# EXPERT TESTIMONY AND THE PRESENTATION OF SCIENTIFIC EVIDENCE IN TOXIC TORT AND ENVIRONMENTAL HAZARDOUS SUBSTANCE LITIGATION

*Roy Alan Cohen**
*Jodi F. Mindnich***

## I. INTRODUCTION

The explosion of toxic tort and environmental litigation has virtually flooded courtrooms throughout the country in recent years. By all accounts, this trend will continue for many years. Through the active efforts of environmental and consumer groups, federal, state and local agencies dealing with occupational and environmental health, and public and private industrial hygiene organizations, our society is laying the legal groundwork for perhaps the next two or three decades.[1] Vast arrays of literature are now available to provide scientists, ex-

* Mr. Cohen is a Litigation Principal of Porzio, Bromberg & Newman, P.C., Morristown, New Jersey, and New York, New York. He is a team leader in the firm's Product Liability and Toxic Tort Litigation Department, Chair of the New Jersey State Bar Association's Product Liability and Toxic Tort Committee, and a Certified Civil Trial Attorney by the Supreme Court of New Jersey.

** Ms. Mindnich is a litigation associate of the firm.

[1] State and federal agencies are actively working to identify toxic waste sites and assess clean up programs. At present, there are approximately 422 hazardous waste sites in New Jersey. *See* NEW JERSEY DEP'T OF ENVTL. PROTECTION *1989 Status Report on the Hazardous Waste Management Program in New Jersey* (Oct. 1989). The Environmental Protection Agency (EPA) has identified 988 priority Superfund sites across the country, with 99 of them located in New Jersey. National Oil and Hazardous Substances Pollution Contingency Plan, 40 C.F.R. § 300, app. B (1990) (national priorities list by rank). *See also Occupational Disease in New Jersey Report to the New Jersey Department of Health*, Div. of Envtl. and Occupational Medicine, Dep't of Community Medicine, Mt. Sinai School of Medicine (1989). This study may well be representative of industrially mature states. In December of 1989, a nine-month evaluation of occupational disease in New Jersey analyzed the best available data on the extent of work-related disease in New Jersey, and reported that between 2,170 and 2,870 deaths and approximately 7,317 to 14,776 new cases arise each year from occupational exposures to hazardous substances. *Id.* at i. The report also noted that the estimated figures were probably lower than the actual incidence of occupationally related diseases, and that there was a serious lack of information available on the potential toxicity of approximately 80% of the 48,000 chemical substances in use today. *Id.* at i, 2. *See also* North, *Occupational Respiratory Diseases, The Big Four*, SAFETY AND HEALTH 40 (Sept. 1989) (identifying air-borne asbestos, silica, lead and carbon monoxide as the four largest sources of occupational disease).

perts and lawyers with background information about potentially toxic substances.[2]

Within this framework, lawyers must represent plaintiffs and defendants in personal injury, wrongful death and property damage claims resulting from exposure to toxic or hazardous substances. Whether the cases involve groundwater contamination or occupational exposure to hazardous substances, the cases will invariably require the use of scientific, technical or medical experts to deal with the increasingly complex issues.[3] These issues range widely and may include such topics as the causal relationship between exposure to a certain toxic substance and a particular injury, the scientific understanding of certain biological systems, or the scientific knowledge available to a defendant or industry at a particular time.

The presentation of scientific evidence and the use of expert witness testimony is crucial to the litigation of complex toxic tort and environmental cases. Issues related to the use and abuse of expert witness testimony, including questions of appropriate qualifications and the admissibility of scientific evidence and novel scientific theories, have led to widespread disagreement by courts and commentators on how to handle the expert testimony. Recommended proposals contemplate drastic changes in the legal system, including the implementation of an expanded judicial role,[4] a redesign of the jury system in complex cases,[5] and

---

[2] From the environmental standpoint, *see* ENVIRONMENTAL EXPOSURE FROM CHEMICALS (Neely & Blau, ed. 1985); P. HOWARD, HANDBOOK OF ENVIRONMENTAL FATE AND EXPOSURE DATA FOR ORGANIC CHEMICALS (1989); J. MONTGOMERY & L. WELKOM, GROUNDWATER CHEMICALS DESK REFERENCE (1990). From the occupational exposure standpoint, *see generally* PROCTORE, HUGHES & FISCHMAN, CHEMICAL HAZARDS OF THE WORKPLACE, (1988); N. SAX & R. LEWIS, SR., DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS (1989); U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES AND USER'S GUIDE (1988); SUSPECT CHEMICALS SOURCEBOOK: A GUIDE TO INDUSTRIAL CHEMICALS COVERED UNDER MAJOR REGULATORY AND ADVISORY PROGRAMS (1990). This reference list is by no means complete, but it will provide the reader with a source of information.

[3] *See, e.g.*, Ott, Teta & Greenberg, *Assessment of Exposure to Chemicals in a Complex Work Environment*, 16 AM. J. OF INDUS. MED. 617 (1989) (complexities in a retrospective occupational hazardous substance exposure study include imprecise estimates of exposure levels, variations in personal work practices, lack of understanding of cancer causation mechanism and the evaluation of the effects of multiple chemical exposures in cancer causation).

[4] *See* Berger, *A Relevancy Approach to Novel Scientific Evidence*, 26 JURIMETRICS J. 245 (1986) (proposing an amendment to FED. R. EVID. 702 which would require the court to evaluate expert witness testimony on novel scientific evidence and allow the testimony when the probative value of the testimony exceeds the danger of confusion, prejudice or delay); Carlson, *Policing the Bases of Modern Expert Testimony*, 39 VAND. L. REV. 577 (1986) (advocating five steps for courts to take in determining

the use of independent scientific boards[6] to decide issues of expert qualifications and the reliability of scientific expert testimony.

Most of the caselaw and commentary on the presentation and admissibility of expert witness testimony on novel scientific evidence has dealt with toxic exposures in the product liability rather than environmental context. In contrast, this article will provide the practitioner with an overview of the types of expert witnesses generally utilized in both types of litigation, and a discussion of the standards for qualification of particular experts, a review of recent court decisions concerning the admissibility of scientific expert witness opinion testimony, and a review of some scientific studies which may be utilized to establish causation in toxic tort cases.

## II. THE TYPES OF EXPERTS

The complex scientific issues involved in toxic tort and environmental hazardous substance litigation require the attorney to call upon experts who are highly specialized in particular scientific and medical areas. Expert witnesses serve as interpreters and translate specialized knowledge into knowledge of common understanding to enable ordinary lay persons to comprehend and decide complex issues which jurors ordinarily would not

---

the admissibility of expert witness testimony); Elliot, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U.L. REV. 487 (1989) (suggesting a rule allowing the court to appoint a "peer review expert" to evaluate proffered expert testimony when there exists substantial doubt concerning the acceptability of the proffered testimony by other experts in the field); Johnston, *Court-Appointed Scientific Expert Witnesses: Unfettering Expertise*, 2 HIGH TECH. L.J. 249 (1987) (stating several proposals for increasing the role of court appointed scientific experts).

[5] *See* Luneburg & Nordenberg, *Specially Qualified Juries and Expert Nonjury Tribunals: Alternatives for Coping With the Complexities of Modern Civil Litigation*, 67 VA. L. REV. 887 (1981) (proposing "special" juries for complex civil cases, consisting of jurors which meet certain minimum educational standards, or alternatively, "expert" non-jury tribunal consisting of judges with the requisite legal and technical training to comprehend and decide the issues); Schwartz, *There is No Archbishop of Science—A Comment on Elliot's "Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence,"* 69 B.U.L. REV. 517 (1989) (rejecting judicial screening of proffered novel scientific evidence because it usurps the fact finding function of the jury).

[6] Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV. 469 (1988) (advocates the use of a Federal Hazardous Substance Science Panel consisting of scientists, business representatives, consumers and workers to make exposure, risk and causation findings).

understand.[7]

In cases involving toxic substance contamination or exposure, expert witnesses are usually considered essential to provide opinions on causation, health issues, medical surveillance techniques and requirements, air and groundwater contamination, and clean-up assessments. The scientific professionals who are capable of proffering such evidence include, but are not limited to, biologists, chemists, civil engineers, chemical engineers, epidemiologists, geologists, hydrologists, industrial hygienists, toxicologists and physicians.

Each area of expertise raises a variety of issues in areas of expert qualifications, substantive admissibility of the expert's opinion and relevancy. For instance, there is a dispute over whether certain experts should be permitted to testify at all.[8] In addressing these issues, therefore, it is essential to have a basic working knowledge concerning the scope of the various scientific disciplines. Biology is the study of the science of living organisms,[9] and the biologist often offers testimony on the adverse effects of hazardous substances on living organisms. Chemistry is the scientific study of the properties, composition and structure of matter;[10] thus a chemist would address the effects which hazardous substance contamination would have on the structure and composition of matter, and the matter's accompanying atomic energy changes. Alternatively, expert witness opinions may be required on issues which involve a hybrid of the biology

---

7 For a general discussion on expert testimony and its use in the legal system, *see Expert Opinion Testimony: Experts, Where Did They Come From and Why Are They Here?*, 13 LAW & PSYCHOLOGY REV. 103 (1989).

8 *See* Epstein & Klein, *The Use and Abuse of Expert Testimony in Product Liability Actions*, 17 SETON HALL L. REV. 656 (1987) (general discussion on abuse of expert testimony with respect to "junk science" evidence and methods available under New Jersey law to combat the abuse); Rothstein & Crew, *When Should the Judge Keep Expert Testimony From the Jury?*, INSIDE LITIGATION 19 (Apr. 1987); Gianelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States A Half-Century Later*, 80 COLUM. L. REV. 1197 (1980) (rejects the *Frye* "general acceptance" test for admissibility of expert testimony in favor of proof that the novel scientific evidence or technique is valid beyond a reasonable doubt in criminal cases and valid by a preponderance of the evidence in civil cases). *See also* Griffith, Strain & Black, *Dare We Trust the Jury?*, THE BRIEF 6 (Fall 1988) (Griffith argues that the jury is competent to evaluate conflicting scientific evidence; Strain and Black maintain that the court should evaluate the validity, accuracy and reliability of the scientific evidence and exclude that testimony which is not in accord with an established science); Imwinkelried, *Science Takes the Stand: The Growing Misuse of Expert Testimony*, 26 SCIENCE 20 (1986).

9 McGRAW-HILL, DICTIONARY OF SCIENCE AND ENGINEERING 99 (1984).

10 *Id.* at 163.

and chemistry sciences. Biochemistry is the study of the chemical substances which occur in living organisms, the processes by which the substances enter into or are formed in the organisms and react with each other and the environment, and the methods by which the substances and processes are identified, characterized and measured.[11] The biochemist will often testify about the reaction and resultant effects of the interplay between chemical substances and the human body.

When litigating issues involving hazardous substances in the environment, it is also vital to determine the impact that the substances have upon the surrounding atmosphere and environment. To provide evidence of such adverse effects, the attorney often will seek the expertise of civil engineers, geologists and hydrologists. Because civil engineering typically involves the planning, design and construction of fixed structures,[12] the civil engineer could offer testimony on the changes in a building's structural stability as a result of soil erosion and movement due to hazardous substance contamination. Geology involves the study of the earth, including the weathering, erosion and sedimentation of soil.[13] Thus a geologist may offer testimony on the effects of hazardous substance contamination on the earth. On the other hand, hydrology is the study of the surface and ground waters of the earth, and includes analysis of the water's occurrence, circulation and distribution, its chemical and physical properties, and the water's reaction with the environment.[14] The hydrologist will often offer testimony on ground water migration, based upon soil and water samples which show that contaminants entering the environment have migrated to different areas.

An industrial hygienist is another specially trained, science professional often called as an expert witness in an occupational exposure case to testify about industrial hygiene conditions or practices. The industrial hygienist's evidence would typically concern the health aspects of exposure to indoor air pollution and the analytical techniques used to quantify the extent of toxic substance exposure upon an individual.[15] In toxic tort cases the

---

[11] *Id.* at 98.

[12] 14 McGRAW-HILL, ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 4 (1982).

[13] 13 McGRAW-HILL, DICTIONARY OF SCIENCE AND ENGINEERING 401 (1984).

[14] *Id.* at 458.

[15] Industrial hygienists evaluate various factors to determine the risk implications of exposure to toxic substances. These factors range widely but typically include the substance's toxicity, the amount of a toxic substance to which a person is exposed, the duration and frequency of exposure, the method of exposure (inges-

witnesses most frequently used for expert testimony are epidemiologists, toxicologists and physicians. Familiarity with these disciplines is essential to understand the role that the experts play in the litigation process.

Epidemiology involves the study of the distribution and causation of diseases in groups of people.[16] Of significant interest in toxic substance litigation are those epidemiologic studies of human populations which correlate the incidence of disease with measured exposures to toxic agents.[17] Typically, epidemiological studies involve a cohort evaluation of a study group and a control group. The study group would consist of individuals who were exposed to the toxic agent, while the control group would consist of unexposed individuals. This is a prospective study wherein the groups are randomly selected and observed over a period of time, often years, to compare the development, or lack thereof, of a particular abnormality associated with a toxic substance. The epidemiologist's testimony would reveal the findings of the cohort studies, and identify the causal relationship, if any, between exposure to the particular toxic substance and the resultant injury or illness.

Encompassing the study of the deleterious effects of chemicals and physical agents on organic systems, toxicology includes the identification of the stimulating agent as well as the means to prevent and treat negative responses to the exposure.[18] The tox-

---

tion, inhalation, or skin contact) and the presence of other toxic substances which might cause similar effects. Industrial hygienists can also evaluate the effects of environmental factors, such as ventilation and temperature, which may increase or decrease the extent of the exposure. For a general discussion on the industrial hygienist in toxic substance cases, *see* Imbus, Buncher, Dyson, Thomas & Nothstein, *Health Professionals as Experts*, TOXIC TORTS, LITIGATION OF HAZARDOUS SUBSTANCES CASES 553 (1984) [hereinafter Imbus]. For a comprehensive list of chemical substances and acceptable exposure values, *see 1990-1991 Threshold Limit Values for Chemical Substances in the Work Environment*, AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS; *1990-1991 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices*, AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS.

16 A good overview of the epidemiologist's role in the legal process can be found in Imbus, *supra* note 15, at 561 and Enterline, *The Role of Epidemiology and Biostatistics in Toxic Substances Litigation*, THE ROLE OF SCIENCE IN TOXIC TORT LITIGATION 126 (1988).

17 *Id. See also* Barnes & Conley, *Statistical Evidence in Litigation: Methodology, Procedure, and Practice* (Supp. 1989); Black & Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732 (1984); Heafey, *Trial by Lottery: The Misuse of Epidemiology and Statistics to Prove Causation in Drug and Chemical Litigation*, 38 DEF. L.J. 673, 674 (Dec. 1989).

18 14 MCGRAW-HILL, ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 4 (1982). For a general discussion on toxicologists and expert witness testimony, *see* INDUSTRIAL

icologist will often testify on the chemical characteristics of a toxic substance, the extent to which the substance could invade human beings and the environment and the substance's toxic effect. The toxicology field is divided into sub-disciplines with the three major sub-disciplines consisting of (1) environmental toxicology, (2) clinical toxicology and (3) forensic toxicology.

Environmental toxicology concerns the study of those agents which are purposely or accidentally added to food products, air, water and soil. Environmental toxicology also studies toxic agents which exist in the workplace. The environmental toxicologist identifies contaminating agents to understand their movement in the biosphere, reveal their mechanism of action on biotic systems, and define the limits of their safe use. Clinical toxicologists are concerned with the clinical management of diseases that are associated with chemicals of exogenous origin. Forensic toxicology primarily concerns the medicolegal aspects of a chemical's effects on the human body. Forensic toxicology determines the circumstances leading up to a cause of death and also plays a significant role in the identification of specific hazards of various chemicals.

For personal injury claims based on exposure to certain toxic substances, medical experts will typically testify about the potential causes and effects of exposure to the hazardous substance in question. Whether the medical expert is a pulmonologist, radiologist, oncologist, cardiologist, epidemiologist or an occupational health specialist depends on the type of injury or disease. All of these physicians have the requisite scientific training and knowledge to formulate opinions in causation.[19] In addition, through

---

TOXICOLOGY (Williams and Burson, eds. 1985); Imbus, *supra* note 15, at 573. For a list of several of the numerous sources available on the existence and toxicity of various agents in the environment, see *supra* note 2. *See also* J. FAWELL & S. HUNT, ENVIRONMENTAL TOXICOLOGY: ORGANIC POLLUTANTS (1988); B. CARSON, H. ELLIS & J. MCCANN, TOXICOLOGY AND BIOLOGICAL MONITORING OF METALS IN HUMANS (1986).

[19] Commentators, however, have long questioned the nature and quality of physicians who give expert medical testimony. *See, e.g.*, Wick & Kightlinger, *Impartial Medical Testimony Under the Federal Civil Rules: A Tale of Three Doctors*, 24 INS. COUNS. L.J. 115, 122 (1967) (advocating impartial expert medical witness, selected by a medical association, in order to overcome the obvious biases of a party's proffered expert witness); Van Dusen, *The Impartial Medical Expert System: The Judicial Point of View*, 34 TEMP. L.Q. 386 (1961) (federal district judge suggests that the "battle of the experts" wastes time, money and does not aid the jury in the fact finding mission); Peck, *Impartial Medical Testimony: A Way to Better and Quicker Justice*, 22 F.R.D. 21 (1959) (former New York Supreme Court justice argues that expert medical witness testimony results in jury receiving confusing, untrustworthy and unreliable data).

diagnosis of the plaintiff's condition or disease, the physicians may testify on the increased risk of disease and the need for medical surveillance of the plaintiff over a stated period.[20] In many cases, psychologists or psychiatrists may offer valuable testimony where the plaintiff seeks recovery for "fear of cancer" or other phobia-based emotional distress damages.[21]

## III. THE EXPERT'S QUALIFICATIONS

While the qualifications of an expert as a basis for excluding expert witness testimony have received less attention lately, the New Jersey case law may be viewed as a microcosm of the national experience in this area. Substantial attention has been heaped on the "junk science" phenomenon, and the number of cases involving complex scientific issues has increased so vastly that courts have attempted to gain more control over the admissibility of expert witness evidence. A court's initial inquiry ordinarily involves the qualification of the expert witness under the appropriate rules of evidence. The rules, however, do not establish any express standards by which a trial court can determine whether the proffered witness has the requisite experience, training or education to qualify as an expert.[22] As expected, the judi-

---

[20] In both occupational and environmental exposure cases, the issues of increased risk of cancer and medical monitoring costs are most often evaluated by medical testimony. *See In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829, 850-51 (3d Cir. 1990) (a claim for medical monitoring is viable, even absent present indications of physical injury, if competent expert testimony proves to a reasonable degree of medical certainty that monitoring is necessary to properly diagnose the disease's warning signs); Stites v. Sundstrand Heat Transfer, Inc., 660 F. Supp. 1516, 1523-26 (W.D. Mich. 1987) (summary judgment granted for defendant because plaintiff's expert medical witnesses could not quantify plaintiff's enhanced risk of disease); Mauro v. Raymark Indus., 116 N.J. 126, 139, 561 A.2d 257, 265 (1989) (risk of future incidence of disease must be established by testimony based on reasonable medical probability); Ayers v. Jackson Township, 106 N.J. 557, 597-99, 525 A.2d 287 (1987) (damages for enhanced risk of contracting cancer denied in the absence of proof of reasonable medical probability; damages for medical surveillance costs granted due to competent medical testimony establishing surveillance as an established medical practice); Martin v. Johns-Manville Corp., 508 Pa. 154, 165 n.5-6, 494 A.2d 1088, 1094 n.5-6 (1985) (possibility of harm inadmissible; plaintiff must present non-speculative, competent medical evidence).

[21] *See generally* Sterling v. Velsicol Chemical Corp., 855 F.2d 1188, 1206 (6th Cir. 1988) (plaintiff allowed recovery for emotional distress suffered because of the fear of contracting a toxic exposure disease); *Mauro*, 116 N.J. at 137, 561 A.2d at 263 (plaintiff with physical injury from exposure to toxic chemicals may recover damages for emotional distress when there is a reasonable concern of an enhanced risk of additional disease).

[22] The expert witness qualification standards are found in FED. R. EVID. 702 and N.J. EVID. R. 19, respectively. Rule 702 provides in full:

cial decisions on this issue clearly require a case-by-case analysis.

In *Rubanick v. Witco Chemical Corp.*,[23] a biochemist with extensive qualifications in the area of cancer research was precluded from testifying about the causal relationship between colon cancer and PCB exposure because the trial court found that the witness was not a physician and therefore lacked the requisite education, training and experience in treating cancer patients to qualify as an expert.[24] On appeal, the court reversed and concluded that the biochemist was qualified to express opinions on cancer causation and related scientific matters, notwithstanding that the opinions included medical subjects. The court ruled that "[d]eficiencies in the qualifications of an expert is a matter to be weighed by the jury," with appropriate instructions.[25]

---

> Testimony by Experts.
> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

FED. R. EVID. 702. The New Jersey expert witness qualification standard provides in part:

> Prerequisites of Personal Knowledge and Experience. As a prerequisite for the testimony of a witness there must be evidence that he has personal knowledge of the matter, or experience, training, or education, if such be required. Such evidence may be provided by the testimony of the witness himself . . . . In exceptional circumstances the judge may receive the testimony of the witness conditionally, subject to the evidence of knowledge, experience, training or education being later supplied in the course of the trial.

N.J. EVID. R. 19. Although the rules fail to provide standards for determining the adequacy of a witness's proffered qualifications, the commentators' language is certainly geared to a liberal approach. *See* Mitchell, *The Proposed Federal Rules of Evidence: How They Affect Product Liability Practice*, 12 DUQ. L. REV. 551, 563-64 (1974) (Rule 702 expands the scope of political expert witnesses to "any area of 'specialized' knowledge" and expands the scope of when the testimony may be used to whenever it is "helpful" to the trier of fact); BIUNNO, CURRENT N.J. RULES OF EVIDENCE, Comment 3 to Evid. R. 19 (1991) (trial court has broad discretionary power to allow or exclude expert testimony).

[23] 242 N.J. Super. 36, 576 A.2d 4 (App. Div. 1990), *rev'g*, 225 N.J. Super. 485, 542 A.2d 975 (Law Div. 1988).

[24] 225 N.J. Super. at 493-95, 542 A.2d at 979-80. The trial court found that the witness was a biochemist with a doctorate in biochemistry and further, that he had worked as a biochemist for Sloan-Kettering Institute for Cancer Research for over 37 years, published extensively on carcinogenesis, and was head of a research group primarily concerned with investigating the case, treatment and diagnosis of colon cancer. *Id.* at 492, 542 A.2d at 979. The court found, however, that the biochemist never conducted a medical examination of a human patient, never conducted a clinical diagnosis, nor prescribed a recommended course of treatment. *Id.* at 493, 542 A.2d at 979.

[25] 242 N.J. Super. at 48, 576 A.2d at 10. The appellate court noted that the

In *Landrigan v. Celotex Corp.*,[26] the plaintiff produced an epidemiologist/biostatistician to testify on the causal relationship between the decedent's exposure to asbestos and the decedent's resulting colon cancer. The trial judge concluded that the expert had no qualified medical training and rejected the proffered expert testimony. The appellate court agreed, concluding that the epidemiologist's expertise was in the statistical study of the occurrence of disease in various population groups, not medicine. While the witness was qualified to testify as an expert on the causal relationship between exposure to asbestos and the incidence of colon cancer, the court found that the epidemiologist was not qualified to testify as to the asbestos being the cause of the decedent's cancer.[27]

Thus, whether a witness has the appropriate qualifications to testify as an expert on a particular subject in New Jersey continues to depend on the expert's knowledge, skill and experience in that area.[28] Many of the recent Third Circuit decisions show a more liberal approach toward the qualification of expert witnesses. In the Third Circuit's most recent opinion on this issue, *In re Paoli Railroad Yard PCB Litigation*,[29] the court concluded that

---

biochemist's experience and educational background possibly rendered him more qualified as an expert witness than a medical doctor. *Id.* at 48 n.8, 576 A.2d at 10 n.8.

26 243 N.J. Super. 449, 462, 579 A.2d 1268, 1274 (App. Div. 1990).

27 *Landrigan*, 243 N.J. Super. at 462-63, 579 A.2d at 1274. The appellate division panel distinguished the physical science qualifications and experience of the expert in *Rubanick*, discussed at notes 23-25 and accompanying text, as "materially different" from those of the proffered expert, whom the court termed a statistician interested in the subject of carcinogenesis. *See infra* notes 23-25 and accompanying text; *id.* at 463, 579 A.2d at 1275. *See also* Gideon v. Johns-Manville Sales Corp., 761 F.2d 1129, 1136 (5th Cir. 1985) (the *Landrigan* epidemiologist was allowed to testify as to the ability of asbestos to cause cancer, but not on whether the asbestos was the actual medical causative agent for the particular plaintiff).

28 *See generally* Crespo v. McCartin, 244 N.J. Super. 413, 420-422, 582 A.2d 1011, 1015-16 (App. Div. 1990) (orthopedist was not qualified to render an expert opinion regarding diagnosis of an ectopic pregnancy because he never practiced obstetrics or gynecology nor did he ever perform surgery to terminate an ectopic pregnancy); Thompson v. Merrell Dow Pharmaceutical, Inc., 229 N.J. Super. 230, 240-42, 551 A.2d 177 (App. Div. 1988) (pharmacologist not qualified to render an opinion on the causal link between ingestion of Bendectin and birth defects because he never conducted Bendectin research, nor examined the plaintiff); Bock v. American Cyanamid Co., No. L-082158-86, slip op. at 11 (N.J. Super. Law Div. Jul. 3, 1989) (medical doctors precluded from testifying as experts on the effects of malathion because they lacked knowledge of malathion, its effect on the human body and whether malathion could possibly be the cause of plaintiff's ailments).

29 916 F.2d 829, 855-56 (3d Cir. 1990) (rejecting district court's requirement of specific education or experience to qualify as an expert and holding that FED. R. EVID. 702 is to be liberally construed). *See also*, DeLuca v. Merrell Dow Pharmaceu-

the trial court had abused its discretion by excluding portions of testimony from several purported experts. In particular, the testimony of a toxicologist was excluded because she was neither qualified to testify as a chemist about gas chromatography tracing nor qualified to testify as a medical doctor on the cause of the plaintiff's physical injuries.[30] The district court also excluded portions of a microbiologist's testimony on the effects of PCBs on human beings because the witness was not trained in differential diagnosis, and the testimony of a physicist regarding a study concerning PCB levels in the American population because of his curriculum vitae. The circuit court reviewed the witnesses' respective qualifications and concluded that "[i]n light of the liberal Rule 702 expert qualification standard," the experts should not have been precluded from testifying "simply because the experts did not have the degree or training which the district court apparently thought would be most appropriate."[31]

In another recent third circuit case, *DeLuca v. Merrell Dow Pharmaceutical, Inc.*,[32] the district court precluded pediatric pharmacologist testimony that the drug Bendectin caused limb reduction birth defects and that, to a reasonable degree of medical certainty, the drug caused the plaintiff's birth deformities. After careful examination of the witnesses' credentials, the circuit court concluded that a witness should not be precluded from testifying as an expert simply because of the absence of a particular degree,

---

tical, Inc., 911 F.2d 941, 953 (3d Cir. 1990) (the inquiry into proffered expert witness' qualifications involves liberal criteria); Habecker v. Copperloy Corp., 893 F.2d 49, 51-53 (3d Cir. 1990). *Cf.* Trustees of Univ. of Pa. v. Lexington Ins. Co., 815 F.2d 890, 903 (3d Cir. 1987) (although trial court has broad discretion in determining an expert's qualifications, proffered insurance claim examiner was rightfully excluded from rendering expert opinion because the examiner had no experience with large damage claims).

30 *In re Paoli*, 916 F.2d at 855.

31 *Id.* at 856. A petition for certiorari to the United States Supreme Court was recently denied. See General Electric Co. v. Knight, 111 S. Ct. 1584 (1991). *See also Habecker*, 893 F.2d at 49 (3d Cir. 1990) (non-engineer safety specialist, with a master's degree in safety education, and a doctorate degree in human factors design and product safety design, permitted to testify on whether the forklift manufacturer's failure to equip the forklift with seat belts caused the operator's death). Hammond v. International Harvester Co., 691 F.2d 646 (3d Cir. 1982) (expert allowed to testify in a product liability case involving lack of a rollover protective structure on tractors, although his only qualifications were teaching high school automobile repair and some automotive and agricultural equipment sales experience); Knight v. Otis Elevator Co., 596 F.2d 84 (3d Cir. 1979) (safety engineer permitted to render expert opinion on whether unguarded elevator control buttons constituted a design defect, regardless of the fact that he was not a design engineer familiar with elevators or their components).

32 911 F.2d 941 (3d Cir. 1990), *rev'g*, 131 F.R.D. 71 (D.N.J. 1989).

without also considering the witness' experience, knowledge and specific training.[33]

This brief overview of Third Circuit and New Jersey case law indicates that there are many avenues which a witness can travel to obtain sufficient expert witness qualifications. Both formal education and practical experience can suffice to qualify an individual as an expert, even absent particularized experience.[34] Professional witnesses will not be excluded[35] nor will an expert who is a party or an interested party be excluded for these reasons alone.[36] Expert witnesses may even testify outside of their field of expertise when there is a logical nexus between the expert's field of expertise and the elicited testimony.[37] In short, there are no mechanical rules or objective standards upon which to evaluate an expert's qualifications. The judicial trend, however, certainly appears to be in favor of admissibility as long as the expert's qualifications comply with the broad language of the applicable evidence rule.

---

[33] 911 F.2d at 953.

[34] *See, e.g.*, Davis v. United States, 865 F.2d 164, 168 (8th Cir. 1988) (public health inspector with a degree in journalism qualified as expert witness on sexually transmitted disease because of over eight years experience investigating and managing sexually transmitted disease cases); Davis v. American Jet Leasing, Inc., 864 F.2d 612, 615 (8th Cir. 1988) (licensed pilot with maintenance and repair supervisory experience was qualified to render expert opinion on defendant's aircraft maintenance and inspection program); Loudermill v. Dow Chemical Co., 863 F.2d 566, 568-69 (8th Cir. 1988) (toxicologist with extensive experience in determining toxicological effects and relation to death was allowed to render expert opinion on causal link between chemical exposure and liver failure, notwithstanding that expert was not a medical doctor); Hermes v. Pfizer, Inc., 848 F.2d 66, 69 n.15 (5th Cir. 1988) (expert's knowledge, experience, education or training is the critical factor, not the degree held by the expert); DaSilva v. American Brands, Inc., 845 F.2d 356, 361 (1st Cir. 1988); Exum v. General Electric Co., 819 F.2d 1158, 1163 (D.C. Cir. 1987); Dixon v. Int'l Harvester Co., 754 F.2d 573, 580 (5th Cir. 1985); Frazier v. Continental Oil Co., 568 F.2d 378, 383 (5th Cir. 1978).

[35] Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799-800 (4th Cir. 1989) (status of professional expert witness does not mandate exclusion of testimony); Snyder v. Whittaker Corp., 839 F.2d 1085, 1089 (5th Cir. 1988) (witness cannot be excluded from testifying simply because the witness spends much of the time consulting with trial attorneys and testifying).

[36] *See, e.g.*, Tagatz v. Marquette Univ., 861 F.2d 1040, 1042 (7th Cir. 1988) (plaintiff, an expert in the evaluation of statistical evidence in employment discrimination actions, allowed to testify as expert witness in his own employment discrimination case).

[37] *See, e.g.*, Carroll v. Otis Elevator Co., 896 F.2d 210 (7th Cir. 1990) (experimental psychologist was permitted to testify as expert witness concerning escalator design, limited to the actions of young children with regard to red stop buttons).

## IV. ADMISSIBILITY OF EXPERT WITNESS TESTIMONY

There is one general proposition with which most courts and commentators will agree — if a witness is qualified as an expert, the expert's testimony will be admissible when (1) the expert's "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue,"[38] and (2) the "facts or data in the particular case upon which an expert bases an opinion or inference . . . [are] . . . of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject."[39] The inquiry, therefore, is whether the expert witness opinion will help the jury to understand the issues and whether the expert's opinion is reliable.

In most instances, expert testimony will assist the jury in its determinations, unless the circumstances of the case are extraordinary.[40] A review of the case law reveals a clear tendency toward allowing the expert's opinion even if the testimony only permits the jury to focus their collective common sense. Therefore, the emphasis in almost all cases dealing with scientific evidence, novel theories and "junk science" is the reliability of the expert witness testimony. Reliability can be challenged by attacking the underlying scientific data used by the expert in forming an opinion or the manner in which the scientific data is utilized by the expert.[41] The use of *in limine* hearings to evaluate the reli-

---

[38] FED. R. EVID. 702. The Federal Rules of Evidence and New Jersey Evidence Rule 56(2) are identical in all relevant respects.

[39] FED. R. EVID. 703. The Federal Rules of Evidence and Rule 56(2) of the New Jersey Rules of Evidence are identical in all relevant respects.

[40] Expert testimony will normally be allowed if the subject is beyond the average person's "ordinary experience, education, and knowledge," State v. Odom, 116 N.J. 65, 71, 560 A.2d 1198, 1201 (1989), or if the testimony is "so esoteric that jurors of common judgment and experience cannot form a valid judgment" on the issue in question. Butler v. Acme Markets, Inc., 89 N.J. 270, 283, 445 A.2d 1141, 1147 (1982). *See, e.g.*, Ryan v. KDI Sylvan Pools, Inc., 121 N.J. 276, 579 A.2d 1241 (1990) (product defects); Lesniak v. County of Bergen, 117 N.J. 12, 31, 563 A.2d 795, 805 (1989) (extent of permanent injury or disability); State v. Zola, 112 N.J. 384, 412, 548 A.2d 1022, 1036 (1988) (serologists); Rosenberg by Rosenberg v. Cahill, 99 N.J. 318, 325, 492 A.2d 371, 374 (1985) (medical malpractice); Tenore v. Nu Car Carriers, 67 N.J. 466, 483-84, 341 A.2d 613, 622-23 (1975) (economists); Rubanick v. Witco Chemical Corp., 242 N.J. Super. 36, 576 A.2d 4 (App. Div. 1990) (toxicologist); Motor Finance Corp. v. Dir., Div. of Tax, 129 N.J. Super. 19, 25, 322 A.2d 180, 183 (App. Div. 1974), *cert. denied*, 66 N.J. 319, 331 A.2d 19 (1974) (testimony from accountants).

[41] *See* DeLuca v. Merrell Dow Pharmaceutical, Inc., 911 F.2d 941, 954 (3d Cir. 1990) (Federal Rules of Evidence do not require that the expert accept the conclusions of a study if the expert wishes merely to utilize the study's underlying data to

ability of scientific expert witness testimony on complex scientific hazardous substance and toxic tort issues has become the subject of some judicial disagreement.[42] While there is general agreement that courts must carefully review the qualifications and reliability of a proffered expert witness in accordance with the rules of evidence, there is substantial disagreement on the manner and standards of review which are to be utilized in performing the review.

### *A. Who Decides—Judge or Jury?*

An initial controversy surrounds the issue of who should decide questions on the validity and reliability of proffered scientific evidence. In the last ten years, two schools of judicial thought have evolved on whether the judge or the jury should decide these questions.

One school clearly believes that such issues should be left to the jury to decide. This approach was initially discussed in *Ferebee v. Chevron Chemical Co.*,[43] which involved the admissibility of expert testimony to establish a causal connection between paraquat exposure and pulmonary fibrosis. Both the plaintiff's and defendant's experts relied on diagnostic methodology; the experts differed, however, on the conclusions to be drawn from the test results and other data.[44] The Circuit Court of the District of Co-

formulate conclusions); United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985) (acceptance of scientific technique by a certain percentage of the scientific community is a factor, rather than a prerequisite, in determining admissibility). Note, however, that Rule 403 of the Federal Rules of Evidence still requires the evidence to serve its ultimate purpose without "the danger of unfair prejudice, confusion of the issues, or misleading the jury." FED. R. EVID. 403. Many courts believe that if the expert testimony survives scrutiny under Rules 702 and 703, it should not be excluded under Rule 403. *See In re* Paoli, 916 F.2d 829, 859 (3d Cir. 1990).

42 The Third Circuit has held that "where there are numerous experts presenting voluminous testimony on the cutting edge of scientific research, an *in limine* hearing may be a very useful tool in conducting both the inquiry and the fact finding and balancing, which are the hallmarks of Rules 703 and 403 respectively." *In re* Paoli, 916 F.2d at 859. On the other hand, several courts in New Jersey have expressed reservations about the use of *in limine* hearings to decide evidentiary matters, and have instead favored a Rule 8 hearing on the issue during the trial. N.J. EVID. R. 8. *See Rubanick*, 242 N.J Super. at 46, 576 A.2d at 9 (favoring N.J. EVID. R. 8 hearing because the *in limine* hearing was too extensive and caused the trial judge to become the fact-finder, instead of the jury); Bellardini v. Krikorian, 222 N.J. Super. 457, 464 (App. Div. 1988) (advocating cautious and infrequent use of *in limine* hearings because the hearings are frequently conducted in the abstract without a concrete factual basis).

43 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984).

44 *Id.* at 1535.

lumbia refused to analyze the experts' conclusions, asserting that:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low-level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, *if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony.*[45]

Thus, the court perceived the case as a "classic battle of the experts, a battle in which the jury must decide the victor."[46] This "leave it to the jury" approach has also been recognized in other jurisdictions.[47] Both the Third Circuit[48] and the New Jersey courts[49] appear to be leaning in the direction of allowing juries to decide these issues provided the prerequisite expert witness qualification standards have been met.

---

[45] *Id.* at 1534 (emphasis added).

[46] *Id.* at 1535. *See also* Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 745 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986) (district court judge, as fact-finder in non-jury trial, had burden of choosing the victor in the "battle of the experts").

[47] *See* Christopherson v. Allied-Signal Corp., 902 F.2d 362, 364 (5th Cir. 1990), *reh'g en banc granted*, 914 F.2d 66 (5th Cir. 1990) (proper deference should be accorded to the jury's role as factfinder when there are conflicting expert opinions; questions relating to the source and basis of an expert's opinion go to the credibility of the opinion, rather than its admissibility, and should be left to the jury); *Wells*, 788 F.2d at 745 (if the trier of fact finds sufficient evidence of causation in a legal sense, i.e., to a reasonable degree of certainty, it does not matter that the medical community may require more research, studies and evidence prior to conclusively resolving the question); Lanzilotti v. Merrell Dow Pharmaceutical, Inc., WL 7832 (E.D. Pa. Jul. 10, 1986) (a classic battle of the experts boils down to the issue of credibility, a matter which is to be resolved by the jury).

[48] In *In re* Japanese Elec. Prod., 723 F.2d 238, 279 (3d Cir. 1983), *rev'd on other grounds sub nom.* Matsushita Elec. Indus. v. Zenith Radio Corp., 475 U.S. 574 (1986), the Third Circuit held:

> Moreover, the suggestion that the court must, in deciding on admissibility, carefully scrutinize the underlying assumptions, the inferences drawn, and the conclusions reached, if followed rigorously, would result in the trial court, as distinguished from the fact-finder, deciding the weight to be given to the testimony . . . . The jury is intelligent enough, aided by counsel, to ignore what is unhelpful in its deliberations . . . . The question whether such an opinion will be helpful to the jury involves discretion, but that discretion must be exercised consistent with the presumption that expert testimony will be helpful.

*In re* Japanese Elec. Prod., 723 F.2d at 279 (citations omitted). *See also* Knight v. Otis Elevator Co., 596 F.2d 84, 86-88 (3d Cir. 1979) (trial court's exclusion of expert testimony invaded the jury's factfinding function).

[49] *See, e.g.*, Rubanick v. Witco chemical Corp., 242 N.J. Super. 36, 48, 576 A.2d 4 (App. Div. 1990) (the jury must determine the weight, credibility and probative value of the expert witness's testimony).

The second school of thought on the question of who decides expert scientific evidence reliability and validity issues calls for the court to decide. Various judges have taken a very active role in holding medical experts to court-fashioned threshold scientific standards. One of the most renowned cases where this threshold was applied, *In re Agent Orange Product Liability Litigation*,[50] involved the health effects of low-level dioxin (Agent Orange) exposure to Vietnam veterans. The defendant chemical manufacturers moved for summary judgment on the ground that the plaintiffs' scientific proofs were insufficient to prove causation.

The court recognized the two general approaches to applying certain rules of evidence—liberal and strict—and adopted the more restrictive approach.[51] The court held that in cases where the presentation of theories of causation depended almost entirely upon expert testimony, a "rigorous examination" of the expert opinions was especially important.[52] The court further opined that such careful scrutiny of proposed evidence was especially appropriate in the toxic tort area, stating that "[t]he uncertainty of the evidence in such cases, dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gate-keeping under [Rules] 403 and 703 [of the Federal Rules of Evidence] by the court."[53] Thus, under this interpretation of the applicable rules of evidence, certain courts will carefully scrutinize the evidence prior to allowing its presentation to the trier of fact. This strict approach, requiring the trial court to make a detailed, substantive, scientific inquiry into the admissibility of expert testimony, has been followed in several other jurisdictions.[54]

---

[50] 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom.* Lombardi v. Dow Chemical Co., 487 U.S. 1234 (1988).

[51] *Id.* at 1243-44. The restrictive view would require the trial court judge to ascertain whether the underlying scientific data was "untrustworthy" for reasons of hearsay and other similar admissibility reasons. In addition, the trial court would have to decide whether the data which the expert opinion was based upon was the type reasonably relied on by other experts in the field. *Id.* at 1244. In contrast, the liberal view requires that the trial court determine merely that the underlying data is the type reasonably relied upon by other experts in the field. *Id.*

[52] *Id.* at 1244.

[53] *Id.* at 1260.

[54] *See* Head v. Lithonia Corp., 881 F.2d 941, 944 (10th Cir. 1989) (the court's preliminary determination on admissibility of expert testimony necessarily should focus on the foundation for the opinion and its reliability); Richardson by Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 829 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989) (whether an expert witness opinion has an adequate factual basis should be decided by the court as a matter of law); Viterbo v. Dow Chemical Co., 826 F.2d 420, 422 (5th Cir. 1987) (trial court may investigate the foundation and reliability of the expert's opinion); Lynch v. Merrell-National Laboratories, 646 F.

*B. The Standards of Review—*

The admissibility of scientific evidence by way of expert witness testimony cannot depend upon solely the rules of evidence because such rules provide no definitive guidelines on admissibility other than that the "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence"[55] and that the "facts or data . . . [be] of a type reasonably relied upon by experts in the particular field."[56] Analysis on the subject of admissibility of expert testimony concerning novel scientific theories would not be complete without a review of these two critical areas.

1. The Standard of Reasonable Reliance on the Underlying Data or Study

Courts have differed on whether support for determining an expert's reasonable reliance on certain facts or data should come from the court or the expert when there is a question of admissibility. The Supreme Court of New Jersey recently addressed this precise issue in a case involving a swimming pool diving accident.[57] The plaintiff brought a product liability action alleging design defect and inadequate warning against the pool manufacturer. The manufacturer's expert testified that the pool was constructed according to the industry's residential pool standards, and that there was no need for warnings. The expert's opinion was based on reports from various spinal cord injury centers, information obtained through interviews with injured persons, and information from interviews with diving board manufacturers and fabricators of similar swimming pools.

When the trial court inquired as to the reliability of this information, the expert conceded that he did not verify it, and that the manufacturers may have under-reported the number of

---

Supp. 856, 864 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987) (courts must examine the data upon which the expert witness opinion testimony will be based to ascertain whether the data is the type that is typically relied upon by other experts in the field and whether reliance on that data is reasonable); Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1090 (D. Md. 1986), *aff'd without opinion*, 814 F.2d 655 (4th Cir. 1987) (court's evaluation of expert's proffered testimony must ensure that there is a basis, beyond mere speculation, and theory for the opinion); Johnston v. United States, 597 F. Supp. 374, 415 (D. Kan. 1984) (court must evaluate expert's credibility and trustworthiness, which includes evaluating the scientific view and its acceptance in the scientific community).

55 *See* FED. R. EVID. 702; N.J. EVID. R. 19, 56(2).

56 *See* FED. R. EVID. 703; N.J. EVID. R. 56(2).

57 Ryan v. KDI Sylvan Pools, Inc., 121 N.J. 276, 579 A.2d 1241 (1990).

swimming pool related injuries. The expert asserted that the data upon which he based his opinion was the same data utilized by the Consumer Product Safety Commission in the formulations of swimming pool standards. Thus, the expert concluded that it was reasonable to rely on these types of data in formulating an expert opinion. Based upon the findings in the New Jersey Evidence Rule 8 hearing, the trial court ruled that it would not permit the expert to advise the jury as to the number of diving injury incidents. The trial court found that the data which the expert had used as the basis for his opinion was "relatively vague" and would unduly prejudice the plaintiff.[58]

On appeal, the New Jersey Supreme Court was asked to determine whether an acknowledged expert witness' opinion was admissible if it were shown that the opinion was based on potentially unreliable data, but that the data was of the type regularly relied upon by experts in the field in rendering opinions. The court acknowledged that the language of New Jersey Rule of Evidence 56(2) mirrored that of Federal Rule 703, which required the following two inquiries: "(1) do experts in the field in fact rely upon [these] kinds of facts or data? and (2) if so, is their reliance reasonable?"[59] The answer to the first inquiry, the Court found, was typically obtained from the experts themselves, applicable literature in the field, and by judicial notice. As to the second query, the Court noted that an expert could not be allowed to ratify the reasonableness of his reliance on the underlying data and asserted the need for judicial inquiry and findings regarding whether experts in the given field rely on certain information. If so, then reliance on the underlying data would be presumed to be reasonable. Moreover, the court stated that "[t]he focus should be on what the experts in fact rely on, not on whether the court thinks they should so rely."[60] Accordingly,

---

[58] *Id.* at 282, 579 A.2d at 1244. The appellate division affirmed and stated that the expert's opinion was properly excluded under Rule 56(2) because the data was too unreliable and vague. *Id.* at 283, 579 A.2d at 1244.

[59] *Id.* at 287, 579 A.2d at 1247 (quoting MCCORMICK ON EVIDENCE § 15, at 3 (1984 & Supp. 1987)

[60] *Id.* at 289, 579 A.2d at 1248. *See* Grassis v. Johns-Manville Corp., 248 N.J. Super. 446, 591 A.2d 671 (App. Div. 1991). ("courts should be loath to determine whether the particular expert has properly relied upon data which experts in the field generally rely upon"); *In re* Japanese Elect. Prod., 723 F.2d 238, 276-77 (3d Cir. 1983) (when making a Rule 703 analysis to determine the underlying basis of an expert's opinion, the proper inquiry is what experts in the relevant field deem to be reliable, not what the court determines reliable to mean); Indian Coffee Corp. v. Procter & Gamble, 752 F.2d 891, 895 (3d Cir.), *cert. denied*, 474 U.S. 863 (1985) (district courts committed reversible error in failing to make finding as to the types

although certain data may be potentially unreliable, the expert opinion based on that data is admissible if experts in the field regularly rely on those types of data.

2. Is the Expert Witness Opinion Reliable?

This question is by far the most interesting and difficult for courts to grasp and resolve because challenges typically go to either the reliability of the underlying data itself or the manner in which the expert has used the data. The challenged data is most often epidemiological studies, or animal studies, but may also be in the form of anecdotal data, data recalculations or analogous chemical studies. The answer to how courts have resolved these questions depends on the jurisdiction, the court and the standard of review exercised by the court.

A renowned standard for the admissibility of expert opinions concerning scientific evidence is the "general acceptance" test, first articulated in 1923 by the Court of Appeals for the District of Columbia in the seminal case of *Frye v. United States*.[61] The case hinged on the admissibility of the results of a systolic blood pressure deception test, which was a novel scientific test in 1923 and a precursor to the lie detector test. The Court of Appeals set forth the following standard:

> 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*.[62]

Thus, courts which utilized the general acceptance test had to evaluate the status, in the relevant scientific community, of the scientific foundation for the proffered novel evidence and the usual technique for applying the scientific principle, in addition to evaluating the technique used on the particular occasion relevant to the proffered

---

of data experts find reliable). *But see* Soden v. Freightliner Corp., 714 F.2d 498, 504-05 (5th Cir. 1983) (district court's exclusion of expert opinion not reversible error where the court wanted better foundational data for the opinion).

61 293 F. 1013 (D.C. Cir. 1923). This short opinion dealing with the systolic blood pressure test is cited, either favorably or critically, in almost every article or opinion dealing with the issue of expert witness testimony.

62 *Id.* at 1014 (emphasis added).

testimony.[63] Once the scientific foundation was generally recognized and accepted by the scientific community, the judicial review of the foundational requirement was eliminated. The *Frye* general acceptance standard was quickly accepted and adopted by a majority of jurisdictions.[64] Since the adoption of the Federal Rules of Evidence, however, various courts have tended to reject or modify the general acceptance test on the grounds that it violates the essence of the Federal Rules of Evidence, which generally provide for the admission of expert testimony whenever it would be helpful to the trier of fact.[65]

The general acceptance test has also been rejected because neither the Federal Rules of Evidence nor the accompanying advisory committee notes mention this or any other standard for the admission of novel scientific evidence.[66] In *United States v. Downing*,[67] one of the leading cases rejecting the general acceptance standard, the Court of Appeals for the Third Circuit concluded that the test suffered from serious flaws, and a more flexible three-step anal-

---

63 *See, e.g.*, United States v. Downing, 753 F.2d 1224, 1234 (3d Cir. 1985) (citation omitted).

64 Note, *Novel Scientific Evidence: Does Frye Require That General Acceptance Within the Scientific Community Be Established by Disinterested Scientists?*, 65 DET. L. REV. 147, 148 (1987) (approximately two-thirds of the jurisdictions in the United States follow the *Frye* standard, or derivations thereof).

65 *See, e.g.*, United States v. Williams, 583 F.2d 1194, 1198 (2d Cir. 1978) (admissibility of scientific evidence depends on the established considerations applicable to the admissibility of all evidence such as relevance, materiality, reliability, tendency for prejudice or confusion of the jury). For an in depth discussion and criticism of the *Frye* test, *see* Gianelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States A Half-Century Later*, 80 COLUM. L. REV. 1197 (1980); United States v. Baller, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975) (court suggested that, unless unduly prejudicial, presentation of relevant scientific evidence should be allowed and credibility of this evidence can be refuted on cross-examination); State v. Temple, 302 N.C. 1, 12, 273 S.E.2d 273, 280 (1981) (new scientific evidence can be admitted when its accuracy and reliability have become established and recognized); Coppolino v. State, 223 So.2d 68, 70 (Fla. Dist. Ct. App. 1968), *appeal dismissed*, 234 So.2d 120 (Fla. 1969), *cert. denied*, 399 U.S. 927 (1970) (evidence based on scientific tests is allowed when the tests are recognized and accepted by the scientists in that field or when the test is reasonably demonstrable).

66 *See* 3 J. WEINSTEIN AND M. BERGER, WEINSTEIN'S EVIDENCE 02[03], at 702-13 (1990) (the failure of Rule 702 and the Advisory Committee Notes to mention the *Frye* decision manifests a rejection of the general acceptance rule); 22 C. WRIGHT & K. GRAHAM, FEDERAL PRACTICE AND PROCEDURE § 5168, at 86-90 (1978) (criticizing *Frye* and concluding that the Federal Rules of Evidence repealed the general acceptance rule); *In re* Agent Orange Product Liability Litig., 611 F. Supp. 1223, 1242 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 827 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988) (the *Frye* general acceptance standard has been replaced by the Federal Rules of Evidence balancing test the reliability, relevance, and usefulness versus the risk of prejudice, waste or confusion).

67 753 F.2d 1224 (3d Cir. 1975).

ysis was developed.[68] The circuit court stated that a court must first inquire into the reliability of the scientific process or technique used to generate the novel scientific information:

> the 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. The district court in assessing reliability may examine a variety of factors in addition to scientific acceptance. In many cases, however, the acceptance factor may well be decisive, or nearly so . . . . On the other hand, a known technique which has been able to attract only minimal support within the scientific community is likely to be found unreliable.[69]

The Third Circuit declared that where the novel science has no prior litigation record to establish its acceptance or reliability, the court can then examine other factors, including the comparison of the novel technique with established scientific analysis techniques, review of specialized literature on the technique, existence of critical analysis of the technique by the scientific community, the expert's professional stature and qualifications, and the novel technique's error rate and the type of errors.[70]

The second step requires balancing the possibility that the novel scientific information or technique would overwhelm or confuse the jury against the court's assessment of the technique's reliability. In contrast to enumerating the factors to be used in performing the reliability analysis, the Third Circuit provided no meaningful guidelines or mandatory procedures for trial courts to follow in performing the balancing analysis, with the exception of reference to an *in limine* hearing at or before trial.[71] The balancing analysis may or may not be different from the court's determination of whether the probative value of the evidence is substantially outweighed by other dangers, such as undue delay, waste of time or

---

68 753 F.2d at 1236-37.

69 *Id.* at 1238.

70 *Id.* at 1238-39. For a list of other factors which may be utilized in determining reliability, *see* 3 J. WEINSTEIN AND M. BERGER, 02[03], at 702-41 to 702-43 (1990). The *Downing* "reliability as a condition of admissibility" analysis differs from the *Frye* standard which required a scientific "nose-counting" to determine sufficient acceptance within the relevant scientific community.

71 *Downing*, 753 F.2d at 1240-41. Little guidance was provided with the exception that the Third Circuit acknowledged the "presumption of helpfulness" accorded expert testimony under Rule 702 and determined that district court holdings concerning the admission or exclusion of novel scientific evidence would be reviewed on an "abuse of discretion" standard.

needless presentation of cumulative evidence.[72]

The circuit court noted that the final element of the analysis requires that there be a sufficient nexus between the proffered scientific technique or result and the actual facts of the case, such that the information will aid the jury in its fact finding function. This "relevancy" test, the court held, will require an on-the-record detailed offer of proof, and failure to tender such offer renders the expert testimony excludable.[73]

Since 1985, the Third Circuit has consistently followed this three pronged analysis, reversing and remanding cases which do not closely adhere to the guidelines. In fact, the court's most recent decisions on this issue have expanded the scope of the *Downing* analysis and have held that when a scientist's methodology is attacked, rather than the underlying data, the trial judge must analyze the information by looking to the *Downing* reliability, relevance, and assistance to the jury analysis before ruling on the testimony's admissibility.[74]

The Court of Appeals for the District of Columbia developed a different standard in a case involving the causal relationship between long-term dermal absorption of paraquat and the development of pulmonary fibrosis. In *Ferebee v. Chevron Chemical Co.*,[75] the defendant argued that the plaintiff's proffered expert's opinion on causation was not generally accepted in the medical and scientific community and was sufficiently novel to warrant exclusion.[76] After carefully reviewing all of the scientific evidence, the court concluded:

[A] cause-effect relationship need not be clearly established by

---

72 FED. R. EVID. 403 can be a separate basis for exclusion, particularly with regard to the danger of unfair prejudice. Rule 403 provides in full:

> Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading of the jury, or by considerations of undue delay, waste of time, or needless presentation of evidence.

If the testimony survives the rigors of Rule 702 and 703 analysis, however, "Rule 403 is an unlikely basis for exclusion." DeLuca v. Merrell Dow Pharmaceutical, Inc., 911 F.2d 941, 957 (3d Cir. 1990).

73 *Downing*, 753 F.2d at 1242. *See, e.g.*, United States v. Fosher, 590 F.2d 381, 383 (1st Cir. 1979) (offer of proof insufficient to establish relevancy of the proffered expert testimony to the case at hand, as well as insufficient to establish that the subject matter was beyond the knowledge of ordinary lay person jurors).

74 *See DeLuca*, 911 F.2d at 954-55; *In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829, 857 (3d Cir. 1990). (both courts held that in making reliability determinations, courts should err on the side of admission rather than exclusion).

75 736 F.2d 1529 (D.C. Cir. 1984).

76 *Id.* at 1535.

> animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such conclusion is sound, such as [the] use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused [the plaintiff's] injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That [the plaintiff's] case may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.[77]

Consequently, this "legal sufficiency" standard, which potentially ignores probabilistic evidence, could conceivably allow a court to rely solely on the opinion of one physician or scientist.[78] Moreover, in a more recent case, this same court held that it was not obligated to accept, without further investigation, every technically qualified expert witness.[79]

Within this framework, an examination of the unsettled state of the law in New Jersey is helpful. Historically, New Jersey courts have followed the general acceptance standard to test the reliability of expert testimony:

> To meet the requirement that the expert's testimony be sufficiently reliable, defense counsel must show that the testimony

---

77 *Id.* at 1535-36. *See also* Longmore v. Merrell Dow Pharmaceuticals, Inc., 737 F. Supp. 1117 (D. Idaho 1990) (court distinguished "legal sufficiency" from "scientific certainty" holding that the latter is not required by law, which employs the "more likely than not" standard).

78 Various commentators believe this approach creates a substantial opportunity for abuse in the admission of novel scientific theories. For a critique of *Ferebee* and its progeny, *see* Brennan, *supra* note 6, at 494-501. Other jurisdictions, however, have followed *Ferebee*. *See e.g.*, Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741 (11th Cir.), *reh'g denied*, 795 F.2d 89 (11th Cir.), *cert. denied.*, 479 U.S. 950 (1986) (applied *Ferebee* to a case involving the teratogenic effects of a spermicide); Christopherson v. Allied Signal Corp., 902 F.2d 362 (5th Cir. 1990) (applied *Ferebee* to a wrongful death case involving exposure to toxic fumes).

79 Richardson by Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 829 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989).

> satisfies New Jersey's standard of acceptability for scientific evidence . . . . The technique or mode of analysis used by the expert must have a sufficient scientific basis to produce uniform and reasonably reliable results so as to contribute materially to the ascertainment of the truth.[80]

Thus, New Jersey courts have been inclined to examine carefully the underlying basis, technique or mode of analysis to ensure that the technique is reasonably reliable. In those instances where courts have found that the expert's opinion was nothing more than a bare conclusion, unsupported by appropriate and reliable data, the testimony has been deemed an inadmissible "net opinion."[81]

Several recent decisions, however, indicate that in the area of causation, New Jersey may be restructuring its standard on the admissibility of expert witness testimony beyond the general acceptance standard. For instance, in *Rubanick v. Witco Chemical Corp.*,[82] a toxic tort case involving the causal relationship between polychlorinated biphenyl (PCB) exposure and colon cancer, the trial judge excluded the testimony of the plaintiff's only causation expert, a biochemist specializing in cancer research. The court found that the witness was not qualified to render an opinion on the causation of the plaintiff's illness and that the proofs relied upon by the witness indicated nothing more than a novel scientific opinion which

---

80 State v. Kelly, 97 N.J. 178, 209-10, 478 A.2d 364, 380 (1984) (citations omitted). In *Kelly*, the expert testimony discussed the existence of "battered woman syndrome". *See also* Windmere, Inc. v. Int'l Ins. Co., 105 N.J. 373, 386, 522 A.2d 405, 412 (1987) (general acceptance of voiceprint analysis "is a critical factor in finding that there is sufficient scientific basis to produce uniform and reasonably reliable results"); Romano v. Kimmelman, 96 N.J. 66, 474 A.2d 1 (1984) (general acceptance of breathalyzer analysis); State v. Cavallo, 88 N.J. 508, 443 A.2d 1020 (1982) (general acceptance of psychiatric testimony about rapist characteristics); State v. Hurd, 86 N.J. 525, 432 A.2d 86 (1981) (general acceptance of testimony enhanced by hypnosis).

81 *See* Matter of Yaccarino, 117 N.J. 175, 196, 564 A.2d 1184 (1989) (doctor's opinion on patient was unsubstantiated by the evidence and excludable as a net opinion); Johnson v. Salem Corp., 97 N.J. 78, 91, 477 A.2d 1246, 1253 (1984) (expert's opinion, unsupported by sufficient facts constituted "bare conclusion," inadmissible as a net opinion); Bowen v. Bowen, 96 N.J. 36, 49-50, 473 A.2d 73, 80 (1984) (expert's opinion, based on experience alone without any factual basis, is a net opinion); Buckelew v. Grossbard, 87 N.J. 512, 524, 435 A.2d 1150 (1981) (net opinion rule bars an expert's bare conclusions unsubstantiated by factual data); Pearson v. St. Paul, 220 N.J. Super. 110, 116, 531 A.2d 744, 747 (App. Div. 1987) (medical expert's opinion not considered a net opinion because it was adequately supported by facts and reasonable expert assumptions); Correa v. Maggiore, 196 N.J. Super. 273, 282-83, 482 A.2d 192, 196-97 (App. Div. 1984) (expert's opinion, supported by experience, architect's plans, and established procedures, does not constitute an inadmissible net opinion).

82 225 N.J. Super. 485, 542 A.2d 975 (Law Div. 1988).

was not generally accepted by even a substantial minority of the relevant scientific community.[83] The appellate court reversed and remanded on two grounds. First, the court found that the biochemist was qualified to express novel medical expert opinions on causation, provided that the proffered opinion was based on adequate experience, training or education of the witness, and the opinion was not "illogical, outlandish or totally speculative such that no reasonable jury could accept the opinion."[84] Secondly, the court rejected the general acceptance standard and adopted the broad proposition that "[s]tudies establishing a statistically sound causal relationship between a chemical and human cancer may be supportive of a causation theory, notwithstanding the fact that a majority of the relevant disciplines may not have yet expressed agreement with a particular study."[85] Perhaps the most interesting aspect of this concept is that, according to the court, the admission of expert testimony on novel scientific evidence would be reviewed under a relevancy analysis—probative value weighed against the dangers of admission.[86] The concurring[87] and dissenting[88] opinions clearly questioned the ma-

---

[83] *Id.* at 500, 542 A.2d at 980, 983.

[84] Rubanick v. Witco Chemical Corp., 242 N.J. Super. 36, 41, 576 A.2d 4, 6 (App. Div. 1990).

[85] *Id.* at 51, 576 A.2d at 11-12. In addition, the majority opinion cited Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), in support of the principle that a well-reasoned opinion based upon the expert's education, training and experience should not be excluded merely because the opinion is not generally accepted in the scientific community. *Id.* at 53, 576 A.2d at 13. The court asserted that the credibility, probative value, and weight of the expert testimony would be decided by the jury. *Id.* at 48, 576 A.2d at 10.

[86] *Id.* at 54, 576 A.2d at 13 (*citing* J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE, 02[03] (1988)). The court provides an interesting discussion of the scientist's use of "probable," versus "possible," as opposed to terms of legal significance, such as reasonable probability. The court's implied message — do not get caught up in phraseology; determine whether the expert's opinion concludes that exposure probably caused the cancer in question. *Id.* at 55-56, 576 A.2d at 14-15.

[87] Judge Stern's concurring opinion agreed with the majority that the general acceptance standard is too narrow a governing standard for admission of "causation" evidence in toxic tort cases, as opposed to the reliability of a scientifically novel device, technique or mode of analysis. Judge Stern diverged from the majority opinion on the grounds that it was the trial judge's responsibility to determine whether the proffered expert testimony was sufficiently reliable to assist the jury. Judge Stern emphasized that it was the trial court's decision and there was the possibility that further evidence would have been produced to render the proffered testimony as to causation more reliable. *Id.* at 58-59, 576 A.2d at 15-17 (Stern, J., concurring).

[88] Judge Havey's dissenting opinion criticized the majority's use of scientific "nose-counting" and "general acceptance" tests to evaluate causation in toxic tort cases. In contrast, Judge Havey supported a case-by-case analysis of all factual and scientific bases to determine reasonable reliability. *Id.* at 65-67. The dissent was

jority's standard of review and rejected most novel theories as unsupported net opinions.

In accord with *Rubanick* is *Landrigan v. Celotex Corp.*,[89] wherein a different appellate division panel affirmed the exclusion of expert testimony on the causal connection between asbestos exposure and colon cancer because the testimony consisted of unsupported net opinions. The court concluded that:

> [when causation] lies beyond the outskirts of medical knowledge, and plaintiff's proofs are simply incapable of engaging the reasoning processes of a jury . . ., the fact that causation cannot be reasonably demonstrated by presently available evidence is no justification for allowing a jury to guess its way to a result.[90]

Accordingly, the New Jersey decisions on the admissibility of expert testimony on novel scientific evidence have left many unanswered questions. These questions include the scope of judicial review, the procedural test for unreasonable reliance, the procedural validity of an *in limine* review of scientific evidence and the precise standard for determining the reliability of scientific causation evidence. The only clear answer seems to be that all available scientific evidence on the causation issue will need to be presented, reviewed and analyzed to determine its admissibility.

### 3. Types of Scientific Studies Which May Establish Causation

The importance of a multi-disciplinary presentation of scientific studies and data is essential to the admissibility of the proffered causation testimony. Two of the major scientific methods of establishing causation, epidemiology and animal studies, are discussed herein along with other methods, in order to provide the legal practitioner with working knowledge of the methods.

---

concerned that once a technique was deemed "generally accepted," its reliability and test results would be professed by judicial notice, thus obviating the need for proof in every case. The dissent would exclude the proffered causation testimony because it was not supported by a single scientific study and had no factual basis. *Id.* at 63, 576 A.2d at 18 (Havey, J., dissenting).

89 243 N.J. Super. 449, 579 A.2d 1268 (App. Div. 1990). *See also* Vuocolo v. Diamond Shamrock Chem. Co., 240 N.J. Super. 289, 298-300, 573 A.2d 196, 201-02 (App. Div. 1990) (expert testimony considered a net opinion because increased risk of disease could not be established to a reasonable degree of medical certainty or probability).

90 *Landrigan*, 243 N.J. Super. at 461-62, 579 A.2d at 1274.

a. *Epidemiological Studies*

Epidemiology is the study of disease and its incidence or occurrence in human populations. Epidemiologists study groups of people to determine statistically significant correlations between certain diseases and personal characteristics, habits or exposures to different substances.[91] Epidemiological studies, as in other scientific fields, can be prospective or retrospective in nature. The retrospective study uses data already generated (for instance if the symptom or illness has manifested itself), and the epidemiologist compares the affected group with an unaffected control group and seeks a common factor or exposure to explain the occurrence of the illness in the affected group. In contrast, prospective studies track two groups of people over a given period of time, often years, and records the incidence or occurrence of a particular illness. One group consists of persons who were exposed to the substance and the other group, the control group, consisting of unexposed persons.

The prospective study is preferred over the retrospective study because retrospective studies are vulnerable to bias in the selection of the study groups and the significant inability to control outside influences and factors. Nevertheless, retrospective studies continue to be performed because they are relatively inexpensive, can be completed over a short period of time, and avoid the ethical concerns of exposing persons without disease to a suspected harmful agent.[92]

In the context of toxic tort cases, epidemiology attempts to identify a statistical relationship between exposure to a particular toxic substance and the incidence of disease by comparing exposed and unexposed (control) groups. The term "expected mortality" rate refers to the disease mortality rate for the control group, whereas "observed mortality" rate applies to the disease mortality rate of the exposed group. If the mortality rate for a given disease is the same for both groups, the "risk-ratio" or "relative risk" of observed-to-expected mortality is 1.0. From

---

91 For a general discussion of epidemiology and the use of epidemiological studies in litigation, *see* Black & Lilienfeld, *supra* note 17, at 732; Dore, *A Proposed Standard for Evaluating the Use of Epidemiological Evidence in Toxic Tort and Other Personal Injury Cases*, 28 HOWARD L.J. 677 (1985); Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV. ENVTL. L. REV. 429 (1983); Hall & Silbergeld, *Reappraising Epidemiology: A Response to Mr. Dore*, 7 HARV. ENVTL. L. REV. 441 (1983); Heafey, *supra* note 17, at 673; K.J. ROTHMAN, MODERN EPIDEMIOLOGY (1986).

92 Heafey, *supra* note 17, at 674.

the relative risk figure, an epidemiologist can calculate an "attributable risk" factor—that percentage of the diseased person which is statistically attributable to exposure to the toxic substance. Whether these risk figures constitute a "statistically significant association" becomes the crucial issue with regard to admissibility of the scientific evidence.[93] Courts have been fairly consistent on what relative risk figure is statistically significant for the purposes of the admissibility of an expert epidemiological witness' testimony.[94]

Causation based on epidemiological studies, as opposed to other methodologies, is considered to be of prime significance in determining whether the plaintiff's burden of proof has been met in certain jurisdictions.[95] In some cases, the plaintiff's only causation evidence may consist of an epidemiologist's testimony proffered to show a causal connection in probabilistic terms. Courts are suspicious of statistical evidence which falls short of proving causation by reasonable medical probability in a particular individual.[96] Many courts, however, will not reject epidemio-

---

93 Epidemiology is by no means this simple. A plethora of additional factors must be considered by the epidemiologist, including confidence levels (a mathematical expression of the magnitude of possible errors); the method of study (cohort vs. retrospective case-control); sampling errors (small sample of the relevant population); significance testing (through the use of a "P value" to determine the probability that an observed difference between two groups is or is not due to a random chance); and bias (a systematic error or distortion).

94 *See, e.g., In re* Agent Orange Product Liability Litig., 597 F. Supp. 740, 785 (E.D.N.Y. 1984) (plaintiffs must prove at least a twofold increase in the occurrence of the disease); Manko v. United States, 636 F. Supp. 1419, 1434 (W.D. Mo. 1986), *aff'd*, 830 F.2d 831 (8th Cir. 1987) (relative risk of two or less proves exposure is not probable cause of disease); Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1092 (D. Md. 1986), *aff'd sub nom.* Wheelahan v. G.D. Searle & Co., 814 F.2d 655 (4th Cir. 1987) (risk ratios of 1.3 and 1.9 insufficient to prove probable causation, even though the statistical evidence supported a greater than two-fold increased risk); Cook v. United States, 545 F. Supp. 306, 308 (N.D. Cal. 1982) (a relative risk in excess of two, the upper limit of the baseline risk, is necessary to prove causation).

95 *See* Brock v. Merrell Dow Pharmaceutical, Inc., 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166, 167 (5th Cir.), *reh'g denied en banc*, 884 F.2d 167 (5th Cir.), *reh'g denied*, 886 F.2d 1314 (5th Cir.), *cert. denied*. 110 S. Ct. 1511 (1990); Daubert v. Merrell Dow Pharmaceutical, Inc., 727 F. Supp. 570, 575 (S.D. Cal. 1989) (causation evidence from epidemiological studies is the most reliable causation evidence; thus expert opinion not based on epidemiological study evidence is inadmissible to establish causation); *but cf.* Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1094 (D. Md. 1986), *aff'd sub nom.* Wheelahan v. G.D. Searle & Co., 814 F.2d 655 (4th Cir. 1987) (presentation of epidemiological studies is not flatly required in order for plaintiff to meet his burden of proof).

96 *See* Mauro v. Raymark Indus., 116 N.J. 126, 139-41 (1989) (requirement of reasonable medical probability of the future incidence of disease). The exclusion of statistical evidence also occurs because of the inability to prove actual cause and

logical evidence on this basis alone and are willing to examine the scientific underpinnings of the epidemiological study.

Standards for review of epidemiologic evidence are developing and substantial attention has been paid to the subject.[97] The better standard requires an analysis of all reliability factors and places special emphasis on the relative risk and attributable risk figures. To support a finding of legal causation, one commentator writes that the attributable risk must exceed fifty percent in any given case:

> Conceptually, the finder of fact must decide whether it is more likely than not that an individual plaintiff contracted a specific disease as a result of exposure to a factor for which the defendant is legally responsible. From an epidemiologic perspective, the question has two parts: (1) is the factor causally related to the disease, and (2) is the attributable risk greater than [50%]?[98]

There are few New Jersey opinions on this issue. Until recently, the opinions have been consistent in requiring an attributable risk figure in excess of fifty percent or a relative risk figure in excess of 2.0.[99]

Several recent federal court decisions have dealt with an epidemiological study technique known as "meta-analysis." The meta-analysis technique combines the results of different epidemiological

---

effect in the individual case from a statistical study. *See, e.g.*, Robinson v. United States, 533 F. Supp. 320, 330 (E.D. Mich. 1982) (plaintiff unable to prove from statistical evidence that she contracted Guillain-Barre syndrome from swine flu vaccination).

97 *See supra* note 91.

98 Black & Lilienfeld, *supra* note 17, at 767. *See also* Lilienfeld & Black, *The Epidemiologist in Court: Some Comments*, 123 AM. J. EPIDEMIOLOGY 961, 963 (1986) (a relative risk figure of 1.5 allows an inference of attributable risk figure of 33%, which means there is a less likely than not causal connection).

99 *See, e.g.*, *Mauro*, 116 N.J. at 144-145 (epidemiologic evidence must establish reasonable medical probability of incidence of future disease); Landrigan v. Celotex Corp., 243 N.J. Super. 449, 459 (App. Div. 1990) (a relative risk figure of 1.55 and an attributable risk figure of roughly 35% was insufficient to establish causation in an epidemiological study which found 59 deaths where 38 were expected). *But compare,* Grassis v. Johns-Manville Corp., 248 N.J. Super. 446, 591 A.2d 671 (App. Div. 1991). (Expert who was a medical doctor and epidemiologist could proffer causation testimony regarding plaintiff's colon cancer and exposure to asbestos even though the opinion was based in part on epidemiological studies which showed a risk factor of less than 2.0 because the studies were offered as only one of the bases of the expert's opinion and not offered as substantive evidence. The court distinguished *Landrigan* and stated that the expert substantiated her opinion by her own clinical findings, thus the opinion was not a net opinion. Accordingly, there was no need to establish a fixed number as the operative risk factor limitation).

studies, reanalyzes the combined data and determines whether the aggregated data provides proof of causation. The courts which have addressed the reliability of this novel scientific technique, as well as the expert's methodology in performing the meta-analysis, have either remanded for specific findings on reliability issues[100] or have rejected the meta-analysis findings.

b. *Animal Studies*

Animal studies are often the only evidence available to determine whether certain substances are toxic to humans. By way of exposure, observation, assumption, calculation and extrapolation to human beings, animal studies attempt to provide necessary causation evidence through a dose-response procedure. In animal studies, however, there are many problems attendant to the assumptions, variations between animals and humans, and extrapolation of figures. The studies are therefore suspected by the courts as having less reliability.[101]

In the Bendectin cases, the courts evaluated the use of *in vitro* and *in vivo* animal studies to show teratogenic effects, and concluded that the studies were incapable of establishing causation in human beings because of the greater body of contrary epidemiologic evidence.[102] In the Agent Orange cases, animal studies were found inadmissible to establish causation chiefly because of the extraordinarily high dosages given to the biological subjects in the studies and because of the differences between animals

---

100 *See In re* Paoli, 916 F.2d 829, 856-59 (3d Cir. 1990); E.R. Squibb & Sons, Inc. v. Stuart Pharmaceutical, 1990 W.L. 159909 (D.N.J. 1990) (rejecting meta-analysis results because of faulty underlying study data); MacNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., 755 F. Supp. 1206, 1213 (S.D.N.Y. 1990) (rejecting meta-analysis results because the results of the studies upon which the meta-analysis was done were erroneous).

101 For a general discussion of the use of animal studies in toxic tort cases, *see* Landau & O'Riordan, *Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Tort Litigation*, 25 IDAHO L. REV. 521 (1988).

102 DeLuca v. Merrell Dow Pharmaceutical, Inc., 911 F.2d 941, 950 n.10 (3d Cir. 1990). *Accord* Brock v. Merrell Dow Pharmaceutical, Inc., 874 F.2d 307, 313-14 (5th Cir.), *modified on reh'g*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990) (recognizing the limited utility of animal studies to prove causation, but rejecting the proffered animal study evidence due to lack of supporting epidemiological evidence); Richardson by Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989) (rejecting *in vivo* and *in vitro* animal studies as incapable of proving causation in humans); Lynch v. Merrell-National Laboratories, 830 F.2d 1190, 1194 (1st Cir. 1987) (rejecting *in vivo* and *in vitro* animal studies as establishing causation in the absence of supporting epidemiological studies). *But cf.* Oxendine v. Merrell Dow Pharmaceutical, Inc., 506 A.2d 1100, 1108 (D.C. App. 1986) (allowing *in vitro* and *in vivo* animal study data).

and human beings.[103] In two PCB cases, the plaintiffs' expert witnesses relied, *inter alia*, on studies showing PCB-produced cancer in experimental animals. The courts concluded that the reliability factors in animal studies must be more closely explored at the time of trial.[104] In contrast, in cases involving various other substances, courts have allowed expert witness testimony regarding animal studies to prove the carcinogenic effects of chemicals on humans.[105] In general, most courts have dealt with animal studies by carefully evaluating the studies for appropriate relevance and reliability.

c. *Other Methods*

There are various other methods which scientists use to develop causation evidence. For example, the collection of case histories, or anecdotal data, and reports of disease after exposure are often used by physicians to establish the causal link, even though other naturally occurring environmental factors may produce the same disease in the general population. Despite the obvious problems of this approach, some courts have accepted the use of anecdotal data while other courts have rejected it.[106] Recalculations of data from epidemiologic studies are sometimes offered to support causation, but are often questioned because the recalculations frequently involve the rediagnosis of cases from the original database or because the interpretation methods

---

103 *In re* Agent Orange Product Liability Litig., 611 F. Supp. 1223, 1241 (D.C.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied.*, 487 U.S. 1234 (1988) (animal results found so misleading under Rule 403 that they could not serve as an acceptable predicate for an expert opinion under Rule 703). *See also* Viterbo v. Dow Chemical Co., 826 F.2d 420 (5th Cir. 1987) (evidentiary problems encountered with studies of toxicity of herbicide in rats).

104 *In re Paoli*, 916 F.2d at 853 n.27; Rubanick v. Witco Chemical Corp., 242 N.J. Super. 36, 52-53 (App. Div. 1990).

105 *See, e.g.*, Villari v. Terminix Int'l, 692 F. Supp. 568 (E.D. Pa. 1988) (animal studies concerning pesticide toxicity); Marsee v. United States Tobacco Co., 639 F. Supp. 466 (W.D. Okla. 1986) (animal studies concerning smokeless tobacco effects).

106 *See* Osburn v. Anchor Laboratories, Inc., 825 F.2d 908, 914-15 (5th Cir. 1987) (expert's reliance on plaintiff's medical records, scientific studies and case histories is sufficient to establish causation question of fact); Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1535-36 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984) (court accepted three case histories as sufficient to establish causation issue of fact for the jury to resolve). *Compare In re Paoli*, 916 F.2d at 840, 854 (3d Cir. 1990) (better record necessary to evaluate rejection of case histories of similar exposure incidents in Japan in 1968 and Taiwan in 1979), *and* Novak v. United States, 865 F.2d 718, 722 (6th Cir. 1989) (evidence of cases of dermatomyositis allegedly from swine flu vaccination rejected under the general acceptance test as inadmissible to establish causation).

are deemed unreliable.[107] Finally, as another method of establishing causation, courts have been asked to examine chemically similar substances and draw analogous conclusions. Most courts, however, have either rejected the proffer or found the application of limited use.[108]

## V. CONCLUSION

The complex issues presented in toxic tort and hazardous substance litigation mandate the use of expert witness scientific testimony. Such witnesses are required to sift through the myriad of studies, hypotheses and methodologies in an attempt to identify and simplify the basis for finding causation, or lack thereof, by the trier of fact. All courts agree that certain rules must govern the admissibility of expert opinion evidence. The courts disagree, however, on what constitutes the appropriate standard of review and the extent of judicial participation in making such admissibility determinations. In the absence of specific amendments to the rules of evidence, a definitive United States Supreme Court decision, concrete guidelines from appellate courts with consistent application by trial courts, or the development of a uniform standard of review, the use of novel scientific expert opinions and evidence, will surely provide lawyers and judges with fascinating legal and scientific controversies into the next century.

---

107 *See, e.g.*, Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985) (expert's epidemiological meta-analysis results rejected because of the expert's "rediagnosis" of several diagnoses in the underlying data base); Gaul v. United States, 582 F. Supp. 1122, 1128-29 (D. Del. 1984) (expert's epidemiological study reanalysis rejected due to expert's use of different data than was utilized in the underlying studies); O'Gara v. United States, 560 F. Supp. 786, 790 (E.D. Pa. 1983) (expert witness meta-analysis findings insufficient to establish causation because the expert's assumptions and data selection were suspect).

108 Lynch v. Merrell-National Laboratories, 646 F. Supp. 867, 866 (S.D.N.Y. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987) (highly speculative nature of the analogies renders them inadmissible); Richardson by Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 829-30 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989) (chemical structure analysis theory, providing that drugs with a similar chemical structure produce analogous effects, is of limited value and does not, by itself, establish causation). *Cf.* Oxendine v. Merrell Dow Pharmaceutical, Inc., 506 A.2d 1100 (D.C. App. 1986) (chemical structure analysis alone cannot establish causation, unless supported by other scientific study data).