eight observational studies showed no increased risk from Celebrex 200 mg/d compared to patients taking no medication.[3]

In sum, there are no randomized controlled trials or meta-analyses of such trials or meta-analyses of observational studies that find an association between Celebrex 200 mg/d and a risk of heart attack or stroke. And most observational studies, indeed, the observational studies that include 97 percent of the reported adverse cv events, also find no statistically significant association. It is thus unsurprising that most of plaintiffs' experts agree that the available evidence at 200 mg/d is inadequate to prove causation. *See* Deposition Testimony of Dr. Joel Bennett at p. 537, Brown Reply Decl. ***1176** Exh. 108 ("I think that if you look at all the evidence, I think at 200 milligrams it's hard to make a case that Celebrex has toxicity. It doesn't mean that, again, that in individual cases it couldn't, it could be lost in the big scheme of things, but, in fact, the data don't suggest that in a large population it increases the risk."); Deposition Testimony of Dr. Lemue Moye at p. 268, Brown Reply Decl. Exh. 109 ("[T]here's no study that convincingly demonstrates a signal of cardiovascular events at very low does such as 200 per day."); Deposition Testimony of Dr. Nicholas Jewell at p. 130, Brown Reply Decl. Exh. 110 (when asked whether there is reliable scientific evidence to establish that 200 mg/d causes heart attacks and strokes

he responded that the evidence is not sufficient "to be definitive"); Deposition of Dr. James M. Wright at pp. 83-84, 92, Brown Decl. Reply Exh. 106 (stating that it has not been proven that at 200 mg/d Celebrex increases the risk of heart attack because "we don't have enough information").

1. Dr. Neil Doherty

[6] Plaintiffs' cardiology expert, Dr. Neil Doherty, nonetheless asserts "to a reasonable degree of medical probability that the 200 mg dose of Celebrex can increase the risk of MI's [heart attacks]." Written Direct Examination of Dr. Neil F. Doherty III ("Doherty Written Direct") at ¶ 18. He reaches his opinion by first identifying his conclusion-causation at 200 mg/d-and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion. Dr. Doherty's opinion does not reflect scientific knowledge, is not derived by the scientific method, and is not "good science;" it is therefore inadmissible.

[7] First, Dr. Doherty is not qualified to favor certain observational studies over the great weight of the epidemiologic evidence to give an opinion on causation. He is a clinical cardiologist who sees patients 95 percent of his physician time. He does not have any specialized epidemiology training. He has not published any research since 1992, and his 13 publications are unrelated to the subject matter of these lawsuits. He has never participated in an observational study of any kind. He is therefore not qualified to opine that one or two observational studies are correct while all the other studies (the studies that include 97 percent of the adverse cv events) are wrong. Moreover, he only became interested in Celebrex and cv risk *after* he was retained by plaintiffs in this litigation; indeed, although the issue of COX-2 inhibitors and adverse cv events has been well known since at least 2005, he did not discontinue prescribing Celebrex until after plaintiffs retained him as an expert in this case. Doherty Written Direct at ¶ 2. Dr. Doherty's opinion was developed for the purpose of this litigation. *See Daubert II,* 43 F.3d at 1317 ("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.").

Second, apart from his lack of relevant experience and training (or because of it), the foundation of his opinion-wholly rejecting the McGettigan meta-analysis and the other observational studies that do not support his opinion-is not a scientifically valid methodology. For example, while he justifies his wholesale rejection of McGettigan on the blanket ground that meta-analysis is inappropriate for observational studies, plaintiffs' other experts rely on such studies; indeed, Dr. Bennett testified that McGettigan is a "good study." Dr. Bennett Depo. at p. 187-88, Brown Reply ***1177** Decl. Exh. 108. And the American Heart Association Committee that developed a "Science Advisory" on the use of NSAIDs also relied on McGettigan. Finally, Dr. Doherty testified that he prefers the Oxford Centre for Evidence Based Medicine ranking of the levels of evidence that a scientist should consider. Doherty Written Direct at ¶ 21-22. That ranking identifies systematic review, including meta-analysis, as the highest level for each category of evidence. Oct. 10 TR at 350.

Third, Dr. Doherty testified that the "strongest evidence" for his 200 mg/d opinion "is the Andersohn study published in *Circulation* in 2006."[4] Doherty Written Direct at ¶ 18. He attempts to justify his heavy reliance on Andersohn by asserting that it is the "best designed" of all the observational studies. When asked why, however, Dr. Doherty responded only that the study is derived from the United Kingdom database which is among the most complete in the world. Oct. 10 TR at 309-10. He also mentioned that Andersohn is a prospective, rather than retrospective study. *Id.* at 310. But many of the other studies he rejects out of hand are also prospective, and he does not cite anything in the medical literature that suggests that it is a valid scientific method to prefer one study over many that have contradictory results simply because the study that supports the expert's conclusion utilized the United Kingdom database.

Fourth, Dr. Doherty's reliance on Andersohn as "the strongest evidence" of an increased risk at 200 mg/d is undermined by his own testimony that Andersohn's results do not make "biological sense." Oct. 10 TR at 363-64. Andersohn found the increased risk of heart attack was higher at shorter durations of use (less than three months) than at higher durations; indeed, there was no statistically significant association at durations greater than three months, a finding that directly contradicts Dr. Doherty's testimony that the risk of heart attack increases with duration of use. Oct. 10 TR at 359-61. Andersohn also found that the risk of heart attack is statistically significant in patients without cv risk factors, but is not statistically significant in patients with such risk factors. *Id.* at 364. Again, this finding directly contradicts Dr. Doherty's testimony that the risk of heart attack from Celebrex is greater in patients with heart disease. To conclude that Celebrex 200 mg/d causes heart attacks and

strokes based on a study that does not make "biological sense" is not sound science.

Fifth, Dr. Doherty's opinion is based on his fundamental misunderstanding of Andersohn. Dr. Doherty testified that Andersohn is a cohort study and he "puts a lot more weight" into cohort studies as opposed to case control studies. Oct. 10 TR at 255, 309, 350. He repeatedly testified that he relies on Andersohn out of all of the available evidence because it is a good cohort study. *See, e.g., id.* at 313, 315. When he was confronted with Andersohn's own description of the study, however, Dr. Doherty conceded that Andersohn is not a cohort study, but is instead "a case-control study nested within a cohort study." *Id.* at 352.

Dr. Doherty also insisted that Andersohn used cox proportional hazard analysis, the analysis most commonly used for cohort studies. Oct. 10 TR at 320-21, 355. On cross-examination, however, he could not identify where in the study the authors disclose that they used cox-proportional hazard analysis and Dr. Doherty pointedly did not clarify his testimony on re-direct. ***1178** The Court has reviewed Andersohn and it does not indicate that the study authors used cox-proportional hazard analysis; rather, they used logistic regression which resulted in an "odds ratio," an analysis consistent with case control studies. Dr. Doherty's fundamental misunderstanding of the study he "relied most strongly on" to support his opinion, Doherty Written Direct at ¶ 31, is perhaps explained by his inability to explain the difference between a cohort study and case control study "off the top of his head," Oct. 10 TR at 348, and his inability to define the cox proportional hazards model or explain logistic regression analysis. *Id.* In any event, as Andersohn is a case control study, Dr. Doherty's heavy reliance upon it is unreliable in light of his own blanket rejection of all of the case control studies showing no association between Celebrex 200 mg/d and cv risk on the ground that case control studies are not as reliable as cohort studies. Doherty Written Direct at ¶ 37.

While Andersohn is the "strongest evidence" supporting Dr. Doherty's opinion, he also cited an additional observational study, Gislason.[5] Gislason, however, had few events and merely evaluated COX-2 inhibitors and the risk of a heart attack in patients who had already had a heart attack. Moreover, the study failed to control for smoking, a well-known risk for heart attack, as well as aspirin use, even though another of plaintiffs' experts, Dr. Maryilyn Rymer, criticized another observational study for not adjusting for aspirin use. Dr. Maryilyn Rymer Written Direct Testimony ("Rymer Written Direct") at ¶ 34. In light of these limitations, and the totality of the available evidence, Gislason does not salvage Dr. Doherty's opinion that Celebrex at 200 mg/d can cause heart attacks.

Dr. Doherty also relied on the "imbalance hypothesis" as evidence that it is biologically plausible that Celebrex causes heart attacks. This hypothesis asserts that COX-2 inhibitors as a class, that is, Vioxx, Bextra and Celebrex, create an imbalance in the arteries by blocking prostacyclin (an anti-clotting agent). Under this theory, the imbalance caused by ingesting a COX-2 will lead to an adverse cv event if the patient already has a risk factor, such as high blood pressure, smoking, or high cholesterol. Dr. Doherty argues that this hypothesis means that it makes sense that Celebrex increases the risk of heart attacks and strokes. He did not explain, however, how he reconciles this theory with Andersohn-the strongest evidence of his causation opinion-which showed a greater risk of heart attacks in patients with no cv risk factors.

In any event, both Dr. Doherty and Dr. Joel Bennett-plaintiffs' imbalance hypothesis expert-agree that the only way to prove the hypothesis is to look at the data from epidemiological studies. Oct. 10 TR at 373. For example, Dr. Bennett agreed that the only method available to determine how much Celebrex is needed (that is, what dose) to create an imbalance sufficient to cause a heart attack is patient studies. Oct. 9 TR at 209, 210. As is explained above, the patient studies do not demonstrate an association between Celebrex 200 mg/d and heart attack or stroke; therefore, the imbalance hypothesis-even if true-(and it is only one of many possible explanations for the apparent increased risk of heart attacks from COX-2 inhibitors at certain doses) does not support Dr. Doherty's opinion that Celebrex is capable of causing heart attacks at 200 mg/d.

***1179 2. Dr. Maryilyn Rymer**

[8] Dr. Maryilyn Rymer's testimony does not provide the missing link. Dr. Rymer is a neurologist and plaintiffs offered her as a stroke expert, essentially to opine that Celebrex causes strokes as well as heart attacks. In her written direct testimony she opines that "the totality of the scientifically reliable evidence supports that [Celebrex] can cause strokes and other cardiovascular events at all therapeutic doses, especially in those individuals who are high risk for cardiovascular events." Rymer Written Direct at ¶ 7. She admits that there is no data from randomized controlled trials to support her conclusion at 200 mg/d; instead, she primarily relies on (1) the imbalance hypothesis, (2) the same Andersohn study upon

which Dr. Doherty relies, and (3) the Wellpoint data, an unpublished observational study of unknown design. In other words, Dr. Rymer, as does Dr. Doherty, ignores the vast majority of the evidence in favor of the few studies that support her conclusion.

The Court has already addressed the imbalance hypothesis and the Andersohn study, neither of which provide scientifically valid support for her opinion in light of the great weight of the epidemiologic evidence. It is worth adding, however, that Dr. Rymer's reliance on the Andersohn heart attack study is inconsistent with her criticism of the Andersohn stroke study. The latter study, performed by the same Andersohn as the heart attack study, indeed, it is the same study but focused on stroke rather than heart attack outcomes, found no statistically significant increased risk of stroke associated with Celebrex use at 200 mg/d. Dr. Rymer criticized the stroke study for not controlling for aspirin use and having a 10 percent error rate; yet the Andersohn heart attack study suffers from the same limitations.

Dr. Rymer relies heavily on an unpublished, non-peer reviewed study from a managed care organization ("the Wellpoint Report"). Dr. Rymer attaches to her written direct testimony a letter from Wellpoint to the FDA summarizing the results of the study. The letter discloses a relative risk from Celebrex use of 1.19 when the data is analyzed to control for "age and other cardiovascular risk factors;" however, this very low risk includes *all* doses of Celebrex. Moreover, the letter does not identify study design, the analysis used, or even the confidence intervals. Dr. Rymer admitted on cross-examination that the study also fails to account for critical compounding factors such as smoking. This unpublished, unreviewed study, which combines all doses of Celebrex, and fails to adjust for critical compounding factors such as smoking, is not a scientifically valid basis for Dr. Rymer's rejection of all the other observational data-including meta-analyses-that do not show a statistically significant increase in the risk of heart attack or stroke at 200 mg/d.

Finally, Dr. Rymer cited Gislason, discussed above, and Brophy,[6] as support for causation at 200 mg/d. Brophy, as Gislason, evaluated the risk of heart attack in patients who had already had at least one heart attack. Brophy, however, did not find a statistically significant increased risk of heart attack at 200 mg/d, even in these high risk patients. And while it did show a greater risk in the high risk population (although not a statistically significant risk), the higher risk found in Brophy and Gislason is contradicted by the results of at least nine other studies, including Dr. Doherty's "strongest evidence" of causation, ***1180** the Andersohn heart study. Such data cannot reliably form the basis for rejecting the overwhelming pattern of evidence that fails to show any statistically significant risk at 200 mg/d.

3. Extrapolation

[9] Dr. Doherty, and to some extent Dr. Rymer, also rely on studies of Celebrex 400 mg/d to support their opinion of causation at 200 mg/d. Although Dr. Doherty acknowledges that dose matters with Celebrex, he simply takes the relative risk point estimate of APC for 400 mg/d and cuts it in half (ignoring the confidence interval) to support his opinion that Celebrex at 200 mg/d can cause a heart attack. Oct. 10 TR at 304. When the Court asked Dr. Doherty if there is anything in the scientific literature to support such primitive extrapolation, he failed to identify any scientific support for his method other than his own judgment. *Id.* at 342-43, 378-79. He also admitted that there is no way of knowing what the confidence interval is for 200 mg/d under his unique methodology. *Id.* at 340-41. Such an unscientific, untested methodology cannot support the proffered opinion of causation at 200 mg/d, especially where, as here, Dr. Doherty agrees with all the other experts that there is dose effect with Celebrex.

Plaintiffs' reliance on *In re PPA Products Liab. Litig.*, 289 F.Supp.2d 1230 (W.D.Wa.2003), to argue that causation at 200 mg/d can be inferred from the 400 mg/d data is misplaced. In the *PPA* multi-district litigation the issue was whether PPA, a drug used in cough and cold and appetite suppressant products, can cause strokes. Plaintiffs' experts' opinion that PPA can cause strokes in persons of all ages and genders was based primarily upon a study of women ages 18 to 49. *Id.* at 1235-36. While men were not excluded from the study, their participation was too low to draw any conclusions. *Id.* at 1236. The defendants argued that the evidence was therefore insufficient to support the plaintiffs' experts' opinions that PPA can cause strokes in persons of all ages and genders. *Id.* at 1244. The district court disagreed.

The court found that "it is scientifically acceptable to extrapolate the conclusions of the [study] to these sub-populations." *Id.* at 1244. As to persons older than 49, the court noted that there are no known studies that suggest that drugs get safer as persons get older; thus, it made common scientific sense to extrapolate the results of the study to persons over 49. *Id.* Plaintiffs' experts also attested to the "commonplace" practice of extrapolating between the genders based on "the historical exclusion of women from scientific studies." *Id.*

The justification for extrapolating drug effects between biologically similar demographic groups, however, does not logically extend to the argument that all doses of a compound are harmful; accordingly, plaintiffs' experts could not cite to a single piece of evidence that suggests that their experts' extrapolation is scientifically valid. To the contrary, with nearly all compounds there is usually a threshold that must be met before there is any harm; for example, even water can be harmful if consumed at certain amounts even though there is no harm at smaller amounts. Dr. Doherty claimed that the threshold for Celebrex must be 50 mg/d because that is the dose that is effective for pain relief. That "theory," however, is nothing more than Dr. Doherty's wholly untested, unpublished, and non-peer reviewed justification for his reliance on the 400 mg/d data. Moreover, the great weight of the evidence does not support the extrapolation, that is, studies show that there is no statistically significant association between Celebrex 200 mg/d and the risk of strokes or heart attacks.

***1181** Instead of citing evidence that supports such extrapolation, plaintiffs complain that the evidence of harm at 200 mg/d does not exist because Pfizer did not initiate long term randomized trials at such dose. Such a trial, known as PRECISION, is now underway, but the results will not be available for some time. Plaintiffs cite no case, however, that suggests that they can satisfy their burden of proof based on a lack of evidence; plaintiffs filed these lawsuits and plaintiffs carry the burden of proving today based on currently available scientifically valid evidence that Celebrex can cause heart attacks or strokes at 200 mg/d.

Plaintiffs have not met their burden. In so finding, the Court is relying on the evidence presented by plaintiffs; it has not considered Pfizer's own meta-analyses. And the Court's ruling is not mandated by the lack of randomized clinical trials that show an association at 200 mg/d; plaintiffs could still meet their burden in the absence of such evidence. *See Kennedy v. Collagen Corp.,* 161 F.3d 1226, 1228 (9th Cir.1998). However, the opinion of Dr. Doherty and Dr. Rymer that Celebrex 200 mg/d increases the risk of heart attacks or strokes is not based on a scientific valid methodology; instead, these experts ignore the great weight of the observational studies that contradict their conclusion and instead rely on the handful that appear to support their litigation-created opinion. As the Court explained above, their reasons for doing so are not supported by scientifically valid reasons or methodology. In the words of the Supreme Court, the "analytical gap" between the data and these experts' conclusion is simply too great to make the opinion admissible. *General Elect. Co. v. Joiner,* 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997).

B. 400 mg/d

[10] Pfizer's motion to exclude expert testimony that Celebrex 400 mg/d is capable of causing heart attacks or strokes is defeated by APC, a large, long-term, randomized, placebo-controlled, double-blind, multi-center clinical trial that was halted after 33 months because it demonstrated a statistically significant risk of heart attack, stroke, and heart failure at 400 mg/d (2.6 percent hazards ratio with a confidence interval of 1.1 to 6.1) and 800 mg/d (3.4 percent hazards ratio with a confidence interval of 1.5 to 7.9).[7] The study, co-sponsored by the National Cancer Institute and Pfizer, was designed to compare Celebrex with placebo for the prevention of colorectal adenomas (polyps). The study included a "cardiovascular safety committee" that developed guidelines to evaluate cardiovascular safety. On December 16, 2004, on the basis of the results then available as well as studies of Vioxx and Bextra, and on the recommendation of the safety committee, the APC steering committee stopped the trial. This randomized, placebo-controlled, double-blinded study with an independent committee evaluating cardiovascular endpoints is the "gold standard" of epidemiologic evidence and supports plaintiffs' experts' testimony that Celebrex at 400 mg/d is capable of causing heart attacks or strokes.

Pfizer nonetheless contends that plaintiffs' experts' opinion must be excluded because (1) APC was stopped early, and (2) its results have not been replicated by two other randomized controlled trials that evaluated Celebrex 400 mg/d: ADAPT and PreSAP.

The Court is unconvinced that plaintiffs' experts cannot base their opinions on APC because it was stopped early (after 33 ***1182** months). The APC steering committee halted the trial because the evidence of harm was so significant. To exclude reliance on such studies under these circumstances would mean the more harmful the drug the more difficult it is to prove harm. While such studies must be closely scrutinized due to their early termination, Pfizer's argument goes to the study's weight; Pfizer has not shown that it is not scientifically valid for plaintiffs' experts to rely on the results. Moreover, ADAPT and PreSAP, two studies upon which Pfizer relies, were also halted early because of the APC results.

The Court is also not persuaded that the failure of

ADAPT and PreSAP to replicate APC's results means plaintiffs' expert opinion on 400 mg/d is inadmissible. ADAPT was a randomized, placebo-controlled clinical trial designed to evaluate naproxen and Celebrex 400 mg/d (200 mg twice daily) and the prevention of Alzheimer's dementia.[8] ADAPT found a hazards ratio for Celebrex of 1.10 percent with a confidence interval of .67 to 1.79, that is, no statistically significant association. The study authors, however, cautioned that there are several limitations to their data. First, ADAPT was not designed to detect differences in cardiovascular and cerebrovascular risks and, unlike APC, it did not include a separate cardiovascular safety committee tasked solely with evaluating cardiovascular outcomes. Second, and, according to the authors, the largest limitation of the data is the small number of cardiovascular events. Third, an editorial comment accompanying the study suggests that because study participants eligible to join the trial were required to have a family history of Alzheimer's disease, it is possible the study participants' risk factors differed from the general population. The results of ADAPT need to weighed with the APC results, but ADAPT's conclusions do not make reliance on APC scientifically invalid.

The results of PreSAP, a randomized controlled study with fewer participants than ADAPT or APC, also did not replicate the APC results. PreSAP, as APC, was designed to evaluate Celebrex's effect on the occurrence of colorectal adenomas. Preliminary results from that study did not show a statistically significant increase in cv risk for patients taking Celebrex 400 mg/d, but did not exclude the possibility of a hazards ratio similar to that demonstrated by APC. In addition, PreSAP used the same independent cardiovascular safety committee as APC to assess the risk of Celebrex on adverse cv events. Accordingly, the data from both trials were synthesized to produce a combined estimate of risk of cardiovascular death, heart attack, stroke or heart failure of 1.9 with a confidence interval of 1.1 to 3.1; in other words, combining the raw data showed a statistically significant increase in risk.[9] The study authors combined APC 400 mg/d and 800 mg/d with PreSAP 400 mg/d because the confidence intervals for 400 mg/d and 800 mg/d substantially overlapped. While the weight to be given to this evidence can be argued, in light of this evidence, and the Kearney meta-analysis which found a relative risk greater than one with a confidence interval that barely crossed one, the Court cannot conclude that expert opinion that Celebrex 400 mg/d is capable of causing heart attacks and strokes is scientifically invalid.

***1183 C. Whether Celebrex Causes Heart Attacks or Strokes More Than Three Days After A Patient Stops Taking It**

Plaintiffs do not dispute that Celebrex is not capable of causing hearts attacks or strokes more than three days after a patient stops taking it and they have offered no expert opinion to the contrary. Accordingly, there is no proposed expert testimony on this issue for the Court to exclude.

D. Remaining Issues

1. Strokes

[11] The issue as to whether Celebrex is capable of causing strokes is close. Plaintiffs rely on the testimony of Dr. Rymer, a neurologist and the Medical Director of the Saint Luke's Brain and Stroke Institute at Saint Luke's Hospital in Kansas City, Missouri. She testified that the mechanism of and risk factors for throembolic strokes (excluding cardiogenic embolism) and heart attacks are the same; thus, if Celebrex causes an increased risk in heart attacks it also increases the risk of strokes. Rymer Written Direct ¶ 11-13. Dr. Rymer's testimony is supported by the published literature as nearly all studies of COX-2 inhibitors and cv risk lump strokes together with heart attacks. For example, the Kearney meta-analysis of clinical trials identified the relative risk for "serious vascular events," defined as heart attack, stroke, or vascular death. Indeed, even Pfizer's expert, Dr. Packer, considers the risk of heart attacks and strokes together, and Pfizer does not dispute Dr. Rymer's testimony as to the similar mechanism of heart attacks and strokes.

Pfizer nonetheless asserts that Dr. Rymer's testimony is inadmissible because the randomized controlled trials and observational studies that do separately report strokes and heart attacks do not suggest an association between Celebrex at any dose and strokes. Dr. Rymer explains, however, that none of the randomized controlled studies was designed to look for stroke outcomes, and strokes occur far less often than heart attacks; the studies simply were not designed to find an association or not.

While there is some epidemiologic evidence to dispute her mechanism testimony, that is, evidence that suggests that even though heart attacks and certain strokes are caused by the same mechanism Celebrex does not cause both, there is also some evidence to support her

testimony. On the current record the Court does not find that Dr. Rymer's testimony is scientifically invalid and inadmissible. *See Daubert,* 509 U.S. at 596, 113 S.Ct. 2786 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

2. Duration

[12] The Court also denies Pfizer's motion to exclude testimony that Celebrex is capable of causing heart attacks or strokes only after 33 months of continuous use. Because a statistically significant association did not appear in APC until after 33 months does not mean as a matter of scientific fact that none of the adverse cv events that occurred after a shorter duration were not caused by the patient's ingestion of Celebrex.

3. Specific Causation

Finally, Pfizer asks the Court to "exclude any opinion that Celebrex caused an individual plaintiff's heart attack or stroke absent a relative risk that exceeds 2.0." This is a question of specific causation as to particular plaintiffs; as the Court does not have before it evidence as to any specific plaintiff the Court declines to grant Pfizer's motion.

***1184 II. Plaintiffs' Motion to Exclude**

[13] Plaintiffs move to exclude the meta-analyses performed by Pfizer's experts. Plaintiffs' experts did not perform any of their own meta-analyses; instead, plaintiffs attack Pfizer's experts' methodologies. Plaintiffs' motion is denied. All of plaintiffs' arguments go to the weight a trier of fact gives to the meta-analyses. Plaintiffs have not shown that the methods employed by Pfizer's experts are not based on good science.

Plaintiffs also move to exclude Dr. Packer from testifying as to an alternative theory to the imbalance hypothesis. Dr. Packer's explanation, which accounts for the difference in outcomes between Vioxx and Celebrex, is based on increased blood pressure, a theory actually supported by plaintiffs' expert Dr. Rymer. In any event, Dr. Packer's testimony satisfies *Daubert.*

CONCLUSION

In *Daubert,* the Supreme Court held that federal judges perform a gatekeeping role, 509 U.S. at 597, 113 S.Ct. 2786, and "to do so they must satisfy themselves that scientific evidence meets a certain standard of reliability before it is admitted." *Daubert II,* 43 F.3d at 1316. Plaintiffs' expert testimony that Celebrex 200 mg/d can cause heart attacks or strokes does not meet that standard. Dr. Doherty, a clinical physician with no relevant research experience and who developed his opinion for the purpose of testifying, bases his opinion on a study that he fundamentally misunderstood, is counter to the great weight of the evidence, and, by his own admission, does not make biological sense. The Court cannot find that his opinion is good science. Dr. Rymer's 200 mg/d opinion is also not good science. She ignores all the evidence that contradicts her litigation-created conclusion and instead bases her opinion on the same cherry-picked study as Dr. Doherty, even though that study suffers from the exact same limitations that caused her to reject other studies that do not support her conclusion. She also relies on an unpublished, non-peer reviewed study that does not disclose its design or confidence intervals. If the Court's gatekeeping function means anything, it must mean that these unreliable opinions are not admissible to prove general causation at 200 mg/d.

In all other respects, and for the reasons explained above, the parties' motions are denied.

IT IS SO ORDERED.

All Citations

524 F.Supp.2d 1166, 75 Fed. R. Evid. Serv. 144

Footnotes

1 Patricia Kearney, et al., *Do selective cycol-oxygenase-2 inhibitors and traditional non-steroidal ant-inflammatory drugs increase the risk of atherothrombosis? Meta-analysis of randomized trials,* British Medical Journal 2006, June 3;

332(7553): 1302-8.

2 Patricia McGettigan, et al., *Cardiovascular Risk and Inhibition of Cyclooxygenase: A Systematic Review of the Observational Studies of Selective and Nonselective inhibitors of Cyclooxygenase 2,* JAMA 2006 Oct 4; 296(13): 633-44.

3 S. Hernandez-Diaz et al., *Non-steroidal anti-inflammatory drugs and the risk of acute myocardial infarction,* Basic Clin. Pharmacol. Toxicol. 2006 Mar; 98(3):266-274, at 270, 273.

4 Frank Andersohn, et al., *Use of First-and Second-Generation Cyclooxygenase-2-Selective Nonsteroidal Anti-inflammatory Drugs and Risk of Acute Amuyocardial Infarction,* Circulation, 2006 Apr 25; 113(16): 1950-7.

5 Gunnar H. Gislason, et al., *Risk of Death or Reincarnation Associated With the Use of Selective Cyclooxygenase-2 Inhibitors and Nonselective Nonsteroidal Anti-inflammatory Drugs After Acute Myocardial Infarction,* Circulation, 2006 June 27; 113(25): 2906-13.

6 James M. Brophy, *The coronary risk of cyclo-oxygenase-2 inhibitors in patients with a previous myocardial infarction.* Plaintiffs cited this study as being available at heart.bmj.com or at www.heartjnl. com.

7 Scott D. Solomon, et al., *Cardiovascular Risk Associated with Celecoxib in a Clinical Trial for Colorectal Adenoma Prevention,* N. Engl. J. Med.2005 Mar 17; 352(11): 1071-1080.

8 ADAPT Research Group, *Cardiovascular and Cerebrovascular Events in the Randomized, Controlled Alzheimer's Disease Anti-Inflammatory Prevention Trial (ADAPT),* PLoS Clin Trials 2006; 1(7): e33.

9 Scott D. Solomon, et al., *Effect of Celecoxib on Cardiovascular Events and Blood Pressure in Two Trials for the Prevention of Colorectal Adenomas,* Circulation, 2006 Sep 5; 114(10): 1028-35.

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Neutral
As of: August 9, 2018 2:59 PM Z

In re Bextra & Celebrex

Supreme Court of New York, New York County

January 7, 2008, Decided

762000/2006

Reporter
2008 N.Y. Misc. LEXIS 720 *; 239 N.Y.L.J. 27

In re Bextra and Celebrex

Subsequent History: Motion granted by, Dismissed by *Archibald v. Pfizer, Inc., 2009 N.Y. Misc. LEXIS 3863 (2009)*

Core Terms

Celebrex, stroke, studies, dose, cardiovascular, causation, scientific, patients, plaintiffs', inhibitors, heart attack, epidemiological, relative risk, defendants', reliability, disease, hypothesis, clinical trial, statistical, observational, parties, conclusions, clinical, exposure, causes, increased risk, drugs, confidence, randomized, imbalance

Case Summary

Procedural Posture
In joined products liability actions, defendant pharmaceutical companies made a motion to exclude certain expert testimony and opinions proposed by plaintiff patients relating to the ingestion of an arthritis medication. The patients made a motion to exclude the opinions of and meta-analyses performed by the companies' experts and to exclude the companies' first expert from testifying as to an alternative theory for the "imbalance hypothesis."

Overview
The patients took the position that the dosage of the medication, whether 200, 400, or 800 milligrams (mg), created an increased risk of heart attacks and strokes and that they had suffered cardiovascular injury from taking the medication. The court initially determined that the claim of failure to warn of dangers of which the companies knew, or with adequate testing, should have known was indistinguishable from a negligence claim. Causation in a case involving pharmaceutical personal injury was analyzed in terms of general causation as a threshold issue; as it was impossible to offer direct evidence of causation, the patients could rely on expert analyses based on statistical data. The companies had conceded the risk of taking more than 800 mg. Evidence of an increased risk at 400 mg was presented based on reliable scientific studies. However, the scientific evidence did not support the position of general causation at 200 mg as the analyses of the patients' experts of various trials and studies were inconsistent with generally accepted standards and alternative theories were insufficient to bridge the gap between a possible and a significant risk of association at 200 mg.

Outcome
The court granted the companies' motion to preclude expert testimony that the medication at 200 mg daily could cause heart attacks and strokes; however, the motion was denied as to expert testimony regarding the medication at 400 and 800 mg daily. The balance of the companies' motion to preclude was denied. The patients' motion to exclude the meta-analyses was denied. Both parties' motions regarding the imbalance hypothesis were denied.

LexisNexis® Headnotes

Evidence > Admissibility > Expert Witnesses > Daubert Standard

Evidence > Admissibility > Scientific Evidence > Standards for Admissibility

HN1[] **Expert Witnesses, Daubert Standard**

Daubert, which is based upon the Federal Rules of Evidence, has as its linchpin evidentiary reliability based upon scientific validity. A Daubert hearing, thus, determines whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts in issue. Important to this determination is the following: 1) whether the theory or technique can be tested; 2) whether it has been subjected to peer review and publication, a criterion which the court noted did not necessarily correlate with reliability; 3) submission to the scrutiny of the scientific community; 4) the known or potential rate of error; 5) the existence and maintenance of standards controlling the technique's operation; and 6) general acceptance in the relevant scientific community.

Torts > ... > Elements > Causation > General Overview

Torts > Products Liability > Types of Defects > Marketing & Warning Defects

HN2[] Elements, Causation

Failure to warn of dangers of which the manufacturers knew or with adequate testing should have known, though it may be couched in terms of strict liability, is indistinguishable from a negligence claim. Liability will not be found unless (1) the product is "defective" because it is not reasonably safe as marketed; (2) the product was used for a normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff by the exercise of reasonable care would not have both discovered the defect and apprehended its danger; and (5) the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care. Causation in toxic tort or pharmaceutical personal injury cases is analyzed in terms of general (or generic) causation as a threshold issue; then if plaintiff clears that hurdle, the court (and jury) will grapple with the issue of specific causation--whether the drug or the toxin was the cause "in fact" of the particular plaintiff's disease.

Evidence > Admissibility > Expert Witnesses > Daubert Standard

Evidence > Admissibility > Expert Witnesses

HN3[] Expert Witnesses, Daubert Standard

Where it is impossible to offer direct evidence of causation, New York law allows plaintiffs to rely on expert analyses based on statistical data to meet their burden. The admissibility and scope of expert testimony is addressed to the trial court's sound discretion. To be admissible, an expert must be qualified, and his/her opinion must be generally accepted in the relevant scientific community. General acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions.

Evidence > Admissibility > Scientific Evidence > Standards for Admissibility

HN4[] Scientific Evidence, Standards for Admissibility

A scientifically-reliable methodology to establish the relationship between an individual's disease and a specific factor suspected of causing that disease entails a three-step process: (1) a determination of the plaintiff's level of exposure to the toxin in question; (2) proof gleaned from the scientific literature that the toxin is capable of producing the illness (general causation) and at what level of exposure the toxin produces illness (i.e., the dose-response relationship); and (3) establishment of specific causation by demonstrating the probability that the toxin caused the particular plaintiff's illness, which involves weighing the possibility of other causes of the illness.

Evidence > Admissibility > Expert Witnesses > Daubert Standard

Evidence > Admissibility > Expert Witnesses > Kelly Frye Standard

HN5[] Expert Witnesses, Daubert Standard

When there is no particular novel methodology at issue for which the court needs to determine whether there is general acceptance, the inquiry is more akin to whether there is an appropriate foundation for the experts' opinions rather than whether the opinions are

admissible under Frye. The foundational inquiry shirts away from the general reliability concerns of Frye to the specific reliability of the procedures followed to generate the evidence proffered and whether they establish a foundation for the reception of the evidence at trial. The burden is on the proponent of the evidence to demonstrate the generally accepted reliability of the proffered testimony.

Evidence > Admissibility > Expert Witnesses > Daubert Standard

Evidence > Admissibility > Scientific Evidence > Standards for Admissibility

HN6 **Expert Witnesses, Daubert Standard**

Once a scientific method has been deemed accepted, an inquiry must be made as to whether the accepted method was appropriately employed in a particular case.

Torts > ... > Elements > Causation > General Overview

Torts > ... > Proof > Violations of Law > Rules & Regulations

HN7 **Elements, Causation**

Standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation.

Torts > ... > Elements > Causation > General Overview

HN8 **Elements, Causation**

A determination of whether an association exists between exposure to the agent and the disease must be based on assessment of the totality of the evidence.

Counsel: **[*1]** For the Plaintiffs: Mitchell M. Breit, Whatley, Drake, Kalkis.

For the Defendants: Chris Strongosky, DLA Piper.

Judges: Justice Kornreich

Opinion by: Kornreich

Opinion

Defendants in these joined products liability personal injury actions, Pfizer, Inc., Pharmacia Corporation, Pharmacia & Upjohn Company, G.D., Searle & Co. (formerly known as G.D. Searle LLC), and Monsanto Company (collectively "Pfizer defendants" or "defendants"), move to exclude expert testimony and opinions proposed by plaintiffs asserting claims arising from ingestion of Celebrex. Specifically, defendants ask the court to exclude the following opinions by plaintiffs' proposed experts that: (1) 200 mg of Celebrex daily causes heart attacks and strokes; (2) 400 mg of Celebrex daily causes heart attacks and strokes; (3) Celebrex causes strokes; (4) Celebrex caused any individual plaintiff's heart attack or stroke absent reliable proof of a relative risk that exceeds 2.0; (5) Celebrex causes heart attacks or strokes more than three days after a patient stops taking it; and (6) Celebrex causes heart attacks or strokes at durations of less than 33 months of continuous daily use.

Correspondingly, plaintiffs seek to exclude the opinions of and meta-analyses **[*2]** performed by Pfizer's experts Dr. Muhammad Mamdani, Dr. Milton Packer and Dr. Lee-Jen Wei. Plaintiffs also seek to exclude Dr. Packer from testifying as to an alternative theory for the "imbalance hypothesis" that plaintiffs have proposed as mechanistic evidence of general causation. For the reasons stated below, the court grants defendants' motion to preclude expert testimony that Celebrex at 200 mg daily causes heart attacks and strokes. The remaining motions are denied.

I. Background

Celebrex (known generically as Celecoxib) belongs to a general class of pain relievers known as non-steroidal, anti-inflammatory drugs ("NSAIDs"). This class of drugs contains traditional medications sold either over the counter--such as Motrin/Advil (ibuprofen), Aspirin and Aleve (naproxen)--or by prescription--such as Daypro (oxaprozin) and Voltaren (diclofenac). NSAIDs work by inhibiting cyclooxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body affecting, inter alia, blood clotting.

Traditional NSAIDs have been a longstanding treatment option for relief of chronic or acute inflammation and

pain associated with osteoarthritis, rheumatoid arthritis **[*3]** and other musculo-skeletal conditions. Traditional NSAIDs, however, have significant adverse side effects. Specifically, they greatly add to the risk of gastrointestinal perforations, ulcers and bleeds ("PUBs"). This risk is increased when high doses are ingested, which is often necessary to remedy chronic or acute inflammation and pain.

In the early 1990s, scientists discovered that the COX enzyme had two forms--COX-1 and COX-2--each of which appeared to have several distinct functions. Scientists believed that COX-1 affected the synthesis or production of prostaglandins responsible for protection of the stomach lining. Consequently, scientists hypothesized that "selective" NSAIDs designed to inhibit COX-2, but not COX-1, could offer the same pain relief as traditional NSAIDs with the reduced risk of fatal or debilitating PUBs. In addition, scientists believed that Cox-2 inhibitors might prove beneficial for the prevention or treatment of other conditions where evidence suggested that inflammation may play a causative role, such as Alzheimer's disease and certain cancers.

In light of these scientific advances, Pfizer and several other pharmaceutical companies began the development of **[*4]** "COX-2 inhibitors" or "coxibs." Thereafter, Pfizer produced Celebrex and Bextra, and Merck produced Vioxx, all COX 2 inhibitors. The Food and Drug Administration("FDA") approved Celebrex for adult arthritis in 1998, Vioxx in 1999 and Bextra in 2001. The recommended dose of Celebrex was and remains 200 milligrams a day ("mg/d") for arthritis and was 400 mg/d for rheumatoid arthritis.

Before and after its initial approval, Celebrex was subjected to a number of clinical trials and observational studies, the main sources of data analyzed by statisticians to determine the risks associated with the use of a particular compound. In clinical trials, the investigator controls organization of the comparison groups (by random selection) and administration of the exposure (here Celebrex). In an observational study, the investigator studies subjects in the community who have received an exposure through their own choice (over-the-counter medication), the actions of a healthcare provider (by prescription) or other circumstances. This method of scientific research is known as "epidemiology." Meta-analyses were conducted. A meta-analysis is a systematic technique used to quantitatively summarize and **[*5]** assess data from clinical trials and observational studies.[1] In addition to the epidemiology, a large amount of scientific literature was written on the effects of Celebrex and other COX-2 inhibitors.

The results of a long-term randomized study of Celebrex known as CLASS ("Celecoxib Long-Term Arthritis Safety Study") were published in 2000. The study was designed to evaluate the gastrointestinal side effects of taking Celebrex at 800 mg/d. Based upon investigator reported cardiovascular ("cv") events, the study showed no increased risk of, heart attack or stroke when Celebrex was compared to Diclofenac or Ibuprofen. Pfizer distributed this study widely to physicians and the medical community. After the CLASS trial was published, however, unpublished data from the trial were released. A number **[*6]** of medical articles analyzing CLASS in light of the unpublished data, found that the cv rate for Celebrex at 800 mg/d was in fact increased when compared with a placebo. See Mukherjee, et al., Risk of Cardiovascular Events Associated With Selective COX-2 Inhibitors, JAMA, 2001, 286:954-959 (MDL 1699 Exh. N); Hrachovec, et al., JAMA, 2001, 286:2398-9 (MDL 1699 Exh. O); Juni, Are Selective COX-2 Inhibitors Superior to Traditional Non-Steroidal Anti-Inflammatory Drugs?, BMJ, 2002, 324:1287-8 (MDL 1699 Exh. P); Fitzgerald, Coxibs and Cardiovascular Disease, NEJM, 2004, 351:1709-1711 (MDL 1699 Exh. Q).

Around the same time, a similar study of Vioxx, known as VIGOR, showed a four-fold increase in cv risk for patients, taking Vioxx versus Aleve (naproxen), the most benign of the NSAIDs. The FDA subsequently revised the labels of Celebrex and Vioxx to reflect the cv risk results of these studies. Another Vioxx randomized clinical study, known as APPROVe, was published in 2004. This study demonstrated a two-fold increased risk of cv adverse events for patients taking Vioxx versus a placebo. The APPROVe study contributed to Merck's voluntary removal of Vioxx from the market on September 30, 2004. **[*7]** Meantime, the Adenoma Prevention With Celecoxib Trial ("APC"), a randomized, placebo-controlled study of Celebrex at 200 mg twice daily (400 mg/d) and 400 mg twice daily (800 mg/d) to

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[1] Celebrex clinical trials referred to by the parties are: TARGET, APC, PreSAP, ADAPT, and CLASS. Celebrex observational studies referred to by the parties are: Huang, Schneeweiss, Jick, Helin-Salmivaara, Brophy, Gislason, Johnsen, Andersohn, N.S. Abraham, et al., Motsko, et al., and WellPoint, Inc. Celebrex meta-analyses referred to by the parties are: Caldwell, Chen, Kearney, McGettigan and Wei.

evaluate whether Celebrex prevents the development of colon polyps, showed dose-related increased cv risk for patients taking Celebrex compared to placebo. The cv risk for 200 mg twice daily was doubled, and the risk for 400 mg twice daily was tripled. The APC steering committee discontinued the trial in December 2004 because of these preliminary results.

In February 2005, the FDA convened two Advisory Committees and a 12-member ad hoc panel to review the data on cv risk and NSAIDs, including COX-2 inhibitors. The 32-person panel, relying on much of the same scientific and medical methodologies and data considered by the parties' experts in this litigation, was unanimous in its conclusion that Celecoxib significantly increases the risk of cardiovascular events in a dose-dependent manner. The panel concluded that COX-2 inhibitors, as a class, increase cv risk versus placebo, but that the data was insufficient to determine if traditional NSAIDs also increase cv risk. The panel gave greater weight to clinical **[*8]** trials than observational studies, commenting that the latter are considered supplemental to randomized, controlled clinical trials due to selection bias and residual confounding. The panel considered observational studies "hypothesis generating" in that they provide clues as to whether a manufacturer should conduct randomized, controlled trials. Minutes and transcript of 2/05 FDA advisory committee meeting, plaintiffs' opposition brief, Exhs 30 and 31. With respect to Celebrex, the panel noted that an excessive cv risk was likely with the 800 mg dose and probable at the 400 mg dose. Id. The panel made no finding with respect to the 200 mg dose and found that APC was the "strongest data" in support of an increased risk of serious, adverse cv events. FDA Decision Memorandum, April 6, 2005, at 4, Declaration of Loren Brown ("Brown Decl."), Exh. 16.

The committee recommended that Celecoxib be allowed to remain on the U.S. market under several conditions, such as the addition of a "black box" warning to the labeling, restrictions on direct-to-consumer advertising and the development of a patient medication guide. Assumptions included that if Celecoxib was to be used, it should be: in patients **[*9]** who have not achieved pain control with nonselective NSAIDs; used in the lowest possible dose for the shortest time necessary and with information to high-risk cardiac patients about the excess cardiovascular risks. The FDA asked Pfizer to remove Bextra from the market, but determined that the benefits of Celebrex outweigh its risks. Celebrex is the only COX-2 inhibitor currently being sold.

The FDA also directed all NSAIDs, including Celebrex, to include a black box warnings on, their labels (not dose related): "CELEBREX may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have similar risk. This risk may increase with duration of use. Patients with cardiovascular disease may be at greater risk." Bennett, et al., Use of Nonsteroidal Antiinflammatory Drugs, An Update for Clinicians: A Scientific Statement From the American Heart Association; circulation 1-9, 2007: 115 (MDL 1699 Exh. EE). The black box warning does not comment on the magnitude of the increase in risk, relative or absolute, and there is no mention of the recommendation for low doses or short duration of treatment. It contains the **[*10]** general statement that "[a]ll NSAIDs may have a similar risk," but includes no recognition of known differences among the nonselective NSAIDs. Id.[2]

Thereafter, thousands of patients and patient representatives filed lawsuits against Merck and Pfizer alleging that the patient had suffered a serious cardiovascular injury due to ingestion of Vioxx and/or Celebrex and/or Bextra. All of the Federal court claims against Merck were consolidated by the Multi-District Litigation Panel ("MDL") and transferred to the Federal District Court in New Orleans. All of the Federal court claims involving Celebrex and Bextra were consolidated in an MDL action and transferred to Judge Charles R. Breyer of the Federal District Court in San Francisco and all of the New York State Celebrex and Bextra claims were joined **[*11]** and transferred to this court. A joint Federal/ New York State hearing on general causation in the Celebrex cases was held in the District Court on October 9-11, 2007, regarding the issues raised in the instant motions. This court and Judge Breyer presided at that hearing with Judge Fern Smith, special master. On November 19, 2007, Judge Breyer issued his memorandum and order determining that plaintiffs failed to demonstrate scientifically reliable evidence that Celebrex causes heart attacks or strokes when ingested at the 200 mg/d dose. Judge Breyer denied defendants' motion to exclude opinion testimony that Celebrex causes heart attacks or strokes when

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[2] The European Medicine Agency also has issued recommendations on coxibs' use. It recommends that selective COX-2 inhibitors be considered contraindicated in patients with ischemic heart disease and/or stroke, that they be avoided in patients with risk factors for coronary heart disease and that all patients take the lowest effective dose for the shortest time necessary to control symptoms. Id

ingested at the 400 or 800 mg/d doses. In all other respects, the parties' motions were denied.[3]

II. The Parties' Positions

Plaintiffs assert that the scientific tests and literature show that Celebrex significantly increases the risk of cardiovascular thrombotic events at all doses and for all durations. Plaintiffs further contend that the underlying biological mechanism of action (the "imbalance hypothesis" or "Fitzgerald theory") not only explains why certain of the clinical trials and observational studies show a significantly increased risk of cardiovascular events, but also constitutes independent proof of general causation at any dose. Plaintiffs rely on the conclusions of six proposed **[*13]** experts, reports and opinions issued by the Food and Drug Administration ("FDA") and the American Heart Association ("AHA"), the FDA's requirement that Celebrex's label include a "black box warning" and certain clinical and observational studies which establish a significant risk of cardiovascular thrombotic events, myocardial infarction and stroke from the ingestion of Celebrex.

Four of plaintiffs' experts testified at the joint hearing. Dr. Joel S. Bennett, a hematologist and professor of pharmacology, was presented to support the opinion that Celebrex increases the risk of cardiovascular events at all doses and that causation can be shown through the underlying biological mechanism of action, the imbalance theory. Dr. Neil E. Doherty III, a clinical cardiologist, testified to his opinion that Celebrex increases the risk of cardiovascular events at all doses and at all durations. Dr. Nicholas P. Jewell, a statistician, was presented to opine that Celebrex at 200 mg/d is capable of causing a myocardial infarction ("MI"). And, plaintiffs' fourth expert to testify, Dr. Marilyn M. Rymer, a neurologist with a sub-specialty in stroke, opined that because the mechanism for ischemic stroke **[*14]** is the same as for heart attacks, data showing that Celebrex increases the risk of heart attacks also applies to strokes.

Defendants challenge the qualifications of plaintiffs' experts and the reliability of their methodologies and conclusions. Defendants' expert Dr. Milton Packer, a cardiologist and professor of clinical research, testified at the joint hearing. Additionally, defendants presented the written testimony and analyses of Muhammad Mamdani, an epidemiologist/and Professor Lee Jen-Wei, a bio-statistician, opining on the results of the many clinical trials and observational studies, which they argue show the lack of causation for stroke at any dose, the lack of causation for MIs at 200 mg or 400 mg and the lack of causation for stroke or MI at any dose absent a relative risk that exceeds 2.0. Plaintiffs characterize defendants' arguments as going to the weight and not the admissibility of plaintiffs' experts' conclusions.

III. Legal Principles

Liability here is predicated on *HN2*[↑] failure to warn of dangers of which the manufacturers knew or with adequate testing should have known. See *Wolfgruber v. Upjohn Co., 72 AD2d 59, 423 N.Y.S.2d 95*, aff'd on opn below *52 NY2d 768, 417 N.E.2d 1002, 436 N.Y.S.2d 614 (1979)*. Such a claim, though **[*15]** it may be couched in terms of strict liability, is indistinguishable from a negligence claim. Id. Accord *Enright v. Eli Lilly & Co., 77 N.Y.2d 377, 387, 570 N.E.2d 198, 568 N.Y.S.2d 550 (1991)*. Liability will not be found unless: (1) the product is "defective" because it is not reasonably safe as marketed; (2) the product was used for a normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff by the exercise of reasonable care would not have both discovered the defect and apprehended its danger; and (5) the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care. *Wolfgruber, supra at 62*. Causation in toxic tort or pharmaceutical personal injury cases is analyzed in terms of general (or generic) causation as a threshold issue; then if plaintiff clears that hurdle, the court (and jury) will grapple with the issue of specific causation--whether the drug or the toxin was the cause "in fact" of the particular plaintiff's disease. See, e.g., Mary Sue Henifin, Howard M. Kipen & Susan R. Poulter, Reference Guide on Medical Testimony, in REFERENCE MANUAL ON SCIENTIFIC

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[3] Judge Breyer made his determination using the Daubert, not the Frye, standard. See *Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*. *HN1*[↑] Daubert, which is based upon the Federal Rules of Evidence, has as its linchpin evidentiary reliability based upon scientific validity. *Daubert, id. at 588-90*. A Daubert hearing, thus, determines "whether the reasoning or methodology underlying the testimony is scientifically valid and whether **[*12]** that reasoning or methodology properly can be applied to the Facts in issue." *Id. at 592-3*. Important to this determination's the following: 1) whether the theory or technique can be tested; 2) whether it has been subjected to peer review and publication, a criterion which the Court noted did not necessarily correlate with reliability; 3) submission to the scrutiny of the scientific community; 4) the known or potential rate of error; 5) the existence and maintenance of standards controlling the technique's operation; and 6) general acceptance in the relevant scientific community. *Id. at 593-4*.

EVIDENCE 439, 444 (Fed. Jud. Ctr., 2d ed. 2000). The pending motions concern **[*16]** the issue of general causation--whether plaintiffs have met their burden of proving that Celebrex is capable of causing the types of cardiovascular injuries allegedly suffered by plaintiffs in these consolidated actions.

HN3[↑] Where, as here, it is impossible to offer direct evidence of causation, New York law allows plaintiffs to rely on expert analyses based on statistical data to meet their burden. See *Nonnon v. City of New York, 32 A.D.3d 91, 105, 819 N.Y.S.2d 705 (1st Dept. 2006)*. "The admissibility and scope of...[expert] testimony is addressed to the trial court's sound discretion." *Hudson v. Lansingburgh Cent. School Dist., 27 AD3d 1027, 1028-1029, 812 N.Y.S.2d 678 (3d Dept. 2006)*. To be admissible, an expert must be qualified and his/her opinion must be generally accepted in the relevant scientific community. *Frye v. United States, 54 App. D.C. 46, 293 F. 1013 (D.C. Cir. 1923)*. See *People v. Wesley, 83 N.Y.2d 417, 422, 423 n.2, 633 N.E.2d 451, 611 N.Y.S.2d 97 (1994)* (Court utilized Frye standard and specifically stated *Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*, was not applicable in New York); *Heckstall v. Pincus et al., 19 A.D.3d 203, 797 N.Y.S.2d 445 (1st Dept. 2005)*. "[G]eneral acceptance does not necessarily mean that a majority of the scientists involved **[*17]** subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions."[4] *Beck v. Warner-Lambert Co. (NYLJ, Sept. 13, 2002, at 18, col 2), 2002 N.Y. Misc. LEXIS 1217, 2002 NY Slip Op 40431(U)*. See *Lewin v. County of Suffolk, 18 A.D.3d 621, 622, 795 N.Y.S.2d 659 (2d Dept. 2005)* (where no scientific organization or national board had expressly recognized plaintiff's theory and peer-reviewed scientific articles and textbooks relied upon by plaintiff's experts did not establish causal relationship, expert's testimony was "fundamentally speculative" and inadmissible); *Pauling v. Orentreich Med'l. Group, 14 A.D.3d 357, 787 N.Y.S.2d 311 (1st Dept.)*, lv. denied *4 N.Y.3d 710, 830 N.E.2d 1146, 797 N.Y.S.2d 817 (2005)* (plaintiff failed to meet burden of proof at Frye hearing where no medical literature submitted to support theory and no scientific or medical board recognized causal relationship); *Marsh v. Smyth, 12 A.D.3d 307, 785 N.Y.S.2d 440(1st Dept. 2004)* (Frye test met where expert's deductions were supported by medical literature); *Saulpaugh v. Krafte, 5 A.D.3d 934, 774 N.Y.S.2d 194 (3d Dept.)*, lv. denied *3 N.Y.3d 610, 820 N.E.2d 292, 786 N.Y.S.2d 813 (2004)* (broad statement of scientific acceptance without accompanying support, insufficient **[*18]** to establish scientific acceptance of theory); *Lara v. N.Y.C. Health and Hosp. Corp., 305 A.D.2d 106, 757 N.Y.S.2d 740 (1st Dept. 2003)* (Frye test not met where no reported medical cases or formal studies supported theory); *Selig v. Pfizer, Inc., 290 A.D.2d 319, 735 N.Y.S.2d 549 (1st Dept.)*, lv. denied *98 N.Y.2d 603, 772 N.E.2d 605, 745 N.Y.S.2d 502 (2002)* (where clinical data did not support expert's theory of causal link and expert failed to set forth other scientific evidence based on accepted principles to support causal link, expert precluded).

HN5[↑] When there is "no particular novel methodology at issue for which the Court needs to determine whether there is general acceptance..., the inquiry...is more akin to whether there is an appropriate foundation for the experts' opinions, rather than whether the opinions are admissible under Frye." *Parker v. Mobil Oil Corp., 7 NY3d 434, 447, 857 N.E.2d 1114, 824 N.Y.S.2d 584 (2007)*. The foundational inquiry shirts away from the "general reliability concerns of Frye to the specific reliability of the procedures followed to generate the evidence proffered and whether they establish a foundation for the reception of the evidence at trial." *People v. Wesley, supra at 429*. Accord *People v. LeGrand, 8 N.Y.3d 449, 457, 867 N.E.2d 374, 835 N.Y.S.2d 523 (2007)*. The burden is on the proponent of the evidence to demonstrate the generally accepted reliability of the proffered testimony. *Parker, supra at 437*. Thus, plaintiffs here must show that their experts not only rely on generally **[*20]** accepted scientific principles and methodologies, but also that in arriving at their conclusions, they look at the totality of the

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[4] *HN4*[↑] A scientifically-reliable methodology to establish the relationship between an individual's disease and a specific factor suspected of causing that disease entails a three-step process: (1) a determination of the plaintiff's level of exposure to the toxin in question; (2) proof gleaned from the scientific literature that the toxin is capable of producing the illness (general causation) and at what level of exposure the toxin produces illness (i.e., the dose-response relationship); and (3) establishment of specific causation by demonstrating the probability that the toxin caused the particular plaintiff's illness, which involves weighing the possibility of other causes of the illness. *Manusco v. Consolidated Edison Co. of New York, Inc., 56 F. Supp. 2d 391, 399 (1999)*; **[*19]** *In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1131 (1995)*; *Wills v. Amerada Hess Corp., 2002 U.S. Dist. LEXIS 1546, 2002 WL 140542 (SD NY, Jan. 31, 2002)*; *Amorgianos v. National R.R. Passenger Corp., 303 F.3d 256, 268 (2002)*; *Castellow v. Chevron, 97 F. Supp. 2d 780, 795-798 (2000)*.

evidence and do not ignore contrary data. See *Selig v. Pfizer, Inc., 185 Misc.2d 600, 607, 713 N.Y.S.2d 898 (Sup. Ct. N.Y.County 2000)* (finding that expert failed to follow accepted scientific methodology by ignoring contrary clinical studies), aff'd, *290 AD.2d 319, 735 N.Y.S.2d 549 (1st Dept. 2002)*.

IV. Principles of Epidemiology

Nearly all of the scientific evidence regarding the efficacy and risk of Celebrex is derived from epidemiological sources, that is, statistical analysis of data from clinical trials and observational studies. Epidemiology is hardly novel. It is a reliable scientific methodology that focuses on the question of general causation (i.e., is the agent capable of causing disease?) rather than that of specific causation (i.e., did it cause disease in a particular individual?). Reference Guide on Epidemiology (p 336), found in the Reference Manual on Scientific Evidence (2d ed) (2000) ("the Guide"). The Guide emphasizes that "an association is not equivalent to causation" [id. (emphasis in original)], and that the question of "specific causation... [is] beyond the domain of **[*21]** the science of epidemiology." Id. at 381. The parties' experts, by and large, agree with these fundamental principles of epidemiological evaluation as related to causation.

The parties further acknowledge the method for applying these principles as explained in the Guide. Hence, an expert must first determine "whether an association exists between exposure to the agent and the disease." Id. at 348. An association must be based on an assessment of the totality of the evidence and must be statistically significant, that is, beyond the play of chance. Id. "Once an association has been found between exposure to an agent and development of a disease, researchers consider whether the association reflects a true cause-effect relationship." Id.

Epidemiologists speak in the statistical language of risks and probabilities. The risk of injury from a suspected cause is expressed as relative risk. To calculate relative risk, the number of occurrences of an illness or injury in an exposed group is divided by the number of occurrences in the control, or unaffected group. If the given illness or injury occurs with equal frequency between the exposed and control groups, the relative risk would be 1.0. **[*22]** A relative risk of 1.0 is considered inconclusive, in that a researcher cannot state that a suspected agent does or does not cause the illness or injury (i.e., the "null hypothesis" or "no association"). Id. A relative risk of less than 1.0 suggests that a suspected agent does not cause the disease. A relative risk greater than 1.0 suggests that the substance may cause a given disease.

To gauge the reliability and credibility of their reports, statisticians use a proposition known as the confidence interval. The confidence interval is not a "burden of proof" in the legal sense. Rather, it is a common sense mechanism upon which statisticians rely to confirm their findings. The confidence interval has two components--a percentage and an interval or range. The percentage portion is established by the statistician in advance of performing the studies. Frequently, this percentage is set at 95 percent, although that value is somewhat arbitrary. The interval, on the other hand, represents a range of possible values at high and low ends of a scale of relative risk. Id. See, e.g., Kenneth Rothman, Modern Epidemiology 119 (1986). At a 95 percent interval the true relative risk value will be between **[*23]** the high and low ends of the confidence interval 95 percent of the time. See Neil Cohen, Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge, *60 N.Y.U.L. Rev. 385, 398-400 (1985)* ("Confidence in Probability").

As Judge Breyer so aptly explained in his recent opinion in the Celebrex MDL litigation, "[I]f a given study showed a relative risk of 1.40 (a 40 percent increased risk of adverse events), but the 95 percent confidence interval is .8 to 1.9, we would say that we are 95 percent confident that the true value, that is, the actual relative risk, is between .8 and 1.9. Because the confidence interval includes results which do not show any increased risk, and indeed, show a decreased risk, that is, it includes values less than 1.0, we would say the study does not demonstrate a 'statistically significant' increased risk of an adverse outcome." When a study does show a relative risk where both the top and the bottom values are greater than 1.0, the study supports finding a "statistically significant" increased risk. See *In Re Silicone Gel Breast Implant Prod. Liab. Lit., 318 F.Supp.2d 879, 892 (C.D. Ca. 2004)*. Proof that a relative risk is greater than 2.0 **[*24]** is arguably relevant to the issue of specific, as opposed to general, causation and is not required for plaintiffs to meet their burden in opposing defendants' motion.

Even when an appropriately designed study yields evidence of a statistical association between a given substance and a given health outcome, epidemiologists generally do not accept such an association by itself as proof of a causal relationship between the exposure and the outcome. Epidemiologists generally look to several additional criteria to determine whether a statistical

association is indeed causal. These criteria are sometimes referred to as the Bradford Hill criteria, after the author of a leading statement of the relevant principles, which are: (1) strength of association; (2) consistency of association; (3) specificity of association; (4) temporality of the association; (5) biological plausibility; (6) coherence; (7) experimental verification; (8) biological analogy; and (9) dose-response relationship. A. Bradford Hill, The Environment and Disease: Association or Causation, 58 PROC. ROYAL SOC'Y MED. 295, 295-300 (1965).

V. Conclusions of Law

The lion's share of evidence offered by plaintiffs to carry their burden **[*25]** is comprised of epidemiological data, an established and reliable scientific field based on the gathering of data and the statistical analysis of the information. The issue before the court, therefore, is not the general acceptance of epidemiology by the relevant scientific community, but rather the challenged experts' application of the accepted scientific principles--the foundation for the experts' opinions. See *Parker, supra at 447* (***HN6***[↑] once method deemed accepted, inquiry made as to whether accepted method appropriately employed in particular case).

A. Dose

The court is in complete accord with the MDL court's conclusions that "dose matters" and that plaintiffs' experts have essentially conceded this point. MDL court's decision at p.10. As stated in the Reference Manual on Scientific Evidence, "a dose-response relationship means that the more intense the exposure, the greater the risk of disease." Ann. Ref. Man. Sci. Evid. 2d ed., 2005-06, p.531. Plaintiffs rely heavily on the Parker decision to argue that dose should not be material to this court's decision. The Court of Appeals in Parker determined that specific quantification of the dose or exposure level is not always necessary to **[*26]** find an expert opinion on causation reliable. *Parker, supra, 7 N.Y.3d at 448*. The Parker decision did not, however, distinguish between proof of general versus specific causation, but rather concluded that the proffered evidence fell short of proving either level of causation. *Id. at 449* (finding insufficient reliable proof supporting experts' conclusion that exposure to benzene as component of gasoline caused plaintiff's illness). Key to the Parker decision was the difficulty in an environmental toxin exposure case of establishing with specificity the level of toxicity in general, as well as any individual's actual exposure. Environmental toxin cases are distinguishable from pharmaceutical cases; pharmaceuticals are dose-specific. Moreover, the plaintiffs in Parker presented no epidemiological studies showing an increased risk of the plaintiff's illness as a result of exposure to the specific toxin in question. Nor was there a plethora of scientific evidence showing a lack of significant association. The exception to the general rule that dose is an important factor in assessing causation, noted in *Parker*, simply does not apply here.

B. Celebrex at 400 and 800 mg/d

Defendants rightfully **[*27]** have conceded that taking more than 800 mg/d of Celebrex for more than a brief period increases the risk of cardiovascular injury. Direct Examination of Muhammad Mamdani at p. 24 [CONCLUSION]; Direct Examination of Milton Packer at p. 8; Defendants' Motion at p. 7; Packer Hrg. Tr. at 628. The court's analysis, therefore, will focus on the more commonly prescribed doses, 200 (discussed below) and 400 mg/d. Evidence of increased risk at 400 mg/d exists. As discussed above, APC was a large, long-term, randomized, placebo-controlled, double-blind, multi-center clinical trial. It was designed by defendant Pfizer with the National Cancer Institute, to compare Celebrex with a placebo for the prevention of polyps, and it included a committee to develop guidelines and monitor cardiovascular safety. That committee stopped the trial after 33 months because it demonstrated a statistically significant risk of heart attack, stroke and heart failure at 400 mg/d (confidence interval of 1.1 to 6.1), and 800 mg/d (confidence interval of 1.5 to 7.9). People were getting hurt, and the committee made the ethical decision to stop administering the drug.

Plaintiffs' reliance on the APC results is not, as **[*28]** defendants argue, "cherry-picking." The APC trial was the only long-term trial of its size and duration to date. As defendants themselves concede, double-blind, randomized clinical trials are the "gold standard" for assessing whether an exposure is associated with an outcome. Mamdani Direct at p. 6. Although defendants note certain imperfections in APC--it was stopped early and its results have not been replicated by other randomized controlled clinical studies--these imperfections do not render APC so unreliable as to exclude it from the scientific evidence underlying the experts' opinions. Further, PreSAP, a colon polyp prevention clinical trial of Celebrex at 400 mg/d, also sponsored by the National Cancer Institute and Pfizer, was stopped early by the same safety committee that stopped APC and for the same reasons (a demonstrable risk of harm to the participants). The PreSAP trial results, when not viewed in a vacuum, did

not exclude the possibility of a risk ratio like the one found by APC. In 2006, however, a published analysis of the combined data from APC and PreSAP concluded, "Celecoxib at 200 or 400 mg twice daily showed a nearly 2-fold-increased cardiovascular risk." Solomon, **[*29]** et al., Effect of Celecoxib on Carsdiovascular Events and Blood Pressure in Two Trials for the Prevention of Colorectal Adenomas, Circulation, 2006; 114:1028-1035 (MDL 1699 Exh. L). The weight of this evidence can be debated by the parties' experts at trial, but the court will not exclude it and the opinions based on it at this preliminary stage.

Moreover, there was ADAPT, an Alzheimer's trial of Celebrex at 200 mg twice daily (400 mg/d). Although it showed no increased cv risk for Celebrex versus placebo, certain factors individual to this study suggest that the results are questionable. For example, as the American Heart Association found, the ADAPT trial had "major limitations." The trial included a very high rate of patients lost to follow-up (almost 10 percent), a large number of enrollees who did not receive their study medication, a lack of specified criteria for the cardiovascular events, no central adjudication of the reported non-fatal events and a small number of reported cardiovascular deaths, myocardial infarctions and strokes. See Use of Non-steroidal Antiinflammatory Drugs, An Update for Clinicians: A Scientific Statement From the American Heart Association; circulation **[*30]** 1-9, 2007 (MDL 1699 Exh. EE). Further, as the MDL court recognized, it is possible that the study participants' risk factors differed from the general population because their eligibility to participate hinged on a family history of Alzheimer's disease. This court agrees that "the results of ADAPT need to be weighed with the APC results, but ADAPT's conclusions do not make reliance on APC scientifically invalid." MDL opinion at p. 23. Indeed, the Kearney meta-analysis of all randomized clinical trials comparing Celebrex 400 mg/d to a placebo or naproxen, found a relative risk greater than 1.0 with a confidence interval that barely crossed 1.0. This result could be fatal to plaintiffs' case if the underlying trials were shown to be identical, as well as perfectly constructed and implemented. Alas, that was not the case. Otherwise the parties would have nothing about which to argue.

The parties, too, have presented the court with a wealth of additional materials, including published and unpublished studies, meta-analyses of studies and articles. Some appear to support plaintiffs' position and some appear to support defendants' position, depending on which set of experts is interpreting **[*31]** the results. The reliability of each of these studies was hotly debated by the parties, and the court has reviewed each study and the parties' various interpretations and conclusions. It appears that when a particular study reaches a result unsupportive of one party's position, the latter has an argument as to why that study is unreliable. Although close analysis does reveal a certain element of unreliability in some of the studies (e.g., Andersohn, discussed infra), and the relevance of certain studies is questionable for various reasons (e.g., the study was not stratified by dose, it combined Celebrex with other coxibs or it was the wrong type of study [cohort vs. case control, etc.], there is still enough evidence to admit plaintiffs' expert conclusions as to the higher doses of Celebrex, particularly as to patients with a history of cardiovascular problems or who use aspirin. E.g., APC, APC combined with PreSAP, Brophy Study, Gislason Study, Singh Study, Abraham Study, Johnsen Study. As discussed below, however, the same cannot be said for Celebrex at 200mg/d.

C. Celebrex at 200 mg/d

1. Regulatory and Industry Warnings and Opinions

To the extent that plaintiffs and their experts rely **[*32]** on conclusions reached by the FDA advisory panel, as expressed in its April 6, 2005 Decision Memorandum and related materials, their reliance is misplaced. Although the panel's conclusions were reached after a review of scientifically reliable data, the conclusions themselves do not address the issue of whether 200 mg/d of celebrex is capable of causing heart attacks and strokes. The FDA's advisory panel reviewed a large body of data: an internal survey by the FDA's Center for Drug Evaluation and Research of available data regarding the cardiovascular safety issues for COX-2 inhibitors and NSAIDs; the regulatory histories, New Drug Applications, and post-marketing databases of the various NSAIDs; FDA and sponsor background documents prepared for the advisory committee meeting; all the materials, data and presentations of interested parties; and the results of the numerous clinical trials and epidemiological studies concerning NSAIDs. Yet, neither the panel nor the FDA concluded from the plethora of materials, that 200 mg/d of Celebrex poses a significant cv risk. Nor is the Black Box Warning required by the FDA on all marketed Celebrex (200 mg/d being the commonly prescribed dose) **[*33]** dose specific. It speaks only of a possible increase in risk for people with heart disease.

Plaintiffs and their experts also rely on the warnings of the American Heart Association, as expressed in the

Guidelines on coxib use they issued in 2005 and the Update they issued in 2007, co-authored by plaintiffs' expert Dr. Joel S. Bennet.[5] Although the court finds the recommendations and analyses of both the FDA advisory panel (comprised of prestigious scientists and scientific organizations) and the AHA persuasive, they do not establish the necessary causative link. As the court in Parker recognized, "[S]tandards*HN7*[↑] promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation." *7 N.Y.3d at 450*.

2. Epidemiological Evidence

The scientific evidence does not support plaintiffs' position of general causation at 200 mg/d. Plaintiffs' experts' analyses of the various trials and studies, in key respects, are inconsistent with generally accepted standards, **[*34]** and their alternative theories are insufficient to bridge the considerable gap between a possible and a significant risk of association at 200 mg/d. The court wants to emphasize that its decision is based on the statistical evidence presented by plaintiffs, which represents the evidence known to date on the toxic effects of Celebrex. As repeatedly noted by plaintiffs, that evidence does not include long-term, randomized clinical trials at the 200 mg/d dose. [6] Future studies, such as the PRECISION trial, might yield different results. However, the instant motions must be decided on the science and data available today.

To begin, the meta analyses do not support causation at 200 mg/d. A meta-analysis cited by all of the experts ("Kearney meta-analysis") included published and unpublished tabular data from 138 randomized trials (145,373 patients) comparing COX-2 inhibitors either to placebo or to a traditional NSAIDs. Patricia Kearney, et al., Do selective cycol-oxygenase-2 inhibitors and traditional nonsteroidal **[*35]** antinflammatory drugs increase the risk of atherothrombosis? Meta-analysis of randomized trials, British Medical Journal 2006. See Direct Examination of Dr. Milton Packer, Exh. 7. The Kearney meta-analysis included information on myocardial infarction, stroke and vascular death rates in patients treated with Celebrex, and it combined the particular doses. At 200 mg/d the mean was below 1.0, which indicates lack of a significant risk at that dose. The study concluded, "Overall, we found no significant difference in the incidence of a serious vascular events between selective COX-2 inhibitors and traditional NSAIDs." Id.

Similarly, a meta-analysis of 11 observational studies of patients taking Celebrex at doses commonly used in the community that was conducted by Patricia McGettigan, the most comprehensive analysis of Celebrex observational studies published to date, showed that while Vioxx increased the risk of adverse cv events, Celebrex as compared to Naproxen, did not. McGettigan, et al., JAMA 2006; 296:1633-44 [Brown Aff., Exh. 38]. See Bennett Deposition at 249-50, 515-16, 572-73; Moye Bibliography, Ref. 100 [Brown Aff., Exh. 39]; Rymer Deposition at 337; Bennett Hrg. Tr. at 165. **[*36]** Dr. Wei's meta-analysis is consistent with these meta-analyses.

Moreover, out of 32 studies (29 published) cited by defendants, plaintiffs chose only 8 to plead their case. This smacks of "cherry-picking", skewing their analysis by only looking at the helpful studies. Such practice contradicts the accepted method for an expert's analysis of epidemiological data. As explained in the Guide (cited supra at 348), *HN8*[↑] determination of "whether an association exists between exposure to the agent and the disease" must be based on assessment of the totality of the evidence. Adding insult to injury, of the 8 studies plaintiffs cite, 2 do not provide any analysis stratified by dose (Johnsen and Helin-Salmivaara). Consequently, plaintiffs' experts cannot rely on them as a sufficient foundation for their opinions regarding 200 mg/d.

Three of the studies did evaluate the relation of Celecoxib dose to cardiovascular event, and in that regard, they have greater relevance. Nonetheless, on closer scrutiny, these studies do not hold up. The Brophy, et al. study, published on line in 2006 and in hard copy in 2007 (MDL 1699 Exh. W), found a significant risk for patients with a history of myocardial infarction **[*37]** (95 percent CI: 1.06 to 1.84) and no significant risk for patients with no such history (95 percent CI: 0.88 to 1.20). The finding with respect to patients with a prior MI history, however, was limited to those using higher doses of Celebrex, AE200 mg/d (95 percent CI: 1.00 to 2.54). Two studies by Andersohn, et al. (MDL 1699 Exh. S) showed a significant risk of MI for patients taking low and high doses of Celebrex, but the findings are questionable. They suggested an increased

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[5] Interestingly, Dr. Bennett conceded at the hearing that he could not say that at 200mg/d, the preponderance of clinical evidence suggests celebrex is associated with cv events (Bennett Hrg. Tr. at 166-167).

[6] The court cannot help but recognize at this juncture, that plaintiffs claim that ingestion of Celebrex at any duration increases cv events. Thus, short term studies are relevent.

risk only where patients took the drug for less than 3 months, not for longer durations, a finding contrary to the standard warning accompanying the marketed product. Additionally, the second Anderson study, which focused on patients who had experienced a schemetic stroke, found no increased risk associated with Celebrex as a function of dose or duration. Then too, Anderson involved only 15 events. All of the experts emphasized that the fewer the events, the less reliable the study results.

Another study completed in 2006 by Gislason (MDL 1699 Exh. X) and cited by plaintiffs, used two study designs which yielded contradictory results. Data analyzed using the first design did find a significant risk in patients **[*38]** with a history of cv problems, but data analyzed using the case-crossover design, an analysis employed to compensate for confounders, showed no significant risk associated with use of Celebrex at low doses. Furthermore, the study did not control for smoking or aspirin use, both acknowledged confounding factors, and involved only 6 events.

Finally, plaintiffs rely on an unpublished, non-peer reviewed study from a managed care organization ("the Wellpoint Report"). However, the Wellpoint Report combined all doses of Celebrex and failed to account for critical confounding factors such as smoking. Rymer, Hrg. Tr. 512-519, 544-546. As the MDL court observed in its opinion, "[I]t is thus unsurprising that most of plaintiffs' experts agree that the available evidence at 200 mg/d is inadequate to prove causation." MDL opinion at p. 12; Hrg Tr. at 159:1-11, 166:8-167:19 [Bennett]; Bennett Depo. at 92-93; 537 [Brown Reply Aff., Exh. 108]; Wright Depo. at 82-83, 92 [Brown Reply Aff., Exh. 106]; Moye Depo. at 268 [Brown Reply Aff., Exh. 109]; Jewell Depo. at 130-31 [Brown Reply Aff., Exh. 110]. See Jewell Hrg. Tr. At 412, 417, 418, 422.

3. Other Arguments

Plaintiffs seek to fill the statistical gap **[*39]** by making the following arguments: (1) You can extrapolate from statistical results for higher doses of Celebrex (400 ansd 800 mg/d) or for other COX-2 drugs (Vioxx and Bextra); (2) Dose is not dispositive because COX-2 drugs "as a class" significantly increase the risk of thrombotic events; and (3) The underlying biological mechanism of action, the imbalance theory, independently establishes a significant risk of thrombotic events. The court will address these arguments in the context of discussing the qualifications and opinions of particular experts.

Dr. Neil Doherty

Plaintiffs' cardiology expert Dr. Neil Doherty is simply not qualified to draw expert conclusions based on the use of epidemiological evidence. He is a clinical cardiologist who sees patients 98 percent of his physician time. He does not have any specialized epidemiology training. He has not published any research since 1992, and his 13 publications are unrelated to the subject matter of these lawsuits. He has never participated in an observational study of any kind, had not designed a clinical trial since 1977 while a student, and his testimony displayed his lack of experience regarding epidemiological principles and **[*40]** terminology. Doherty, Hrg Tr at 32S-357. [7]

Doherty's testimony also conflicted with that of plaintiffs' other experts in key respects. At his deposition, Doherty identified the heart attack portion of the Andersohn study as the "strongest" evidence of risk at 200 mg/d, even though that portion of the study failed to adjust for confounding factors such as aspirin use and the severity of heart disease. Doherty later contradicted himself and testified at the hearing that studies should adjust for heart disease, which was consistent with the testimony of plaintiffs' stroke expert Dr. Rymer, who criticized the stroke portion of the Andersohn study for its failure to adjust for aspirin use. Andersohn, et al. STROKE 2006; 37:1725-1730, at 1727; Doherty Rep. at 8; Doherty, Hrg Tr at 322:6-9; Rymer Written Direct Examination P34. Although Doherty had based his expert opinion primarily

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[7] For example, during Doherty's deposition he was unable to explain the difference between a cohort study and a case control study, the two main types of observational studies. He, then, managed to deliver a scholarly response at the joint hearing, showing that his education on this subject had occurred between the time of his deposition and the hearing. Doherty, Hrg Tr at 348-355. A cohort study identifies patients who are taking the drug and those who are not, them follows both groups for a certain amount of time to determine if they have the alleged bad outcome, which in this case could be a cardiovascular problem of some kind. The study then compares the rate of bad outcomes in both groups to compute the "relative risk." See Federal Judicial Center, Reference Manual on Scientific Evidence 338-340 (2d ed. 2000), cited supra. A control study identifies people who had a cardiovascular problem, then reviews their medical records to determine how many of them were taking the drug around the time their problem manifested. The study then identifies an equal number of people who did not have a cardiovascular problem and determines how many of them **[*41]** were taking the drug. An "odds ratio" is then computed from the data, and if it is 1.0, then it means that the percentage of people taking Celebrex in both groups is the same, or that taking Celebrex did not increase their risk of a cardiovascular problem. Id.

on the Andersohn study, he incorrectly identified it as a "cohort" study and insisted that the **[*42]** analysis used by that study was a "cox proportional analysis," the one.most commonly used for cohort studies. As the MDL court noted, the Andersohn study was instead a "case control study nested within a cohort study," and it used a "logistic regression" analysis. MDL decision at pp. 15-16. Doherty's lapses are more than minor faux pas; they reveal a fundamental flaw in his ability to reliably analyze epidemiological information. What is more, Doherty apparently became interested in Celebrex and its possible association with cv risk after he was retained by plaintiffs in this litigation, well after the connection between COX-2 inhibitors and adverse cv events became an issue of public concern.

Doherty (and Dr. Rymer to some degree) sought to overcome the lack of direct statistical evidence by arguing that you can extrapolate general causation at 200 mg by looking at the results of trials and studies involving 400 and 800 mg/d. Doherty's rationale for this theory is just another example of his lack of scientific experience and expertise. He testified that you can take the relative risk point for 400 mg/d and just cut it in half, ignoring the confidence interval; he failed to identify **[*43]** any scientific support for this theory. Doherty, Hrg. Tr. at pp. 304, 340-343, 378-79. Nor did plaintiffs provide any scientific or other support for Doherty's theory, which is contradicted by the evidence developed to date showing no significant risk of association between 200 mg/d of Celebrex and cv problems.

For all of these reasons, Doherty is excluded as an expert witness for plaintiffs on the issue of general causation. If, however, the plaintiffs wish to call him as a clinical cardiologist to establish specific causation of a particular plaintiff's cv problems and his testimony is relevant to the underlying biological mechanism of disease (not the imbalance hypothesis), then the court will consider whether to allow such testimony at the appropriate time.

Dr. Joel S. Bennett

Dr. Joel S. Bennett, a Hematologist and Professor of Pharmacology, testified to his opinion to a reasonable degree of medical certainty that Celebrex increases the risk of cardiovascular events. Dr. Bennett is eminently qualified to testify as an expert regarding the thrombotic risks associated with taking Celebrex, both from a mechanistic and epidemiological standpoint. Although he is neither a cardiologist **[*44]** nor a statistician, he has abundant experience working with the relevant scientific concept and COX-2 inhibitors, including Celebrex. He has authored a plethora of published journal articles, texts, chapters, editorials and abstracts, has received numerous awards, including in the area of cardiology, has lectured extensively, and is jointly board certified in both Internal Medicine and Hematology. He is a member of numerous national societies, including the American Heart Association (AHA). His accomplishments are impressive, and include his co-authoring an article for the AHA entitled, Use of Nonsteroidal Antiinflammatory Drugs, An Update for Clinicians: A Scientific Statement From the American Heart Association; circulation 1-9, 2007: 115 (MDL 1699 Exh. EE). Prior to publication of that Update, which was issued by the AHA to guide physicians in their recommendations about the use of NSAIDS, including Celecoxib, he was also a co-author of a 2005 Advisory from the AHA on the use of NSAIDS. The Use of Nonsteroidal Anti-Inflammatory Drugs (NSAIDS):A Science Advisory from the American Heart Association; Circulation; 111:1713-1716, 2005 (MDL Exh. 41).

As a result, Dr. Bennett's testimony **[*45]** that the clinical evidence does not demonstrate a significant risk of Celebrex at 200 mg/d increasing cardiovascular risk on a population basis, is compelling. Bennett Hrg. Tr. at 159, 166-7. [8] He explicitly stated that he was not testifying to causation (id. at 160) and refused to testify that Celebrex at 200mg/d could be a causative factor. Id. at 161. Nevertheless, Dr. Bennett testified that regardless of the statistical results, the underlying biological mechanism of action (the "imbalance hypothesis" or the "Fitzgerald theory"), could be a risk factor contributing to the causation of cardiovascular problems in a given patient. Id. at 159-161. Dr. Bennett explained the hypothesis, which was originally developed by Dr. Garrett Fitzgerald. In essence, the hypothesis asserts that COX-2 inhibitors as a class, inhibit the COX-2 enzyme, thereby, preventing the cells in arteries from making prostacyclin (an anti-clotting agent) and making them more reactive to "aggregates" like thrombaxane, which promote clotting. Hence, the hypothesis posits, the resulting imbalance could increase the risk of a thrombus (clot) occurring when plaque ruptures, causing blood flow to the heart or brain to **[*46]** cease. Id. at 100-160, 203. See Gunnar H. Gislason, et al., Risk of Death or Reincarnation Associated With the Use of Selective Cyclooxygenase-2 Inhibitors and Nonselective Nonsteroidal

[8] Dr. Jewell also testified that the statistical evidence does not show an increased risk at 200 mg/d (Jewell Hrg. Tr. at 412, 417, 418, 422).

Antiinflammatory Drugs After Acute Myocardial Infarction, Circulation, 2006 June 27; 113(25): 2906-13.

The court is troubled by Dr. Bennett's testimony that the theory is premised on a biological effect of COX-2 inhibitors as a class, instead of identifying the effect of specific COX-2s, since he also testified that Vioxx, Celebrex and Bextra "are different drugs, and they are different biochemically" (id. at 123:2-3), and he explained that biochemical differences in drugs relate to different potencies. Id. at 123:23-25. Accordingly, any use of this theory to establish causation would have to be tailored to Celebrex, as opposed to a different COX-2 or Cox-2s in general. More important, Dr. Bennett testified, "An hypothesis is an idea that leads to experimentation so you can derive Facts." Id. at 217. The Facts derived from experimentation, here, do not support the **[*47]** hypothesis that Celebrex at 200mg/d causes cv events. As explained supra, there is insufficient statistical evidence to support any conclusion that Celebrex is capable of causing cv problems at 200 mg/d. So, at least with respect to that category of cases, the Fitzgerald Hypothesis is irrelevant. Without proof of an association, the hypothesis is inadmissible.

Dr. Marilyn M. Rymer

Dr. Rymer, plaintiffs' stroke expert, is a Professor of Medicine at UMKC School of Medicine and Medical Director for the Brain Stroke Institute in Kansas City, one of the prominent stroke programs in the country. She is a Fellow of the American Heart Association, author of the stroke center handbook and of the Stroke Atlas and served as an expert consultant to Pfizer on stroke. She opined, to a reasonable degree of medical certainty, that: (1) because the mechanism for ischemic stroke (not the "imbalance" theory) is the same as for heart attacks, data showing that Celebrex increases the risk of heart attacks also applies to ischemic strokes (Rymer Hrg. Tr. at 482:16-25, 485:13-22.); (2) the mechanism of COX-2 inhibitors, including Celebrex, causes strokes and other cardiovascular events by increasing thrombogenesis **[*48]** due to an increase in prostacyclin synthesis (the imbalance effect) (id. at 485:23-486:5.); and 3) the increase in blood pressure caused by all NSAIDs, but particularly Cox 2 inhibitors, increases the risk of small vessel disease strokes. Id. at 488-9, 491.

The court rejects defendants' argument that Dr. Rymer is unqualified to testify about observational studies. Although a large part of her work has involved clinical trials, she has devised and worked with observational studies involving patients in her institute's stroke database (id. at 467:25-472:4.) and is intimately familiar with the review and analysis of epidemiological evidence. Her specific opinions regarding the toxic effect of Celebrex on stroke pose greater difficulty.

None of the studies or trials that were done were adequately designed or powered to specifically detect stroke. Id. at 521-522. However, as the MDL court concluded, "[N]early all studies of COX-2 inhibitors and cv risk lump strokes together with heart attacks." MDL Opinion at p. 24. Moreover, Dr. Rymer testified that the underlying mechanism for ischemic stroke (blockage of blood flow) is the same as for heart attacks and that people at risk for heart attacks **[*49]** are equally at risk for ischemic stroke. Id. at pp. 481-485, 534-535, 547-551. Further, she testified that hypertension and a rise in blood pressure, a side effect of NSAIDs, is a cause of stroke, particularly small vessel disease stroke. Defendants have not presented the court with any evidence to conclude "there is a generally or widely held view in the scientific community rejecting . . . [Dr. Rymer's] conclusions outright." *Marso v. Novak, 42 A.D.3d 377, 378, 840 N.Y.S.2d 53 (1st Dept. 2007)*. Without definitive scientific proof to the contrary, the court is not prepared to exclude expert testimony finding that Celebrex at doses of 400 mg/d or greater is capable of causing ischemic stroke. On the other hand, with regard to Celebrex at 200mg/d, the scientific evidence, whether for heart attack or stroke, is just not there. Dr. Rymer's reliance on Wellpoint, an unpublished study which did not adjust for major confounders such as smoking and did not distinguish between dose, is to no avail.

4. Remaining Issues

Defendants' seek to exclude any opinion that Celebrex is capable of causing cv events more than three days after a patient stops taking it. This point is not in dispute, and there was no related expert **[*50]** testimony proffered. Consequently, such opinion testimony is precluded. The court, however, denies defendants' motion to exclude any opinion that Celebrex is capable of causing cv events when taken continuously for less than 33 months. The APC trial was ended at 33 months because patients were getting hurt. There is simply no scientific correlation between the 33 month period and the onset of cv problems.

Moreover, the court denies plaintiffs' motion to preclude the testimony of defendants' expert Dr. Milton Packer. Dr. Packer is a cardiologist who has spent his career to date researching the mechanisms of action, and

evaluating the efficacy and safety, of cardiovascular drugs. He has held many leadership positions in the cardiovascular field and received prestigious academic appointments. Dr. Packer is currently the Chair of the Department of Clinical Sciences at the University of Texas Southwestern Medical school, where he also holds the Gayle and Paul Stoffel Distinguished Chair in cardiology and leads a Master's program educating and training physicians on designing, analyzing and interpreting clinical research studies. He has authored nearly 300 papers, articles, reviews, book **[*51]** chapters and other reference materials that have been published in peer-reviewed journals and other scientific venues and has presented to the FDA on the principles and methods of interpreting clinica research studies.

Dr. Packer disputes the validity and relevance of the Fitzgerald "imbalance hypothesis." In brief, Dr. Packer contends that the hypothesis has not been accepted in the scientific community since it has not been clinically proven. Packer, Written Direct at 23. Further, he raises serious concerns about the validity and reliability of the "imbalance" hypothesis grounded in the lack of scientific evidence and medical testimony regarding prostacycline, thromboxane and hypertension. Given his credentials and the scientific bases for his opinions, Dr. Packer's testimony may come in to refute plaintiffs' imbalance hypothesis.

Plaintiffs' motion to exclude the meta-analyses of defendants' experts, also, is denied. Plaintiffs' objections go to the weight of these experts' analyses and testimony, and not their admissibility. Finally, at this juncture, the court denies defendants' motion to preclude evidence of specific causation absent a relative risk that exceeds 2.0. The hearing **[*52]** was concerned with general causation alone. Accordingly, it is

ORDERED that the Pfizer defendants' motion to exclude the opinion by plaintiffs' experts that 200 mg of Celebrex daily is capable of causing cardiovascular injury is granted; and it is further

ORDERED the Pfizer defendants' motion to exclude the opinion by plaintiffs' experts that 400 mg of Celebrex daily is capable of causing cardiovascular injury is denied; and it is further

ORDERED that the Pfizer defendants' motion to exclude the opinion by plaintiffs' experts that 800 mg of Celebrex daily is capable of causing cardiovascular injury is denied; and it is further

ORDERED that the Pfizer defendants' motion to exclude the opinion by plaintiffs' experts that absent reliable proof of a relative risk that exceeds 2.0, Celebrex is capable of causing any individual plaintiff's cardiovascular injury, is denied without prejudice; and it is further

ORDERED that the Pfizer defendants' motion to exclude the opinion by plaintiffs' experts that Celebrex causes heart attacks or strokes at durations of less than 33 months of continuous daily use is denied; and it is further

ORDERED that plaintiffs' motion to exclude the meta-analyses of defendants' **[*53]** experts is denied; and it is further

ORDERED that the parties' motions to exclude testimony both supporting and refuting the imbalance hypothesis is denied.

End of Document

2010 WL 1047618

This decision was reviewed by West editorial staff and not assigned editorial enhancements.

United States District Court,
S.D. New York.

IN RE PFIZER INC. SECURITIES LITIGATION.

Nos. 04 Civ. 9866(LTS)(JLC), 05 md 1688(LTS).
|
March 22, 2010.
|
As Amended March 29, 2010.

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OPINION AND ORDER

LAURA TAYLOR SWAIN, District Judge.

***1** The above-captioned putative class action litigation has been consolidated for pretrial purposes in the Southern District of New York pursuant to the June 21, 2005, order of the Judicial Panel on Multidistrict Litigation. The member actions share factual questions arising from allegations that Pfizer, Inc. ("Pfizer"), and other named defendants violated federal and state securities laws and committed fraud by misrepresenting and/or concealing the safety risks of Pfizer's COX–2 inhibitor drugs, Celebrex and Bextra.

Pending before this Court are Plaintiffs'[1] and Defendants'[2] motions to preclude from introduction into evidence in the above-captioned matter pursuant to Federal Rules of Evidence 702 and 104(a) the testimony of certain experts regarding the cardiovascular risk[3] associated with Celebrex and/or Bextra. Plaintiffs move to preclude the testimony of Defendants' expert Lee–Jen Wei, Ph.D. ("Dr.Wei"). Defendants move to preclude the testimony of Plaintiffs' experts David Madigan, Ph.D. ("Dr.Madigan"), Curt D. Furberg, M.D., Ph.D. ("Dr.Furberg"), Richard A. Kronmal, Ph.D. ("Dr.Kronmal"), Lawrence Baruch, M.D. ("Dr.Baruch"), Joel S. Bennett, M.D. ("Dr.Bennett"), and Nicholas P. Jewell, Ph.D. ("Dr.Jewell"). For the reasons stated below, both motions are denied.

BACKGROUND

Plaintiffs allege that Defendants violated federal and state securities laws and committed common-law fraud by concealing the results of various medical studies concerning two Pfizer drugs, Celebrex and Bextra, and by making misstatements and omissions in their public filings and statements. The surviving allegations and issues in this litigation are summarized in the Court's July 1, 2008, Opinion and Order (docket entry no. 90) concerning Defendants' motion to dismiss the Complaint, familiarity with which is presumed.

At Defendants' request and pursuant to this Court's January 12, 2009, order, a hearing was set "to determine whether, on or before December 17, 2004, there was reliable scientific evidence that Celebrex or Bextra was associated with increased cardiovascular risk (the *Daubert* hearing)." Following the submission of expert reports and the deposition of the experts at issue, both parties filed motions (docket entry nos. 139 and 144) to preclude expert testimony, together with voluminous exhibits. These motions were fully briefed on September 25, 2009. In late October 2009, the Court held a five-day *Daubert* hearing which included thorough direct and cross-examination of certain experts, the use of demonstrative exhibits, and the submission of extensive written direct testimony. Following the conclusion of the *Daubert* hearing, the Court ordered both parties

to file supplemental submissions. These post-hearing submissions and all responses thereto were filed on January 8, 2010. The Court has listened carefully to all of the hearing testimony and has reviewed thoroughly the parties' written submissions, documentary evidence, and demonstratives. Readers' familiarity with that record is presumed. For the reasons that follow, both parties' motions to preclude expert testimony are denied.

DISCUSSION

***2** Federal Rule of Evidence 702 provides that, "[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." (West 2006). Preliminary questions of admissibility are determined by the court. Fed.R.Civ.P. 104(a). Where, as here, the admissibility of expert scientific or technical testimony is challenged, the proponent of the evidence must demonstrate admissibility to the satisfaction of the Court under Rule 104(a) by establishing scientific or technical reliability by a preponderance of the evidence. *See Bourjaily v. United States,* 483 U.S. 171, 175–76, 107 S.Ct. 2775, 97 L.Ed.2d 144 (1987); *Falise v. Am. Tobacco Co.,* 258 F.Supp.2d 63, 66 (E.D.N.Y.2000). The determination as to whether proffered scientific or technical evidence will "assist the trier of fact to understand the evidence or to determine a fact in issue" is in essence a question of the relevance, or "fit," of the proffered evidence. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 590, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Evidence is relevant when it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed.R.Evid. 401 (West 2006). The Court must determine whether the proffered testimony has a sufficiently "reliable foundation" to permit its consideration. *Daubert,* 509 U.S. at 597.

Rule 702 specifically requires examination of the qualifications of the proffered expert to testify to pertinent scientific knowledge, whether the facts or data upon which the expert relies are sufficient, whether the methodology employed is valid and whether its application by the expert in formulating the testimony is proper. *Id.* at 592–93.

In *Daubert,* the Supreme Court held that the trial judge's "gatekeeping responsibility" requires the court to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589. The *Daubert* Court identified a number of factors that, while not constituting a "definitive checklist or test," could be considered by a district court in evaluating the reliability of a proffered expert: "whether a theory or technique had been and could be tested, whether it had been subjected to peer review, what its error rate was, and whether scientific standards existed to govern the theory or technique's application or operation." *Nimely v. City of New York,* 414 F.3d 381, 396 (2d Cir.2005) (citing *Daubert,* 509 U.S. at 593–94). The trial judge should "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). "[T]he law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id.* at 142; *see also id.* at 141 ("[A]s the Court stated in *Daubert,* the test of reliability is 'flexible,' and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case."). Questions of credibility generally do not render an expert's testimony inadmissible. *See Daubert,* 509 U.S. at 596; *Hemmings v. Tidyman's, Inc.,* 285 F.3d 1174, 1188 (9th Cir.2002). Nor should district courts prejudge the weight of conflicting evidence or substitute the judgment of the court for that of the jury. *See In re Joint E. & S. Dist. Asbestos Litig.,* 52 F.3d 1124, 1133 (2d Cir.1995).

***3** Here, Defendants challenge the admissibility of testimony by six individuals trained in medicine and/or statistics proffered by Plaintiffs as evidence of increased cardiovascular risk associated with Celebrex and Bextra prior to December 17, 2004. The Court, having reviewed

carefully the record, is persuaded that Plaintiffs have carried their burden of demonstrating that each of their challenged witnesses is possessed of the requisite qualifications to testify as to his respective opinion regarding the interpretation of clinical trials and/or analysis and interpretation of data.

Defendants contend, among other things, that Plaintiffs' proffered evidence that there was reliable scientific evidence prior to December 17, 2004, that Celebrex and Bextra were associated with increased cardiovascular risk is inadmissible because Plaintiffs' experts have defined cardiovascular risk too broadly and/or inconsistently, and have not presented evidence of statistically significant indicia of thromboembolic risk. As noted above (*see* footnote 3), this argument is inconsistent with Defendants' own articulation of the subject matter of the hearing. It bears noting that this *Daubert* process was initiated at an early juncture in the case, prior to significant discovery and prior to the preparation of the opinions proffered here, at Defendants' request. Defendants cannot now be heard to complain that Plaintiffs failed to tailor their opinions to a view of the issues that Defendants chose not to share until after the opinions had been formulated. Nor is the use of the term "cardiovascular" or attention to non-thromboembolic cardiovascular issues inconsistent with claims in the complaint or, indeed, with a number of statements by Defendants that are quoted in the complaint and challenged as misleading. (*See, e.g.*, Compl. ¶¶ 41, 74–75, 84–87, 90–94, 111, 118–19, 127–29, 144, 169.) The ultimate issues for the fact finder in this litigation do not involve medical causation of injuries but, rather, include whether Pfizer should have disclosed certain information it had earlier than it did, and whether the undisclosed information rendered misleading Defendants' public representations as to the existence of cause for concern about the safety of the two drugs.

Furthermore, Plaintiffs have demonstrated, by competent, credible testimony, that the non-thromboembolic "endpoints" utilized in their analyses of pre-December 2004 Pfizer study data are derived from scientific principles of sufficient validity and/or from Pfizer's own analytical methods. The record is sufficient to demonstrate the relevance of evidence of the associations identified in Plaintiffs' evidentiary proffers and thus to render Defendants' thromboembolic association arguments ones that go to the weight, rather than to the admissibility, of Plaintiffs' evidence.

The Court has considered carefully the record and all of Defendants' other arguments concerning the admissibility of the challenged testimony and finds that Plaintiffs have met their Rule 702 burden with respect to each of the challenged proffers. The Court's principal conclusions with respect to each of Plaintiffs' witnesses are summarized below.

***4** The Court concludes further that Defendants have carried their Rule 702 burden with respect to the proffered rebuttal testimony of Dr. Lee–Jen Wei, principally for the reasons summarized below.

Dr. Madigan

Dr. David Madigan holds a doctorate in statistics, and is currently Professor in and Chair of the Department of Statistics at Columbia University. Dr. Madigan has taught and published extensively in the field of statistics. He has served as Director of Rutgers University's Rutgers Institute of Biostatistics and currently serves as an editor of a peer-reviewed academic statistics journal, *Statistical Science.* Dr. Madigan has consulted for various pharmaceutical companies and otherwise applied his scientific training to questions of drug safety and public health. Dr. Madigan opines as to the import of a meta-analysis he performed on data that was in existence during the relevant period to determine its significance with respect to the cardiovascular safety of Celebrex. Dr. Madigan's credentials as a statistician amply qualify him to testify as an expert with respect to his interpretation of the data he analyzed. Plaintiffs have met their burden with respect to the qualifications of Dr. Madigan.

Dr. Madigan's written submissions and testimony described clearly and justified cogently his statistical methods, selection of endpoints, decisions regarding event classification, sources of data, as well as the conclusions he drew from his analysis. Indeed, Dr. Madigan's meta-analysis was based largely on data and endpoints developed by Pfizer. All four of the endpoints that Dr. Madigan used in his analysis—Hard CHD, Myocardial Thromboembolic Events, Cardiovascular Thromboembolic Events, and CV Mortality—have been

employed by Pfizer in its own research and analysis. The use of Hard CHD in the relevant literature combined with the use of the other three endpoints by Pfizer in its own 2005 meta-analysis will assist the trier of fact in determining Pfizer's knowledge and understanding of the pre-December 17, 2004, cardiovascular safety profile of Celebrex. The assistance Dr. Madigan received from Dr. Lawrence Baruch, a practicing cardiologist whose qualifications are discussed *infra,* and Dr. Curt Furberg, a prominent cardiovascular epidemiology researcher whose qualifications are discussed *infra,* in the classification of deaths that occurred in the studies he reviewed was appropriate given that Dr. Madigan's own training is not in medicine. Any weaknesses in the classification of fatal adverse events made by Dr. Baruch and Dr. Furberg were attributable to the limitations of the data created by and, later in the context of litigation, produced by Pfizer. Given that the goal of Dr. Madigan's analysis was to determine what knowledge Pfizer had or could have had based on the data available to it at the time, any lack of precision in the adverse event classification consultations performed in conjunction with Dr. Madigan's meta-analysis fail to so seriously indict Dr. Madigan's opinion as to render it inadmissible under *Daubert.* Nor are the differences between the fatal event classifications performed by Dr. Baruch and Dr. Furberg, and later relied upon by Dr. Madigan, so significant as to render Dr. Madigan's meta-analysis "junk science." Plaintiffs have met their burden regarding the relevancy of the content of Dr. Madigan's expert opinion to the ultimate questions of drug safety at issue in this securities litigation, as well as its satisfaction of the other Rule 702 criteria.

Dr. Furberg

***5** Dr. Curt D. Furberg is currently Professor of Public Health Sciences and Senior Advisor to the Dean for Health Services Research and Health Policy at Wake Forest University. Dr. Furberg holds both M.D. and Ph.D. degrees and has a broad range of experience and expertise in the field of public health. He has published extensively on topics including clinical trials and non-steroidal anti-inflammatory drugs ("NSAIDs"). Dr. Furberg has been lead investigator in numerous clinical trials and worked in both the public and private sectors, having been asked by both the pharmaceutical industry and the FDA to evaluate safety of COX–2 inhibitors. Plaintiffs offer Dr. Furberg's opinions regarding the review he conducted of the medical literature and clinical studies for Celebrex and Bextra. Based on his reading of the relevant literature and review of the available study data, Dr. Furberg submits that information was available to Pfizer prior to December 17, 2004, that demonstrated a scientifically significant risk of adverse cardiovascular events associated with the use of Celebrex and Bextra.

The breadth of knowledge, experience, and expertise Dr. Furberg brings to proceedings in this case is considerable. Dr. Furberg has wide-ranging training and practice in both clinical and research settings. His opinions are based on individual study data available to Pfizer and, to arrive at them, he employed the methods and analysis he has applied in his lengthy and distinguished career as an expert in the fields of drug safety and clinical trial design. Dr. Furberg's background in and publishing about drug safety and clinical trials well suits him to assist the jury in its determination of what, if any, association between Celebrex and/or Bextra and cardiovascular risk existed on or before December 17, 2004. Defendants' motion to preclude the testimony of Dr. Furberg is therefore denied.

Dr. Kronmal

Dr. Richard A. Kronmal is a Professor of Biostatistics and Statistics at the University of Washington and holds a doctorate in the field of biostatistics. Dr. Kronmal's academic experience involves extensive peer-reviewed publication on the topic of cardiovascular disease. He currently directs a research center at the University of Washington that designs, conducts, and analyzes clinical studies with an emphasis on cardiovascular disease. Dr. Kronmal has served on numerous data safety monitoring boards, which are responsible for ensuring the safety of patients participating in clinical trials and for monitoring such trials for possible early termination due to excessive risks. Plaintiffs offer Dr. Kronmal's opinions concerning his interpretation of Pfizer's clinical trial data, which he finds demonstrate a statistically significant cardiovascular risk associated with Celebrex and Bextra prior to December 17, 2004.

Dr. Kronmal applied his substantial specialized knowledge and experience to assess the design and results of clinical trials of Celebrex and Bextra using established

statistical methods. In his analysis, he relied on SAS data provided by Pfizer, as well as on several other studies. Dr. Kronmal persuasively explained and defended, *inter alia,* his use of non-APTC endpoints and the particular strengths and weaknesses of certain clinical circumstances. Dr. Kronmal's qualifications and methods satisfy the *Daubert* standard and his testimony derived therefrom is relevant to the determination of cardiovascular risk. Therefore, Dr. Kronmal's testimony is admissible.

Dr. Jewell

***6** Dr. Nicholas P. Jewell is a professor of Professor of Biostatistics and Statistics at the University of California, Berkeley. Dr. Jewell's teaching and research has dealt with the design and interpretation of clinical trials. Dr. Jewell has published peer-reviewed articles in the area of the application of statistical analysis to clinical trial data, and has authored a widely used statistics-for-epidemiology textbook. Dr. Jewell is offered by Plaintiffs as a rebuttal expert, and his testimony centers on the methodologies employed in the meta-analysis performed by defense expert Dr. Lee–Jen Wei.

While he does not provide his own analysis or conclusions regarding the safety of Celebrex or Bextra prior to December 17, 2004, Dr. Jewell offers opinions relevant to the ultimate issues in this case. Dr. Jewell's report speaks directly to the weight the jury should assign to Dr. Wei's meta-analysis and his testimony will assist the jury in its interpretation and assessment of Defendants' evidence. Plaintiffs have amply sustained their burden to demonstrate the relevancy and reliability of Dr. Jewell's opinions, and thus his testimony is admissible.

Dr. Baruch

Dr. Lawrence Baruch holds an M.D. and practices cardiology as the Director of the Heart Failure and Echocardiography Programs at the Bronx Veteran Affairs Medical Center. He has also currently serves as an attending cardiologist at Mt. Sinai Hospital in New York City. Dr. Baruch is offered as a rebuttal expert by Plaintiffs. His opinions that the events witnessed in the Bextra CABG clinical trials can be generalized, that Celebrex and Bextra are associated with, contribute to, and can cause cardiovascular events, and that the available clinical data suggest that COX–2 inhibitors increase the risk of cardiovascular events are offered to dispute the testimony offered by Defendant. Dr. Baruch's experience, including his experience training cardiology fellows and medical students, meets Plaintiffs' burden to qualify him as an expert.

Dr. Baruch's training and practice in the field of cardiology as detailed in his expert report qualify him, under *Daubert,* to testify regarding the cardiovascular effects of Celebrex and Bextra, especially on patients undergoing certain surgical procedures. The relationship between the two forms of Bextra, parecoxib and valdecoxib, is also properly within the scope of Dr. Baruch's expertise such that his opinions on the matter are admissible. Dr. Baruch's testimony will assist the jury in its evaluation of the weight to assign to certain clinical studies, such as the CABG trials, in determining whether Pfizer breached disclosure obligations. Defendant's motion to preclude Dr. Baruch's testimony is denied.

Dr. Bennett

Dr. Joel Bennett holds an M.D. and is a Professor of Medicine and Pharmacology at the University of Pennsylvania School of Medicine. His publications include peer-reviewed articles and textbook chapters on platelet function, and he has written specifically about NSAIDs and COX–2 inhibitors. Plaintiffs have satisfied their burden to qualify Dr. Bennett as an expert. The testimony of Dr. Bennett deals with the origin and operation of the FitzGerald (or "Imbalance") Hypothesis, Plaintiffs' posited mechanism for the harm caused by COX–2 inhibitors. This hypothesis has been deemed plausible and credible in the relevant medical literature, and is well within Dr. Bennett's field of expertise based on his training, experience, and history of publication. Dr. Bennett's testimony, while about a mechanism not proven conclusively or uniformly accepted, is far from baseless speculation and concerns a theory that has been subject to, and approved for publication by, peer review. The testimony of Dr. Bennett satisfies the *Daubert* standard and Defendants' motion to preclude his testimony is denied.

Dr. Wei

*7 Dr. Lee–Jen Wei holds a Ph.D. and is currently a Professor of Biostatistics at the Harvard University School of Public Health. He has served on the editorial boards of a number of scientific journals as well as an FDA Advisory Committee. Dr. Wei's publications in peer-reviewed journals are extensive, and he has performed numerous meta-analyses of clinical trial data in the course of his academic career. In the instant litigation, Defendants seek to offer Dr. Wei's meta-analysis of data relating to the safety of Celebrex and his interpretation thereof.[4] Defendants satisfy the standard to qualify Dr. Wei as an expert, and his opinion is clearly relevant to the ultimate issue of alleged misrepresentation or concealment of safety risk.

Dr. Wei's methodology, the validity of which Plaintiffs contest and the novelty of which Plaintiffs seek to highlight, appears to have survived the rigors of peer review at least once, and is subject to critique by virtue of its transparency. Dr. Wei's report, supplemented by his declaration, is sufficient to meet Defendants' burden of demonstrating that his testimony is the product of reliable principles and methods. He has explained his methods, which can be tested. Plaintiffs' critiques of Dr. Wei's choices regarding which trials to include in his own meta-analysis, the origins of the data he used, the date at which he undertook his meta-analysis, and at whose behest he performed his analysis all go to the weight of Dr. Wei's testimony. Given the variety of clinical trials available to aggregate and disagreement regarding which studies were of the highest medical and scientific quality, most "powerful,"[5] and appropriate to extrapolate from, Plaintiffs' main objection to Dr. Wei's methodology—his use of potentially novel "sensitivity analyses"[6] instead of patient years to account for duration when performing his meta-analysis—speaks to the appropriate weight to assign Dr. Wei's testimony, rather than its inadmissibility. Vigorous cross-examination of an expert as to a study's purported inadequacies allows the jury appropriately to weigh the alleged defects and reduces the possibility of prejudice. *Fireman's Fund Fund Ins. Companies v. Alaskan Pride Partnership,* 106 F.3d 1465, 1468 (9th Cir.1997); *United States v. L.E. Cooke Co.,* 991 F.2d 336, 342 (6th Cir.1993). The ultimate conclusions of Dr. Wei's meta-analysis speak directly to the cardiovascular safety of Celebrex and therefore would assist a jury in its determination of Defendants' knowledge of the same. Accordingly, Plaintiffs' motion to preclude Dr. Wei's testimony is denied.

Conclusion

The extensive submissions that are the subject of the instant motions satisfy the standards of qualification and reliability established by Federal Rule of Evidence 702 and elucidated in *Daubert.* While the cross-motions raise significant issues with respect to potential flaws, limitations and credibility of the experts' opinions, these concerns go ultimately to the weight of the opinions. Because the *Daubert* standard is satisfied with respect to all experts whose preclusion was sought, both parties' motions are denied in their entirety.

**8 This order resolves docket entry nos. 139 and 144.

SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2010 WL 1047618, 82 Fed. R. Evid. Serv. 134

Footnotes

1 "Plaintiffs" refers to the putative class of investors who purchased or acquired Pfizer stock between October 31, 2000 and October 19, 2005 (the "Class Period") on whose behalf Lead Plaintiff Teachers' Retirement System of Louisiana is prosecuting this action.

2 "Defendants" refers to Pfizer and corporate officers Henry McKinnell, John LaMattina, Karen Katen, Joseph Feczko, and Gail Cawkwell.

3 Although the complaint (docket entry no. 51–*see, e.g.,* at 18–25) speaks in terms of cardiovascular risk, as did the order (drafted jointly by the parties) setting the Daubert hearing (docket entry no. 120), Defendants sought in this motion practice

to advance the argument that only evidence relating to the narrower subset of thromboembolic (*i.e.,* clot-related) risk should be deemed relevant to the question of Defendants' potential liability in this case. While Defendants are free to argue this point as the case goes on, it is facially inconsistent with the Plaintiffs' articulation of their claims and nothing in the pleadings or in the record thus far persuades this Court that the broader question of cardiovascular risk is so irrelevant to the issues presented in this litigation as to render inadmissible evidence relating to such risk.

4 The Court notes that, moments before Dr. Wei was to be cross-examined at the *Daubert* hearing, Defendants withdrew substantial portions of Dr. Wei's supplemental rebuttal report based on a purportedly "slight error in calculation." (*Daubert* Hr'g Tr. 814–15, Oct. 29, 2009.) Defendants withdrew from Dr. Wei's supplemental rebuttal report Exhibit A; Demonstrative Exhibits DE3, DE4, DE5, DE6; Exhibits 17, 18, 19, 20, 21, and 22 from Appendix D; and Tables 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, and 38. Nothing in this order should be construed to permit the admission into evidence of the withdrawn materials or the analysis on which they rely.

5 The term "powerful" is used here in its statistical sense, referring to "the probability of finding a statistically significant association of a given magnitude (if it exists) in light of the sample sizes used in the study." Michael D. Green et al., Reference Guide on Epidemiology, *in* Reference Manual on Scientific Evidence at 362 (Federal Judicial Center 2d ed.2000).

6 The Court notes that Dr. Wei's "new" method was never given a precise name in the parties' filings or in the *Daubert* hearing testimony. The method referred to was apparently developed in 2007 and subjected to peer review soon thereafter. It was described in contrast to the method of imputation by Plaintiffs' expert Dr. Jewell, and as a "random effects model" by Defendants' rebuttal expert, Dr. William Weintraub. (*Daubert* Hr'g Tr. 753, Oct. 22, 2009.)

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526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238, 67 USLW 4179, 50 U.S.P.Q.2d 1177, 29 Envtl. L. Rep. 20,638, 50 Fed. R. Evid. Serv. 1373, Prod.Liab.Rep. (CCH) P 15,470, 99 Cal. Daily Op. Serv. 2059, 1999 Daily Journal D.A.R. 2645, 12 Fla. L. Weekly Fed. S 141
(Cite as: 526 U.S. 137, 119 S.Ct. 1167)

Supreme Court of the United States
KUMHO TIRE COMPANY, LTD., et al.,
Petitioners,
v.
Patrick CARMICHAEL, etc., et al.

No. 97–1709.
Argued Dec. 7, 1998.
Decided March 23, 1999.

Plaintiffs brought products liability action against tire manufacturer and tire distributor for injuries sustained when right rear tire on vehicle failed. The United States District Court for the Southern District of Alabama, No. 93–0860–CB–S, 923 F.Supp. 1514,Charles R. Butler, J., granted summary judgment for defendants, and plaintiffs appealed. The Court of Appeals for the Eleventh Circuit, 131 F.3d 1433, reversed and remanded. Defendants filed application for writ of certiorari. The Supreme Court, Justice Breyer, held that: (1) *Daubert's* "gatekeeping" obligation, requiring an inquiry into both relevance and reliability, applies not only to "scientific" testimony, but to all expert testimony; (2) when assessing reliability of engineering expert's testimony, trial court may consider the *Daubert* factors to the extent relevant; and (3) trial court did not abuse its discretion in its application of *Daubert to exclude* tire failure analyst's expert testimony that particular tire failed due to manufacturing or design defect.

Reversed.

Justice Scalia filed concurring opinion in which Justice O'Connor and Justice Thomas joined.

Justice Stevens filed opinion concurring in part and dissenting in part.

West Headnotes

[1] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

Evidence 157 ⚿555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and sufficiency. Most Cited Cases

Daubert's "gatekeeping" obligation, requiring an inquiry into both relevance and reliability, applies not only to "scientific" testimony, but to all expert testimony. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[2] Evidence 157 ⚿555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and sufficiency. Most Cited Cases

When assessing the reliability of an engineering expert's testimony, the trial court may consider the *Daubert* factors to the extent relevant, which will depend upon the nature of the issue, the expert's particular expertise, and the subject of his testimony. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[3] Evidence 157 ⚿508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters involving scientific or other special knowledge in general. Most Cited Cases

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Evidence 157 555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and sufficiency. Most Cited Cases

Objective of *Daubert's* "gatekeeping" requirement is to ensure the reliability and relevancy of expert testimony; it is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[4] Evidence 157 555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and sufficiency. Most Cited Cases

Trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[5] Federal Courts 170B 823

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk823 k. Reception of evidence. Most Cited Cases

Court of Appeals is to apply an abuse-of-discretion standard when it reviews a trial court's decision to admit or exclude expert testimony, and when it reviews the trial court's decisions about how to determine reliability as to its ultimate conclusion. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[6] Evidence 157 546

157 Evidence
157XII Opinion Evidence
157XII(C) Competency of Experts
157k546 k. Determination of question of competency. Most Cited Cases

Whether *Daubert's* specific factors are, or are not, reasonable measures of expert's reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine. Fed.Rules Evid.Rules 102, 702, 28 U.S.C.A.

[7] Evidence 157 555.5

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.5 k. Cause and effect. Most Cited Cases

Trial court did not abuse its discretion in its application of *Daubert* to exclude tire failure analyst's expert testimony that particular tire failed due to manufacturing or design defect, on grounds that methodology employed by analyst in analyzing the data obtained in his visual and tactile examination of tire in question was unreliable, even though court did not doubt analyst's qualification as expert, where there was no evidence that other experts in the industry used analyst's particular approach with regard visual and tactile examinations of tires, analyst's own testimony cast doubt upon reliability of both his theory and his proposition about significance of visual inspection of tire in question, and tire bore some of marks that analyst said indicated abuse, rather than defect. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

*****1169** *Syllabus* FN*

FN* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,*

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200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 *137** When a tire on the vehicle driven by Patrick Carmichael blew out and the vehicle overturned, one passenger died and the others were injured. The survivors and the decedent's representative, respondents here, brought this diversity suit against the tire's maker and its distributor (collectively Kumho Tire), claiming that the tire that failed was defective. They rested their case in significant part upon the depositions of a tire failure analyst, Dennis Carlson, Jr., who intended to testify that, in his expert opinion, a defect in the tire's manufacture or design caused the blowout. That opinion was based upon a visual and tactile inspection of the tire and upon the theory that in the absence of at least two of four specific, physical symptoms indicating tire abuse, the tire failure of the sort that occurred here was caused by a defect. Kumho Tire moved to exclude Carlson's testimony on the ground that his methodology failed to satisfy Federal Rule of Evidence 702, which says: "If scientific, technical, or other specialized knowledge will assist the trier of fact ..., a witness qualified as an expert ... may testify thereto in the form of an opinion." Granting the motion (and entering summary judgment for the defendants), the District Court acknowledged that it should act as a reliability "gatekeeper" under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589, 113 S.Ct. 2786, 125 L.Ed.2d 469, in which this Court held that Rule 702 imposes a special obligation upon a trial judge to ensure that scientific testimony is not only relevant, but reliable. The court noted that *Daubert* discussed four factors—testing, peer review, error rates, and "acceptability" in the relevant scientific community—which might prove helpful in determining the reliability of a particular scientific theory or technique, *id.*, at 593–594, 113 S.Ct. 2786, and found that those factors argued against the reliability of Carlson's methodology. On the plaintiffs' motion for reconsideration, the court agreed that *Daubert* should be applied flexibly, that its four factors were simply illustrative, and that other factors could argue in favor of admissibility. However, the court affirmed its earlier order because it found insufficient indications of the reliability of Carlson's methodology. In reversing, the Eleventh Circuit held that the District Court had erred as a matter of law in applying *Daubert.* Believing that *Daubert* was limited to the scientific context, 138138** the court held that the *Daubert* factors did not apply to Carlson's testimony, which it characterized as skill or experience based.

***1** *Held:*

***1** 1. The *Daubert* factors may apply to the testimony of engineers and other experts who are not scientists. Pp. 1174–1176.

***2** (a) The *Daubert* "gatekeeping" obligation applies not only to "scientific" testimony, but to all expert testimony. Rule 702 does not distinguish between "scientific" knowledge and "technical" or "other specialized" knowledge, but makes clear that any such knowledge might become the subject of expert testimony. It is the Rule's word "knowledge," not the words (like "scientific") that modify that word, that establishes a standard of evidentiary reliability. 509 U.S., at 589–590, 113 S.Ct. 2786. *Daubert* referred only to "scientific" knowledge because that was the nature of the expertise there at issue. *Id.*, at 590, n. 8, 113 S.Ct. 2786. Neither is the evidentiary rationale underlying *Daubert's* "gatekeeping" determination limited to "scientific" knowledge. Rules 702 and 703 grant all expert witnesses, not just "scientific" ones, testimonial latitude unavailable to other witnesses on the assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline. *Id.*, at 592, 113 S.Ct. 2786. Finally, it would prove difficult, if not impossible, for judges to administer evidentiary rules under which a "gatekeeping" obligation depended upon a distinction between "scientific" knowledge and "technical" or "other specialized" knowledge, since there is no clear line dividing the one from the others and no convincing need to

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make such distinctions. Pp. 1174–1175.

****1170 *2** (b) A trial judge determining the admissibility of an engineering expert's testimony *may* consider one or more of the specific *Daubert* factors. The emphasis on the word "may" reflects *Daubert's* description of the Rule 702 inquiry as "a flexible one." 509 U.S., at 594, 113 S.Ct. 2786. The *Daubert* factors do *not* constitute a definitive checklist or test, *id.*, at 593, 113 S.Ct. 2786, and the gatekeeping inquiry must be tied to the particular facts, *id.*, at 591, 113 S.Ct. 2786. Those 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 testimony. Some of those factors may be helpful in evaluating the reliability even of experience-based expert testimony, and the Court of Appeals erred insofar as it ruled those factors out in such cases. In determining whether particular expert testimony is reliable, the trial court should consider the specific *Daubert* factors where they are reasonable measures of reliability. Pp. 1175–1176.

2** (c) A court of appeals must apply an abuse-of-discretion standard when it reviews a trial court's decision to admit or exclude expert 139139** testimony. *General Electric Co. v. Joiner*, 522 U.S. 136, 138–139, 118 S.Ct. 512, 139 L.Ed.2d 508. That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion. Thus, whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine. See *id.*, at 143, 118 S.Ct. 512. The Eleventh Circuit erred insofar as it held to the contrary. P. 1176.

***3** 2. Application of the foregoing standards demonstrates that the District Court's decision not to admit Carlson's expert testimony was lawful. The District Court did not question Carlson's qualifications, but excluded his testimony because it initially doubted his methodology and then found it unreliable after examining the transcript in some detail and considering respondents' defense of it. The doubts that triggered the court's initial inquiry were reasonable, as was the court's ultimate conclusion that Carlson could not reliably determine the cause of the failure of the tire in question. The question was not the reliability of Carlson's methodology in general, but rather whether he could reliably determine the cause of failure of *the particular tire at issue*. That tire, Carlson conceded, had traveled far enough so that some of the tread had been worn bald, it should have been taken out of service, it had been repaired (inadequately) for punctures, and it bore some of the very marks that he said indicated, not a defect, but abuse. Moreover, Carlson's own testimony cast considerable doubt upon the reliability of both his theory about the need for at least two signs of abuse and his proposition about the significance of visual inspection in this case. Respondents stress that other tire failure experts, like Carlson, rely on visual and tactile examinations of tires. But there is no indication in the record that other experts in the industry use Carlson's *particular* approach or that tire experts normally make the very fine distinctions necessary to support his conclusions, nor are there references to articles or papers that validate his approach. Respondents' argument that the District Court too rigidly applied *Daubert* might have had some validity with respect to the court's initial opinion, but fails because the court, on reconsideration, recognized that the relevant reliability inquiry should be "flexible," and ultimately based its decision upon Carlson's failure to satisfy either *Daubert's* factors *or any other* set of reasonable reliability criteria. Pp. 1176–1179.

***3** 131 F.3d 1433, reversed.

3** BREYER, J., delivered the opinion of the Court, Parts I and II of which were unanimous, and Part III of which was joined by REHNQUIST, C.J., and O'CONNOR, SCALIA, KENNEDY, SOUTER, THOMAS, ****1171** and GINSBURG, 140140** JJ. SCALIA, J., filed a concurring opinion, in which O'CONNOR and THOMAS, JJ., joined, *post*, p.

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1179. STEVENS, J., filed an opinion concurring in part and dissenting in part, *post*, p. 1179.
Joseph H. Babington, Mobile, AL, for petitioners.

Jeffrey P. Minear, Washington, DC, for the United States as amicus curiae, by special leave of the court.

Sidney W. Jackson, for respondents.

For U.S. Supreme Court briefs, see:1998 WL 541944 (Pet.Brief)1998 WL 734422 (Resp.Brief)1998 WL 802059 (Reply.Brief)

141***141** Justice BREYER delivered the opinion of the Court.

***3** In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), this Court focused upon the admissibility of scientific expert testimony. It pointed out that such testimony is admissible only if it is both relevant and reliable. And it held that the Federal Rules of Evidence "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.*, at 597, 113 S.Ct. 2786. The Court also discussed certain more specific factors, such as testing, peer review, error rates, and "acceptability" in the relevant scientific community, some or all of which might prove helpful in determining the reliability of a particular scientific "theory or technique." *Id.*, at 593–594, 113 S.Ct. 2786.

4** This case requires us to decide how *Daubert* applies to the testimony of engineers and other experts who are not scientists. We conclude that *Daubert's* general holding—setting forth the trial judge's general "gatekeeping" obligation—applies not only to testimony based on "scientific" knowledge, but also to testimony based on "technical" and "other specialized" knowledge. See Fed. Rule Evid. 702. We also conclude that a trial court *may* consider one or more of the more specific factors that *Daubert* mentioned when doing so will help determine that testimony's reliability. But, as the Court stated in *Daubert*, the test of reliability is "flexible," and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case. 142142** Rather, the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination. See *General Electric Co. v. Joiner*, 522 U.S. 136, 143, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) (courts of appeals are to apply "abuse of discretion" standard when reviewing district court's reliability determination). Applying these standards, we determine that the District Court's decision in this case—not to admit certain expert testimony—was within its discretion and therefore lawful.

I

***4** On July 6, 1993, the right rear tire of a minivan driven by Patrick Carmichael blew out. In the accident that followed, one of the passengers died, and others were severely injured. In October 1993, the Carmichaels brought this diversity suit against the tire's maker and its distributor, whom we refer to collectively as Kumho Tire, claiming that the tire was defective. The plaintiffs rested their case in significant part upon deposition testimony provided by an expert in tire failure analysis, Dennis Carlson, Jr., who intended to testify in support of their conclusion.

***4** Carlson's depositions relied upon certain features of tire technology that are not in dispute. A steel-belted radial tire like the Carmichaels' is made up of a "carcass" containing many layers of flexible cords, called "plies," along which (between the cords and the outer tread) are laid steel strips called "belts." Steel wire loops, called "beads," hold the cords together at the plies' bottom edges. An outer layer, called the "tread," encases the carcass, and the entire tire is bound together in rubber, through the application of heat and various chemicals. See generally, *e.g.*, J. Dixon, Tires, Suspension and Handling 68–72 (2d ed.1996). The bead of the tire sits upon a "bead seat," which is part of the wheel

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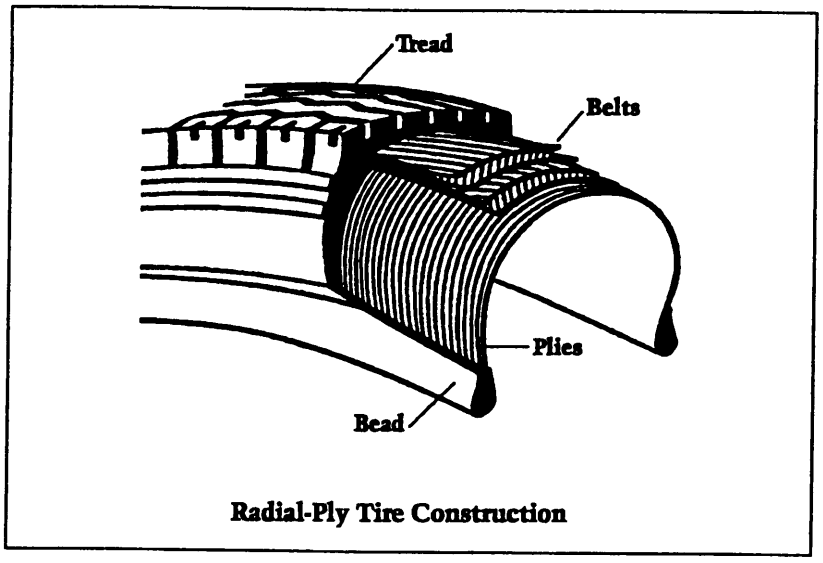
assembly. That assembly contains a "rim flange," which extends over the bead and rests against the side of the 143***143** tire. See M. Mavrigian, Performance Wheels & Tires 81, 83 (1998) (illustrations).



Radial-Ply Tire Construction

****1172 *5** Carlson's testimony also accepted certain background facts about the tire in question. He assumed that before the blowout the tire had traveled far. (The tire was made in 1988 and had been installed some time before the Carmichaels bought the used minivan in March 1993; the Carmichaels had driven the van approximately 7,000 additional miles in the two months they had owned it.) Carlson noted that the tire's tread depth, which was 11/32 of an inch when new, App. 242, had been worn down to depths that ranged from 3/32 of an inch along some parts of the tire, to nothing at all along others. *Id.,* at 287. He conceded that the tire tread had at least two punctures which had been inadequately repaired. *Id.,* at 258–261, 322.

5** Despite the tire's age and history, Carlson concluded that a defect in its manufacture or design caused the blowout. He rested this conclusion in part upon three premises which, 144144** for present purposes, we must assume are not in dispute: First, a tire's carcass should stay bound to the inner side of the tread for a significant period of time after its tread depth has worn away. *Id.,* at 208–209. Second, the tread of the tire at issue had separated from its inner steel-belted carcass prior to the accident. *Id.,* at 336. Third, this "separation" caused the blowout. *Ibid.*

***5** Carlson's conclusion that a defect caused the separation, however, rested upon certain other propositions, several of which the defendants strongly dispute. First, Carlson said that if a separation is *not* caused by a certain kind of tire misuse called "overdeflection" (which consists of underinflating the tire or causing it to carry too much weight, thereby generating heat that can undo the chemical tread/carcass bond), then, ordinarily, its cause is a tire defect. *Id.,* at 193–195, 277–278. Second, he said that if a tire has been subject to sufficient overdeflection to cause a separation, it should reveal certain physical symptoms. These symptoms include (a) tread wear on the tire's shoulder that is greater than the tread wear along

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the tire's center, *id.*, at 211; (b) signs of a "bead groove," where the beads have been pushed too hard against the bead seat on the inside of the tire's rim, *id.*, at 196–197; (c) sidewalls of the tire with physical signs of deterioration, such as discoloration, *id.*, at 212; and/or (d) marks on the tire's rim flange, *id.*, at 219–220. Third, Carlson said that where he does not find *at least two* of the four physical signs just mentioned (and presumably where there is no reason to suspect a less common cause of separation), he concludes that a manufacturing or design defect caused the separation. *Id.*, at 223–224.

6** Carlson added that he had inspected the tire in question. He conceded that the tire to a limited degree showed greater wear on ****1173** the shoulder than in the center, some signs of "bead groove," some discoloration, a few marks on the rim flange, and inadequately filled puncture holes (which can also cause heat that might lead to separation). *Id.*, at 256–257, 258–261,145** 277, 303–304, 308. But, in each instance, he testified that the symptoms were not significant, and he explained why he believed that they did not reveal overdeflection. For example, the extra shoulder wear, he said, appeared primarily on one shoulder, whereas an overdeflected tire would reveal equally abnormal wear on both shoulders. *Id.*, at 277. Carlson concluded that the tire did not bear at least two of the four overdeflection symptoms, nor was there any less obvious cause of separation; and since neither overdeflection nor the punctures caused the blowout, a defect must have done so.

***6** Kumho Tire moved the District Court to exclude Carlson's testimony on the ground that his methodology failed Rule 702's reliability requirement. The court agreed with Kumho that it should act as a *Daubert*-type reliability "gatekeeper," even though one might consider Carlson's testimony as "technical," rather than "scientific." See *Carmichael v. Samyang Tires, Inc.*, 923 F.Supp. 1514, 1521–1522 (S.D.Ala.1996). The court then examined Carlson's methodology in light of the reliability-related factors that *Daubert* mentioned, such as a theory's testability, whether it "has been a subject of peer review or publication," the "known or potential rate of error," and the "degree of acceptance ... within the relevant scientific community." 923 F.Supp., at 1520 (citing *Daubert*, 509 U.S., at 589–595, 113 S.Ct. 2786). The District Court found that all those factors argued against the reliability of Carlson's methods, and it granted the motion to exclude the testimony (as well as the defendants' accompanying motion for summary judgment).

6** The plaintiffs, arguing that the court's application of the *Daubert* factors was too "inflexible," asked for reconsideration. And the court granted that motion. *Carmichael v. Samyang Tires, Inc.*, Civ. Action No. 93–0860–CB–S (S.D.Ala., June 5, 1996), App. to Pet. for Cert. 1c. After reconsidering the matter, the court agreed with the plaintiffs that *Daubert* should be applied flexibly, that its four factors were 146146** simply illustrative, and that other factors could argue in favor of admissibility. It conceded that there may be widespread acceptance of a "visual-inspection method" for some relevant purposes. But the court found insufficient indications of the reliability of

> ***7** "the component of Carlson's tire failure analysis which most concerned the Court, namely, the methodology employed by the expert in analyzing the data obtained in the visual inspection, and the scientific basis, if any, for such an analysis." *Id.*, at 6c.

***7** It consequently affirmed its earlier order declaring Carlson's testimony inadmissible and granting the defendants' motion for summary judgment.

***7** The Eleventh Circuit reversed. See *Carmichael v. Samyang Tire, Inc.*, 131 F.3d 1433 (1997). It "review[ed] ... *de novo* " the "district court's legal decision to apply *Daubert.* " *Id.*, at 1435. It noted that "the Supreme Court in *Daubert* explicitly limited its holding to cover only the

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'scientific context,' " adding that "a *Daubert* analysis" applies only where an expert relies "on the application of scientific principles," rather than "on skill- or experience-based observation." *Id.*, at 1435–1436. It concluded that Carlson's testimony, which it viewed as relying on experience, "falls outside the scope of *Daubert*," that "the district court erred as a matter of law by applying *Daubert* in this case," and that the case must be remanded for further (non- *Daubert*-type) consideration under Rule 702. 131 F.3d, at 1436.

7** Kumho Tire petitioned for certiorari, asking us to determine whether a trial court "may" consider *Daubert's* specific "factors" when determining the "admissibility of an engineering expert's testimony." Pet. for Cert. i. We granted certiorari in light of uncertainty among the lower courts about whether, or how, *Daubert* applies to expert testimony that might be characterized as based not upon "scientific" knowledge, but rather upon "technical" or "other specialized" ***147** knowledge. Fed. Rule Evid. 702; compare, *e.g.*, *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 990–991 (C.A.5 1997), with, *e.g.*, ****1174Compton v. Subaru of America, Inc.*, 82 F.3d 1513, 1518–1519 (C.A.10), cert. denied, 519 U.S. 1042, 117 S.Ct. 611, 136 L.Ed.2d 536 (1996).

II

A

***7** [1] In *Daubert*, this Court held that Federal Rule of Evidence 702 imposes a special obligation upon a trial judge to "ensure that any and all scientific testimony ... is not only relevant, but reliable." 509 U.S., at 589, 113 S.Ct. 2786. The initial question before us is whether this basic gatekeeping obligation applies only to "scientific" testimony or to all expert testimony. We, like the parties, believe that it applies to all expert testimony. See Brief for Petitioners 19; Brief for Respondents 17.

***8** For one thing, Rule 702 itself says:

***8** "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."

***8** This language makes no relevant distinction between "scientific" knowledge and "technical" or "other specialized" knowledge. It makes clear that any such knowledge might become the subject of expert testimony. In *Daubert*, the Court specified that it is the Rule's word "knowledge," not the words (like "scientific") that modify that word, that "establishes a standard of evidentiary reliability." 509 U.S., at 589–590, 113 S.Ct. 2786. Hence, as a matter of language, the Rule applies its reliability standard to all "scientific," "technical," or "other specialized" matters within its scope. We concede that the Court in *Daubert* referred only to "scientific" knowledge. But as the Court there said, it referred to "scientific" ***148** testimony "because that [wa]s the nature of the expertise" at issue. *Id.*, at 590, n. 8, 113 S.Ct. 2786.

***8** Neither is the evidentiary rationale that underlay the Court's basic *Daubert* "gatekeeping" determination limited to "scientific" knowledge. *Daubert* pointed out that Federal Rules 702 and 703 grant expert witnesses testimonial latitude unavailable to other witnesses on the "assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." *Id.*, at 592, 113 S.Ct. 2786 (pointing out that experts may testify to opinions, including those that are not based on firsthand knowledge or observation). The Rules grant that latitude to all experts, not just to "scientific" ones.

***8** Finally, it would prove difficult, if not impossible, for judges to administer evidentiary rules under which a gatekeeping obligation depended upon a distinction between "scientific" knowledge and "technical" or "other specialized" knowledge. There is no clear line that divides the one from the others. Disciplines such as

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engineering rest upon scientific knowledge. Pure scientific theory itself may depend for its development upon observation and properly engineered machinery. And conceptual efforts to distinguish the two are unlikely to produce clear legal lines capable of application in particular cases. Cf. Brief for National Academy of Engineering as *Amicus Curiae* 9 (scientist seeks to understand nature while the engineer seeks nature's modification); Brief for Rubber Manufacturers Association as *Amicus Curiae* 14–16 (engineering, as an " 'applied science,' " relies on "scientific reasoning and methodology"); Brief for John Allen et al. as *Amici Curiae* 6 (engineering relies upon "scientific knowledge and methods").

9** Neither is there a convincing need to make such distinctions. Experts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called "general truths derived from ... specialized experience." Hand, Historical and Practical Considerations Regarding Expert Testimony,149** 15 Harv. L.Rev. 40, 54 (1901). And whether the specific expert testimony focuses upon specialized observations, the specialized translation of those observations into theory, a specialized theory itself, or the application of such a theory in a particular case, the expert's testimony often will rest "upon an experience confessedly foreign in kind to [the jury's] own." *Ibid.* The trial judge's effort to assure that the specialized testimony is reliable and relevant can help the jury evaluate****1175** that foreign experience, whether the testimony reflects scientific, technical, or other specialized knowledge.

***9** We conclude that *Daubert*'s general principles apply to the expert matters described in Rule 702. The Rule, in respect to all such matters, "establishes a standard of evidentiary reliability." 509 U.S., at 590, 113 S.Ct. 2786. It "requires a valid ... connection to the pertinent inquiry as a precondition to admissibility." *Id.*, at 592, 113 S.Ct. 2786. And where such testimony's factual basis, data, principles, methods, or their application are called sufficiently into question, see Part III, *infra*, the trial judge must determine whether the testimony has "a reliable basis in the knowledge and experience of [the relevant] discipline." 509 U.S., at 592, 113 S.Ct. 2786.

B

***9** Petitioners ask more specifically whether a trial judge determining the "admissibility of an engineering expert's testimony" *may* consider several more specific factors that *Daubert* said might "bear on" a judge's gatekeeping determination. Brief for Petitioners i. These factors include:

***9** —Whether a "theory or technique ... can be (and has been) tested";

***9** —Whether it "has been subjected to peer review and publication";

***9** —Whether, in respect to a particular technique, there is a high "known or potential rate of error" and whether there are "standards controlling the technique's operation"; and

***9** 150— ***150** Whether the theory or technique enjoys " 'general acceptance' " within a " 'relevant scientific community.' " 509 U.S., at 592–594, 113 S.Ct. 2786.

***9** Emphasizing the word "may" in the question, we answer that question yes.

***9** [2] Engineering testimony rests upon scientific foundations, the reliability of which will be at issue in some cases. See, *e.g.*, Brief for Stephen N. Bobo et al. as *Amici Curiae* 23 (stressing the scientific bases of engineering disciplines). In other cases, the relevant reliability concerns may focus upon personal knowledge or experience. As the Solicitor General points out, there are many different kinds of experts, and many different kinds of expertise. See Brief for United States as *Amicus Curiae* 18–19, and n. 5 (citing cases involving experts in drug terms, handwriting analysis, criminal *modus operandi*, land valuation,

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agricultural practices, railroad procedures, attorney's fee valuation, and others). Our emphasis on the word "may" thus reflects *Daubert's* description of the Rule 702 inquiry as "a flexible one." 509 U.S., at 594, 113 S.Ct. 2786. *Daubert* makes clear that the factors it mentions do *not* constitute a "definitive checklist or test." *Id.*, at 593, 113 S.Ct. 2786. And *Daubert* adds that the gatekeeping inquiry must be " 'tied to the facts' " of a particular "case." *Id.*, at 591, 113 S.Ct. 2786 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (C.A.3 1985)). We agree with the Solicitor General that "[t]he factors identified in *Daubert* 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 testimony." Brief for United States as *Amicus Curiae* 19. The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.

***10 *151** *Daubert* itself is not to the contrary. It made clear that its list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged. It might not be surprising in a particular case, for example, that a claim made by a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist. Nor, on the other hand, does the presence of *Daubert's* general acceptance factor help show that an expert's testimony is reliable where the discipline itself lacks reliability, as, for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy.

****1176 *10** At the same time, and contrary to the Court of Appeals' view, some of *Daubert's* questions can help to evaluate the reliability even of experience-based testimony. In certain cases, it will be appropriate for the trial judge to ask, for example, how often an engineering expert's experience-based methodology has produced erroneous results, or whether such a method is generally accepted in the relevant engineering community. Likewise, it will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable.

***10** We must therefore disagree with the Eleventh Circuit's holding that a trial judge may ask questions of the sort *Daubert* mentioned only where an expert "relies on the application of scientific principles," but not where an expert relies "on skill- or experience-based observation." 131 F.3d, at 1435. We do not believe that Rule 702 creates a schematism that segregates expertise by type while mapping certain kinds of questions to certain kinds of experts. Life and the legal cases that it generates are too complex to warrant so definitive a match.

10** [3][4] 152152** To say this is not to deny the importance of *Daubert's* gatekeeping requirement. The objective of that requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. Nor do we deny that, as stated in *Daubert*, the particular questions that it mentioned will often be appropriate for use in determining the reliability of challenged expert testimony. Rather, we conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable. That is to say, a trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony.

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11** [5][6] The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable. Our opinion in *Joiner* makes clear that a court of appeals is to apply an abuse-of-discretion standard when it "review[s] a trial court's decision to admit or exclude expert testimony." 522 U.S., at 138–139, 118 S.Ct. 512. That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion. Otherwise, the trial judge would lack the discretionary authority needed both to avoid unnecessary "reliability" proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises. Indeed, the Rules seek to avoid "unjustifiable expense and delay" as part of their search for153** 153"truth" and the "jus[t] determin[ation]" of proceedings. Fed. Rule Evid. 102. Thus, whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine. See *Joiner, supra,* at 143, 118 S.Ct. 512. And the Eleventh Circuit erred insofar as it held to the contrary.

III

11** [7] We further explain the way in which a trial judge "may" consider *Daubert's* factors by applying these considerations to the case at hand, a matter that has been briefed exhaustively by the parties and their 19 *amici*. The District Court did not doubt Carlson's qualifications, which included a masters degree in mechanical engineering, 10 years' work at Michelin America, Inc., and testimony as a tire failure consultant in other tort cases. Rather, it excluded the testimony because, despite those qualifications, it initially*1177** doubted, and then found unreliable, "the methodology employed by the expert in analyzing the data obtained in the visual inspection, and the scientific basis, if any, for such an analysis." Civ. Action No. 93–0860–CB–S (S.D.Ala., June 5, 1996), App. to Pet. for Cert. 6c. After examining the transcript in "some detail," 923 F.Supp., at 1518–1519, n. 4, and after considering respondents' defense of Carlson's methodology, the District Court determined that Carlson's testimony was not reliable. It fell outside the range where experts might reasonably differ, and where the jury must decide among the conflicting views of different experts, even though the evidence is "shaky." *Daubert,* 509 U.S., at 596, 113 S.Ct. 2786. In our view, the doubts that triggered the District Court's initial inquiry here were reasonable, as was the court's ultimate conclusion.

12** For one thing, and contrary to respondents' suggestion, the specific issue before the court was not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection to determine whether overdeflection had caused 154154** the tire's tread to separate from its steel-belted carcass. Rather, it was the reasonableness of using such an approach, along with Carlson's particular method of analyzing the data thereby obtained, to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.* That matter concerned the likelihood that a defect in the tire at issue caused its tread to separate from its carcass. The tire in question, the expert conceded, had traveled far enough so that some of the tread had been worn bald; it should have been taken out of service; it had been repaired (inadequately) for punctures; and it bore some of the very marks that the expert said indicated, not a defect, but abuse through overdeflection. See *supra,* at 1172; App. 293–294. The relevant issue was whether the expert could reliably determine the cause of *this* tire's separation.

***12** Nor was the basis for Carlson's conclusion simply the general theory that, in the absence of evidence of abuse, a defect will normally have caused a tire's separation. Rather, the expert employed a more specific theory to establish the

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existence (or absence) of such abuse. Carlson testified precisely that in the absence of *at least two* of four signs of abuse (proportionately greater tread wear on the shoulder; signs of grooves caused by the beads; discolored sidewalls; marks on the rim flange), he concludes that a defect caused the separation. And his analysis depended upon acceptance of a further implicit proposition, namely, that his visual and tactile inspection could determine that the tire before him had not been abused despite some evidence of the presence of the very signs for which he looked (and two punctures).

***12** For another thing, the transcripts of Carlson's depositions support both the trial court's initial uncertainty and its final conclusion. Those transcripts cast considerable doubt upon the reliability of both the explicit theory (about the need for two signs of abuse) and the implicit proposition (about the significance of visual inspection in this case). Among other things, the expert could not say whether the tire had traveled ***155** more than 10, or 20, or 30, or 40, or 50 thousand miles, adding that 6,000 miles was "about how far" he could "say with any certainty." *Id.*, at 265. The court could reasonably have wondered about the reliability of a method of visual and tactile inspection sufficiently precise to ascertain with some certainty the abuse-related significance of minute shoulder/center relative tread wear differences, but insufficiently precise to tell "with any certainty" from the tread wear whether a tire had traveled less than 10,000 or more than 50,000 miles. And these concerns might have been augmented by Carlson's repeated reliance on the "subjective[ness]" of his mode of analysis in response to questions seeking specific information regarding how he could differentiate between a tire that actually had been overdeflected and a tire that merely looked as though it had been. *Id.*, at 222, 224–225, 285–286. They would have been further augmented by the fact that Carlson said he had inspected the tire itself for the first time the morning of his first deposition, and then only for a few hours. (His initial conclusions were based on photographs.) *Id.*, at 180.

****1178 *13** Moreover, prior to his first deposition, Carlson had issued a signed report in which he concluded that the tire had "not been ... overloaded or underinflated," not because of the absence of "two of four" signs of abuse, but simply because "the rim flange impressions ... were normal." *Id.*, at 335–336. That report also said that the "tread depth remaining was 3/32 inch," *id.*, at 336, though the opposing expert's (apparently undisputed) measurements indicate that the tread depth taken at various positions around the tire actually ranged from .5/32 of an inch to 4/32 of an inch, with the tire apparently showing greater wear along *both* shoulders than along the center, *id.*, at 432–433.

***13** Further, in respect to one sign of abuse, bead grooving, the expert seemed to deny the sufficiency of his own simple visual-inspection methodology. He testified that most tires have some bead groove pattern, that where there is reason 156 ***156** to suspect an abnormal bead groove he would ideally "look at a lot of [similar] tires" to know the grooving's significance, and that he had not looked at many tires similar to the one at issue. *Id.*, at 212–213, 214, 217.

***13** Finally, the court, after looking for a defense of Carlson's methodology as applied in these circumstances, found no convincing defense. Rather, it found (1) that "none" of the *Daubert* factors, including that of "general acceptance" in the relevant expert community, indicated that Carlson's testimony was reliable, 923 F.Supp., at 1521; (2) that its own analysis "revealed no countervailing factors operating in favor of admissibility which could outweigh those identified in *Daubert*," App. to Pet. for Cert. 4c; and (3) that the "parties identified no such factors in their briefs," *ibid.* For these three reasons *taken together*, it concluded that Carlson's testimony was unreliable.

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13** Respondents now argue to us, as they did to the District Court, that a method of tire failure analysis that employs a visual/tactile inspection is a reliable method, and they point both to its use by other experts and to Carlson's long experience working for Michelin as sufficient indication that that is so. But no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience. Nor does anyone deny that, as a general matter, tire abuse may often be identified by qualified experts through visual or tactile inspection of the tire. See Affidavit of H.R. Baumgardner 1–2, cited in Brief for National Academy of Forensic Engineers as *Amicus Curiae* 16 (Tire engineers rely on visual examination and process of elimination to analyze experimental test tires). As we said before, *supra*, at 1977, the question before the trial court was specific, not general. The trial court had to decide whether this particular expert had sufficient specialized knowledge to assist the jurors "in deciding the particular issues in the case." 4 J. McLaughlin, Weinstein's Federal Evidence ¶ 702.05[1], p. 702–33 (2d ed.1998); see also Advisory 157157** Committee's Note on Proposed Fed. Rule Evid. 702, Preliminary Draft of Proposed Amendments to the Federal Rules of Civil Procedure and Evidence: Request for Comment 126 (1998) (stressing that district courts must "scrutinize" whether the "principles and methods" employed by an expert "have been properly applied to the facts of the case").

***14** The particular issue in this case concerned the use of Carlson's two-factor test and his related use of visual/tactile inspection to draw conclusions on the basis of what seemed small observational differences. We have found no indication in the record that other experts in the industry use Carlson's two-factor test or that tire experts such as Carlson normally make the very fine distinctions about, say, the symmetry of comparatively greater shoulder tread wear that were necessary, on Carlson's own theory, to support his conclusions. Nor, despite the prevalence of tire testing, does anyone refer to any articles or papers that validate Carlson's approach. Cf. Bobo, Tire Flaws and Separations, in Mechanics of Pneumatic Tires 636–637 (S. Clark ed.1981); C. Schnuth, R. Fuller, G. Follen, G. Gold, & J. Smith, Compression Grooving and Rim Flange Abrasion as Indicators of Over–Deflected Operating Conditions in Tires, presented to Rubber Division of the American Chemical Society, Oct. 21–24, 1997; J. Walter & R. Kiminecz, Bead ****1179** Contact Pressure Measurements at the Tire–Rim Interface, presented to the Society of Automotive Engineers, Inc., Feb. 24–28, 1975. Indeed, no one has argued that Carlson himself, were he still working for Michelin, would have concluded in a report to his employer that a similar tire was similarly defective on grounds identical to those upon which he rested his conclusion here. Of course, Carlson himself claimed that his method was accurate, but, as we pointed out in *Joiner*, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." 522 U.S., at 146, 118 S.Ct. 512.

14** 158158** Respondents additionally argue that the District Court too rigidly applied *Daubert's* criteria. They read its opinion to hold that a failure to satisfy any one of those criteria automatically renders expert testimony inadmissible. The District Court's initial opinion might have been vulnerable to a form of this argument. There, the court, after rejecting respondents' claim that Carlson's testimony was "exempted from *Daubert*-style scrutiny" because it was "technical analysis" rather than "scientific evidence," simply added that "none of the four admissibility criteria outlined by the *Daubert* court are satisfied." 923 F.Supp., at 1521. Subsequently, however, the court granted respondents' motion for reconsideration. It then explicitly recognized that the relevant reliability inquiry "should be 'flexible,' " that its " 'overarching subject [should be] ... validity' and reliability," and that " *Daubert* was intended neither to be exhaustive nor to apply in

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every case." App. to Pet. for Cert. 4c (quoting *Daubert,* 509 U.S., at 594–595, 113 S.Ct. 2786). And the court ultimately based its decision upon Carlson's failure to satisfy either *Daubert's* factors *or any other* set of reasonable reliability criteria. In light of the record as developed by the parties, that conclusion was within the District Court's lawful discretion.

***15** In sum, Rule 702 grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case. The District Court did not abuse its discretionary authority in this case. Hence, the judgment of the Court of Appeals is

***15** *Reversed.*

Justice SCALIA, with whom Justice O'CONNOR and Justice THOMAS join, concurring.

15** I join the opinion of the Court, which makes clear that the discretion it endorses—trial-court discretion in choosing the manner of testing expert reliability—is not discretion to 159159** abandon the gatekeeping function. I think it worth adding that it is not discretion to perform the function inadequately. Rather, it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky. Though, as the Court makes clear today, the *Daubert* factors are not holy writ, in a particular case the failure to apply one or another of them may be unreasonable, and hence an abuse of discretion.

Justice STEVENS, concurring in part and dissenting in part.

***15** The only question that we granted certiorari to decide is whether a trial judge "[m]ay ... consider the four factors set out by this Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), in a Rule 702 analysis of admissibility of an engineering expert's testimony." Pet. for Cert. i. That question is fully and correctly answered in Parts I and II of the Court's opinion, which I join.

***15** Part III answers the quite different question whether the trial judge abused his discretion when he excluded the testimony of Dennis Carlson. Because a proper answer to that question requires a study of the record that can be performed more efficiently by the Court of Appeals than by the nine Members of this Court, I would remand the case to the Eleventh Circuit to perform that task. There are, of course, exceptions to most rules, but I firmly believe that it is neither fair to litigants nor good practice for this Court to reach out to decide questions not raised by the certiorari petition. See *General Electric Co. v. Joiner*, 522 U.S. 136, 150–151, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) ****1180** (STEVENS, J., concurring in part and dissenting in part).

***15** Accordingly, while I do not feel qualified to disagree with the well-reasoned factual analysis in Part III of the Court's opinion, I do not join that Part, and I respectfully dissent from the Court's disposition of the case.

U.S.Ala.,1999.
Kumho Tire Co., Ltd. v. Carmichael
526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238, 67 USLW 4179, 50 U.S.P.Q.2d 1177, 29 Envtl. L. Rep. 20,638, 50 Fed. R. Evid. Serv. 1373, Prod.Liab.Rep. (CCH) P 15,470, 99 Cal. Daily Op. Serv. 2059, 1999 Daily Journal D.A.R. 2645, 12 Fla. L. Weekly Fed. S 141

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