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THE SCIENTIFIC BASIS OF CAUSALITY IN TOXIC TORT CASES

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THE SCIENTIFIC BASIS OF CAUSALITY IN TOXIC TORT CASES

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I. INTRODUCTION

A *toxic tort,* as the term is used in this Article, is a cause of action that arises when a plaintiff has developed a disease following long-term exposure to a physical agent—either a chemical or a form of energy such as electromagnetic fields (EMFs). Typically, the defendant's economic activity resulted in the plaintiff's exposure to the agent. Courts essentially must determine whether the plaintiff's exposure and subsequent disease are causally related, as that relationship is defined by the applicable law, or whether the exposure and disease are associated merely by chance. For example, did the asbestos inhaled by the plaintiff cause his[1] lung cancer? Did the radar gun used by the traffic-control officer cause his testicular cancer? Did the Bendectin taken by the plaintiff cause the birth defects that occurred thereafter? Traumatic injury occurs instantaneously, but disease develops over a period of time. The cause of disease, therefore, cannot be the direct object of the senses and can only be inferred.

It is possible to imagine a legal system in which the absence of direct observation of the genesis of disease would constitute an absolute bar to a plaintiff's recovery. Although such a system may have merit, it is not the law in American courts. Rather, under appropriate safeguards, a scientific expert is permitted to offer an opinion[2] concerning the ultimate issue; whether the defendant's economic activity caused the plaintiff's disease.

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1. The masculine form is used in this article for both genders, except where it obviously applies to only one.

2. Since *knowledge* and *opinion* with respect to expert witness testimony may have overlapping meanings, it is worthwhile to adopt consistent definitions for these terms. An *opinion* is a statement colorably sounding as intellectual knowledge, and that the speaker accepts as true (that is, sufficiently justified), but which either is not accepted or has not yet been accepted by the listener. *Knowledge* is justified belief in the truth of a statement. Sensory knowledge ("I heard the crash") is typically provided by the fact witness. Intellectual knowledge ("poison ivy causes a rash"), provided by the expert, is achieved when experience and understanding are focused on sensory knowledge. Scientific knowledge is intellectual knowledge of or pertaining to *science. See infra* note 8 and accompanying text. Despite the subjective certitude and passion with which statements reflecting sensory and intellectual knowledge are sometimes made, it is clear that the possibility of error cannot be eliminated. What permits putative knowledge to be characterized as knowledge is the nature and degree of the justification that can be provided to indicate that the statement is true.

This Article examines the valid use of expert testimony with respect to causal knowledge in furtherance of justice. The expert may employ the causal concepts of science when expressing purely scientific knowledge. Indeed, it is the layman's lack of such specialized knowledge that is the fundamental justification for the law's use of expert testimony. Ultimately, however, application of the principle of causality remains the exclusive province of the trier of fact because the law employs the layman's concept of causality for the resolution of causal issues.[3]

This Article is solely concerned with causality in the context of harm that manifests after a period of time has elapsed from the subject's initial contact with the putative causal agent. This situation presents the most troubling and complex issues regarding the determination of causal relationships using scientific knowledge. Excluded from consideration is the Bhopal-type disaster, in which a chemical escapes from a broken pipeline and causes almost immediate death.[4] Although, in such a disaster causality is a necessary element in a subsequent cause of action, causality is not likely to be its most important element.

For convenience, this Article assumes the underlying legal theory in a toxic tort case is ordinary negligence.[5] Thus, the plaintiff has the responsibility of pleading and proving the toxic agent proximately caused the plaintiff's disease or injury. The concept of proximate causality consists of "legal causation" and "causation-in-fact."[6] Legal causation involves issues of foreseeability, duty, and policy. Ordinarily, legal causation is not a pivotal issue in toxic tort cases because a defendant's breach of the duty not to cause cancer or other disease necessarily leads to a finding of legal causation. Thus, in a toxic tort case, proof of causation-in-fact is tantamount to satisfying the element of proximate causality. This Article, therefore, will focus on issues involving causation-in-fact, rather than legal causation.[7]

The decision to undertake this Article was prompted in part by our perception that much of the legal scholarship dealing with the relation of science and law is unenlightening and circular because of failure to define

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3. HERBERT L.A. HART & TONY HONORÉ, CAUSATION IN THE LAW 428-30 (2d ed. 1985).

4. Between the second and third of December 1984, winds blew a lethal gas, known as methyl isocyanate, from a chemical plant operated by Union Carbide India Limited, into densely populated areas of Bhopal, India. Over 2,000 people were killed and more than 200,000 were injured. *See* Union Carbide Corp. Gas Plant Disaster v. Union Carbide Corp., 809 F.2d 195 (2d Cir. 1987).

5. There are other legal theories under which scientific testimony involving causality might be used, such as fraud or misrepresentation, battery, nuisance, breach of fiduciary duty, and breach of contract. Nevertheless, if an expert can render an opinion regarding the causal issues in a toxic tort case, the expert also can do so with respect to any legal theory where scientific causality is a pertinent element. Thus, a toxic tort suit in negligence is an appropriate context within which to evaluate the legal implications of scientific testimony regarding causality.

6. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 41, at 263-72 (5th ed. 1984).

7. *See* RESTATEMENT (SECOND) OF TORTS § 9, at 16 (1965).

terms, employ them consistently, and give examples to aid in the understanding of general statements. We have attempted to avoid these perceived shortcomings by providing definitions throughout the Article and in the Glossary, and by the liberal use of examples. Most of the examples and hypotheticals involving scientific matters and legal issues used in this article are based on the personal experiences of Andrew A. Marino. Citations to the original materials are given when further details might be helpful in understanding the matter being discussed.

II. CAUSALITY IN SCIENCE

In a toxic tort case, the expert is not required or expected to have knowledge regarding the law or legal concepts, or to take them into account when testifying. Thus, "proximate cause," "legal cause," "foreseeability," "duty," and other legal terms of art are not pertinent to an expert's testimony. Rather, the expert's testimony is confined to the area of human knowledge called *science*. In its broadest conceptualization, science consists of making valid observations, inferring reasons for the observations, and offering mechanistic explanations; success in this endeavor is measured by the resulting ability to predict future events. In principle, science is independent of the values of the practicing scientist; this ideal characteristic distinguishes science from law, and from other human activities such as philosophy, theology, and art. In contrast to mathematics, which is axiomatic and seeks reasons based on logic, science is observational and seeks reasons based on experience.

Scientific knowledge is based on observations made within a philosophical and procedural framework.[8] The applicability of scientific knowledge outside that framework depends on whether scientific knowledge extends to society at large, where the underlying philosophy is not always logical empiricism, value and policy have a recognized role, and the existence of a causal relationship is proved differently. If a particular scientific inference cannot be extended from science to society, scientific knowledge has no utility in a toxic tort case.[9]

It is a daunting task to formulate rules within which the potential societal significance of scientific knowledge can be recognized and evaluated. One of the barriers to such an effort is the traditional absence of scientific training in

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8. The dominant philosophical basis of modern science is the tradition known as *logical empiricism*. *See* RICHARD BOYD ET AL., THE PHILOSOPHY OF SCIENCE, (MIT Press 1991). The philosophical underpinnings of science are unimportant for the purposes of this Article, but it is important to recognize that modern scientific reasoning occurs within the context of a system of assumptions. A scientific statement, therefore, is not necessarily meaningful outside the context of that system.

9. For example, cigarette manufacturers urged this theory regarding inferences that smoking can lead to lung cancer. *See Hearings on S. 772 Before the Senate Comm. on Labor and Human Resources*, 98th Cong., 1st Sess. 98, at 253-56 (1983) (statement of Sheldon C. Sommers, M.D., consultant in pathology, Lenox Hill Hospital, New York, N.Y.).

the formal education and practical experience of judges and lawyers. Nevertheless, the cost and importance of scientific knowledge are so great that such rules must be developed.

It is intuitively clear that an effort to incorporate scientific knowledge into the legal system must begin with an appreciation of what a scientist means by stating "x caused y." The meaning of such a statement depends on whether the putative relationship involves living or nonliving things.[10]

The *physical sciences* (physics and chemistry, for example) involve the study of nonliving things, such as an atom of hydrogen, a beam of light, or the planet Jupiter. An entity called *force*[11] is postulated to be the necessary and sufficient cause for every event (also called an *observation, effect,* or *phenomenon*). Thus, "x caused y" means that "x" was the set of forces that was *necessary and sufficient* for "y" to happen.[12]

The *biological sciences* (biology and physiology, for example) involve the study of animals and plants. The complexity of living organisms is such that myriad factors can affect them, and any such factor is labeled a *cause*. Thus, "x caused y" means that "y" would not have occurred under the circumstances as and when it did *but for* the presence of "x." For example, consider the relationship between smoking and cancer. Smoking is not always a sufficient cause of cancer because not everyone who smokes a similar amount for a similar time period develops cancer. Moreover, it is not a necessary cause because not everyone who develops cancer has a history of smoking. But the scientific evidence shows that cancer occurs more often among those who smoke. It follows, therefore, that among smokers who developed cancer, smoking was sufficient in the circumstances to cause cancer in some instances. That is, smoking was a sufficient cause in some cases.

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10. In attempting to explain the notion of causality as it applies in toxic tort cases, many authors make exclusive use of examples involving physical laws, such as the law of gravity. These authors simply assume the notion of causality involved in such examples is directly applicable to the biological sciences. Such, however, is not the case. Biology is an autonomous science with its own methods and procedures, which do not necessarily depend on the paradigm of physics (including its conception of causality) for their ultimate rationale or validity. This error results in the fostering of a falsely precise notion of the kind of scientific knowledge that is relevant to toxic tort cases.

11. Four different forces are recognized. The *gravitational* and *electromagnetic* forces are the causes of essentially all phenomena familiar to the layman. The other two forces are the *strong force*, which is responsible for the stability of atoms and for events that are observed in particle accelerators, and the *weak force*, which causes radioactive decay of atoms.

12. The goal of the physical sciences is the identification and quantification of the forces responsible for phenomena; this is accomplished by systematically varying the conditions of observation, and then formulating mathematical equations that can be used to predict future similar observations. This process has been extraordinarily successful—with the exception of esoteric situations such as those that existed at the time the universe began or that occur in supercolliders, the causes of all physical phenomena are known and their occurrence is predictable with mathematical precision. This knowledge of inanimate reality, which was achieved within the last three centuries, does not indicate that all consequences of physical laws are known; only that all known physical phenomena can be understood as consequences of known laws, and can be reproduced by anyone who cares to do so.

The essential meaning of *cause* in biological sciences, that of a factor sufficient in the circumstances to modify a subsequent event, is essentially identical to its lay meaning. For example, "the cause of death was a gunshot wound" means that the death would not have occurred when, where, and to whom it occurred but for the wound. The wound was not necessary for the victim to die, and in other circumstances may not have been sufficient to result in death. The wound was simply sufficient in the circumstances to cause death.[13]

In toxic tort cases, it is important to distinguish between *causes* and *mechanisms*. For example, it can be inferred from valid observations that consumption of aspirin causes headaches to abate, or that living beside high-voltage powerlines causes cancer, but the validity of each of these causal conclusions is independent of knowledge of the underlying mechanical causes. That is, the particular cellular location at which aspirin acts, and the signal transduction and gene expression caused by EMF's need not be understood prior to, or as part of, the process by which the validity of the causal relationship is evaluated. Since the mechanistic causes of few biological phenomena—and no putative toxic torts—are known with reasonable precision, there cannot be a toxic tort cause of action if the element of proximate causality is interpreted to require proof of mechanistic causes.[14]

A. Generalization in Science: From Caused to Can Cause

In an experiment involving laboratory rats and asbestos, suppose "x" was a specific amount of asbestos per cubic meter of air in the room that housed a particular gender and strain of rats (e.g., ten micrograms/cubic meter, and Sprague-Dawley males), "y" was the observation of cancer at a particular rate (e.g., twenty percent), and "*x caused y*" was justified in the experiment by means of a statistical test. Clearly, if "*x caused y*" is true,[15] it follows that "*x can cause y*" is also true.

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13. Since many factors could potentially influence any particular biological observation, the method of *controlled observation* is usually employed to study putative causal relationships. The method consists of standardizing all pertinent environmental factors in a homogeneous population of living organisms except for a single factor, the effect of which is to be studied, and then varying that factor with respect to only some of the individuals (the *experimental* group). If a difference between the experimental group and the remaining subjects (the *control* group) is subsequently observed at the appropriate level of statistical certainty (greater than 95%), the factor that differed between the groups is accepted as the cause of the difference. See *infra* Appendix, at 58-62 for a discussion of the logical structure and principal types of biological studies.

14. *Mechanistic causes* are the Holy Grail of biological scientists and are equally difficult to find. They can never be precisely identified because it is impossible to prove that a particular mechanism is operative; the best that can be done is to produce evidence for or against a particular mechanism. Further, whenever evidence supporting a particular mechanism is found, it is always possible to ask: What is the mechanism of *that* mechanism? Thus, every mechanistic explanation is, at best, a partial explanation, and it is always possible to argue that the mechanism underlying a particular phenomenon is not known.

15. This means that an appropriate statistical test showed that the probability that the statement was true was greater than 95%. *See* discussion *infra* Appendix, at 58-62.

Suppose that we contemplate the meaning of "x can cause y" where "x" now represents a higher concentration of asbestos particles than was used in the actual experiment. The conclusion that "x can cause y" was originally rationalized by reference to the observation that "x *caused* y," but it is incorrect to say "caused" at the higher concentration because that experiment has not been performed. If it *were* performed, the observed cancer rate might be different. In fact, for any "x" other than that used in the study, "x can cause y" would be untrue because the statement is specifically applicable to a particular "x" and "y," and not based on the results of an experiment.

How, then, are the results of studies generalized so that the results may be used to state a proposition applicable in situations other than the precise circumstances of the original study? Such an inductive conclusion is justified when a sufficient number of additional studies yield mutually consistent results. The induction may then be expressed by removing the terms qualifying the subject and the predicate. The result is that the assertion becomes "X can cause Y," where "X" is *asbestos*,[16] and "Y" is *cancer*.[17] Thus, reasoning in biology proceeds from a group of specific observations to an inductive statement, the generality and applicability of which depends completely on the quality, quantity, and degree of relevance of the component studies.

In biology, the induction is expressed in words rather than in a precise mathematical expression as in physics. Hence, scientists' views of the truth of an inductive biological judgment will differ just as individuals' views regarding the importance of various items of evidence used to justify a judgment will differ.[18] One factor affecting differing views is the scientist's choice of scientific reports considered. Another factor is the weight the scientist affords particular studies. Perhaps the most important factor is the degree of certitude a scientist implicitly incorporates in his inductive generalization. Some scientists instinctively demand many studies and a high degree of certitude, while others find a general cause-and-effect relationship on the basis of only a few studies. If the meanest scientific data led a scientist to posit a causal link, or if the strongest possible data did not do so, the scientist would not be a proper expert witness because the scientist would no longer be acting as a scientist, but as an advocate. It is the responsibility of counsel to expose the expert's personal standards so that the trier of fact can appropriately judge the scientist's reasoning process.[19]

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16. Not any specific amount or under any particular conditions of exposure.

17. Not any specific incidence or type of cancer. Throughout this Article, "x" designates a specific cause, "y" designates a specific effect, "X" designates a general cause, and "Y" designates a general effect. *See infra* Glossary.

18. Disagreements among scientists are foreseeable because scientists differ with regard to ability, personal values, and amount and type of experience. It is *not* true that scientists would necessarily agree on any particular judgment, if only they took the time and trouble to examine the data carefully.

19. When examining an expert, counsel must ensure that the preponderance of the evidence standard, and nothing more stringent, is applied.

B. Can't Cause in Science

In a toxic tort case, the plaintiff must prove that the toxic agent caused the disease. The thrust of the defendant's evidence will attempt to illustrate that such a causal inference is not warranted.[20] Alternatively, the defendant may attempt to affirmatively establish that the toxic agent can't cause the plaintiff's type of disease. For example, if a defendant in an asbestos case could prove that asbestos cannot cause cancer, it would be unnecessary to consider the actual dose the plaintiff received because the safety of asbestos under all reasonable circumstances would have been established.

Consider, for example, an attempt to rationalize the statement "asbestos can't cause cancer." Such an undertaking would consist of a series of animal experiments in which various doses were applied under specific conditions, and the resulting incidence of cancer was determined. If a range of doses was tested and increased cancer was not observed, then it would be true to say that no evidence favoring "asbestos can cause cancer" was found. Expressed in other language, a valid inference would be that "asbestos can't cause cancer" in the circumstances of the studies. *Cannot*, therefore, tentatively might be inferred from a series of *did not* observations. The negative inference becomes a nullity, however, when even one animal study is positive. If the results were uniformly negative when the study was repeated using ten different asbestos doses, and the eleventh study was positive, it would no longer be true to infer that asbestos cannot cause cancer. Thus, one valid affirmative study may destroy a plausible inference that was based on numerous valid negative observations.[21]

An affirmative defense of *can't cause*, therefore, is nearly impossible from a scientific viewpoint because a null hypothesis can be disproved, but it cannot be proved. Furthermore, such a defense is usually strategically unwise because it may be perceived as an attempt to prove too much. A defendant should rarely prevail in a toxic tort suit on the basis of a *can't cause* affirmative defense because there are few, if any, commercially significant physical agents for which there are no relevant well-conducted positive studies.

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20. The defendant will seek to prove that, although a causal inference could be true, one would not be justified in accepting it as true.

21. The logical relationship between positive and negative observations is a familiar feature of everyday life. For example, if 1,000 holes are drilled to varying depths at separate locations in a search for oil and no oil is found, a valid conclusion would be that there is no oil. But irrespective of the number of dry holes, if even a single hole results in the appearance of oil, the proposition that drilling a hole can lead to oil is established, and the evidentiary value of dry holes becomes reduced. Now, the dry holes indicate only that oil does not occur under a particular set of circumstances. As in science, even one positive observation rationalizes a positive conclusion even though there are numerous negative observations.

III. QUALIFICATIONS OF THE EXPERT IN TOXIC TORTS

A. Causality

An expert is a person who has knowledge not ordinarily possessed by the layman. Historically, the courts have permitted experts to testify when specialized knowledge is relevant to an issue in a case. If a court agrees that expert testimony is needed, the court determines the specialty or profession that encompasses the required expertise and whether the witness has the requisite training and experience.[22]

In a toxic tort case, the gist of the expert's testimony is a causal assertion such as: "the asbestos caused . . .," "the Bendectin caused . . .," or "the electromagnetic field caused . . . ." The toxic tort expert, therefore, must have training and experience sufficient to analyze and explain the laboratory and epidemiological studies pertinent to the effects of the toxic agent at issue on animals and human beings. The expert must sufficiently understand the studies that have been conducted in order to ascertain whether the data and conclusions are valid, and if so, how the data and conclusions apply to the facts of the case. Evidence of this ability consists of documented academic attainment and a demonstrated history of adducing and evaluating scientific data, ideally including data involving the toxic agent pertinent to the case. No expert should be permitted to testify regarding causality if the expert lacks academic attainment and actual experience of the appropriate type, and few experts should be permitted to testify if they possess only one such qualification.[23] If

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22. For example, in a personal injury case, if the breaking strength of an automobile fuel tank is at issue, the court might determine that an engineer who has experience with studies and measurements of the mechanical strength of fuel tanks is qualified to offer relevant testimony.

23. Typically, the academic attainment expected of a scientific expert involves completion of undergraduate and graduate courses designed to teach mastery of the knowledge, principles, and methods applicable to all biological sciences. In the United States, post-graduate education usually consists of approximately two years of classroom studies, followed by an apprentice period of three to five years devoted to the study and use of the methods of science employed for generating scientific knowledge. Performance of an independent scientific investigation, culminating in a dissertation deemed acceptable by the student's mentor and advisory committee, as memorialized by the degree of Doctor of Philosophy (Ph.D.), is evidence that the principles of scientific methodology and reasoning have been mastered.

Traditional distinctions among various biological sciences have largely been blurred as a result of the rapid growth of biological science and increasing specialization within the past 20 years. Although the names and number of academic departments awarding the Ph.D. have not changed appreciably, the number of areas and amount of biological specialization has increased dramatically. At a meeting of one group of biological specialists (Experimental Biology '94, April 24-28, 1994, Anaheim, CA), more than 100 different specialized biological categories were necessary to classify the presentations. Other groups of biological specialists employ many additional categories. Multiple classifications within non-biological science are similarly numerous and diverse. For example, the American Society for Testing and Materials lists 280 categories of specialization. *See* AM. SOC'Y FOR TESTING AND MATERIALS, DIRECTORY OF SCIENTIFIC AND TECHNICAL CONSULTANTS AND EXPERT WITNESSES (1993-94). As a result, the name of the university department that awarded the expert's Ph.D.—for example, physiology, biophysics, immunology, or biochemistry—is not a useful guide for determining whether the expert has the required training.

the witness was trained appropriately, performed many experiments, and published many scientific articles dealing with the biological effects of the toxic agent involved in the case, the court would have a firm basis to regard the witness as qualified to offer opinions in the case.

A reasonable approach to matching the expert's knowledge to a particular case is to inquire whether the causal issue—which must be framed in the pleadings since it is an element of the cause of action—is within the training and experience of the proffered expert. First, does the expert's academic background indicate training in the scientific methods and processes for inferring causality? An earned Ph.D. in any science indicates that the witness satisfies this requirement, although other evidence such as actual experience may suffice. Second, has the witness demonstrated a familiarity with the scientific studies that embody the current scientific knowledge regarding the effects on living organisms produced by the toxin of interest? The best such evidence would consist of scientific publications or other suitable written reports authored by the expert and dealing with the issue of the biological effects of the toxic agent. If the expert possesses these two characteristics, the causal issue should be within the training and experience of the expert.

B. Non-Causal Knowledge

The relationship between the amount of exposure to the toxic agent experienced by subjects in particular scientific studies and the amount of the plaintiff's exposure is always an important consideration in deciding whether the toxic agent caused the plaintiff's disease. For example, if the amount of asbestos the plaintiff breathed was infinitesimally small compared with the amount shown to cause adverse effects in laboratory animals or associated with cancer in human observational studies, there would be no reasonable basis for an expert to assert the likelihood of a cause-and-effect relationship between the plaintiff's dose and the plaintiff's disease.

Scientific studies conducted under laboratory conditions usually describe the amount of the agent used in the study. This is rarely the case with epidemiological studies because epidemiological studies are usually retrospective in nature and therefore involve an analysis of events that existed prior to the design and conduct of the study. This situation necessarily precludes measurement by the investigator of the levels of the toxic agent actually experienced by the epidemiological study subjects.[24] The fact of exposure is determined based on place of residence or occupation, but the actual exposure levels can only be estimated, using situations similar to those that existed during the study. For example, individuals living beside a high-voltage

24. *See* discussion *infra* Appendix, at 58-62.

powerline or airport radar, working as electrical engineers, or operating ham radios were regarded as being exposed to electromagnetic fields,[25] but the specific levels of the electromagnetic fields involved were not stated in the published studies.

The expert must know and understand the scientific laws and principles that apply to movement or propagation of the toxic agent in the environment and in the body. The expert must demonstrate that he is qualified to make relative evaluations of the exposure levels or doses used in laboratory studies, the dose of toxin experienced by the subjects in the epidemiological studies, and the dose experienced by the plaintiff.

Knowledge of dosimetry[26] is distinct from knowledge of scientific causality. For example, suppose that Dr. Able, Chairman of the Department of Epidemiology at State University and author of several published studies involving the biological effects of asbestos, offers to testify that the plaintiff's disease was caused by occupational exposure to asbestos fibers. Since studies have shown that asbestos workers exhibit higher than expected cancer rates, it is reasonable to conclude that asbestos can cause cancer. Dr. Able, therefore, is qualified to testify to that effect. It does not necessarily follow, however, that Dr. Able is qualified to testify that asbestos caused the plaintiff's cancer unless Dr. Able can also evaluate the *levels* of asbestos experienced by the subjects in the published studies in relation to the exposure levels experienced by the plaintiff.

The ability to analyze technical reports to determine whether measurements were made properly, and to infer exposure levels from descriptions of conditions attendant to the plaintiff's exposure, cannot necessarily be inferred from the demonstration that Dr. Able is an expert in the epidemiology of asbestos. In Dr. Able's published studies, for example, the technical expertise regarding dosimetry of asbestos may have been the responsibility of one of his co-authors. It is proper for such a community of expertise to be formed in the

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25. Children living beside powerlines were considered to be exposed to electromagnetic fields, in comparison with similar children who did not live beside powerlines. Nancy Wertheimer & Ed Leeper, *Electrical Wiring Configurations and Childhood Cancer*, 109 AM. J. EPIDEMIOL. 273 (1979). Adults who lived near powerlines were considered to be exposed to electromagnetic fields in comparison to adults who did not live near powerlines. F. Stephen Perry et al., *Environmental Power-Frequency Magnetic Fields and Suicide*, 41 HEALTH PHYS. 267 (1981). People who lived near airport radars were considered to be exposed in comparison with others. John R. Lester & Dennis F. Moore, *Cancer Incidence and Electromagnetic Radiation*, 1 J. BIOELECTRICITY 59 (1982). Working in various electrical occupations including electricians, electrical engineers, and powerline workers was considered to represent increased exposure to electromagnetic fields, in comparison with non-electrical occupations. Michel Coleman et al., *Leukemia Incidence in Electrical Workers*, i LANCET 982 (1983). Being a ham radio operator was considered to indicate increased exposure to electromagnetic fields, compared with other individuals who were not ham radio operators. Samuel Milham, Jr., *Increased Mortality in Amateur Radio Operators Due to Lymphatic and Hematopoietic Malignancies*, 127 AM. J. EPIDEMIOL. 50 (1988).

26. Dosimetry is the study of the amount of a toxic agent actually received by a subject under a specific set of conditions.

context of a scientific publication.[27] In the courtroom, however, Dr. Able must explain and defend any assertion that the plaintiff's dose of asbestos was comparable to the levels that occurred in his published studies. Absent specific indications in Dr. Able's background that he has the qualifications to analyze technical reports regarding measurements of asbestos levels under various conditions applicable to the plaintiff's situation, Dr. Able is not qualified to opine regarding the specific cause-and-effect relationships involving the plaintiff. Knowledge of dosimetry is an essential element in the expert's causal conclusion. The issue of dosimetry, therefore, cannot properly be framed as a hypothetical, with supporting evidence supplied by another expert.

If Dr. Able had no training or experience in evaluating animal experiments, Dr. Able would be incompetent to distill information from animal studies that might be crucial to the issue of dosimetry.[28] For example, suppose animal studies showed that asbestos breathed by animals was rapidly removed from the lungs by the lymphatic system so that actual levels of asbestos did not build up in lung tissue until the level of airborne asbestos was above a specific amount. Such information is pertinent because it tends to establish a threshold below which adverse consequences from asbestos would not occur since the asbestos was rapidly removed from lung tissue and hence not present to cause any adverse effects. Without such knowledge, therefore, Dr. Able would be incompetent to testify regarding the specific cause-and-effect relationship.

C. Scientific and Medical Experts Distinguished

Physicians make causal inferences in different ways and for different purposes than do scientists.[29] Although the training of Ph.D.s and M.D.s in the biological sciences are similar in both college and the first two post-graduate years, the pathways diverge thereafter, as is necessary for the acquisition of skill in two fundamentally different areas of human knowledge. The three to five year training period in the methods of science, which is an integral part of

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27. It is also possible that *none* of the authors of an epidemiological study is an expert in the area of doses and exposure levels.

28. Epidemiology is a nonlaboratory based specialty. Consequently, an epidemiologist is usually not qualified to testify on the ultimate issues in a toxic tort case if relevant laboratory evidence is available, unless the epidemiologist has acquired expertise regarding animal studies.

29. A physician is a specialist in the diagnosis and treatment of human disease. In the United States, a physician must graduate from a four-year post-graduate course of study at an accredited school, leading to the degree of Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.). Typically, the first two years of medical school are spent in the classroom, and the last two years are devoted principally to learning the accepted forms of treatment for various clinical conditions, and to developing the ability to make diagnoses and administer treatment. Internship, the first year after medical school, is an apprentice year. Thereafter, the physician begins to exercise independent medical judgment in a clinical practice, or enters a residency program in a particular medical specialty. The latter path involves an additional three to five years of detailed study of the methods of diagnosis and treatment of a limited set of human diseases, such as those that occur in the musculoskeletal system (orthopaedic surgery), children (pediatrics), or women (gynecology).

the education of the Ph.D. student, has no counterpart in the education of the physician. Consequently, even though a physician may actually possess scientific knowledge, a physician is not necessarily an expert in the process of inferring causality from scientific data to the degree required to qualify as a courtroom expert. A physician has a received view of science and is charged with its implementation on behalf of his patients, not with the evaluation or expansion of that received view. It would be no more reasonable to presume that a physician was an expert in the process of scientific inference than it would be to expect a scientist to diagnose and treat disease.[30]

Both diagnosis and treatment of disease involve scientific and causal considerations, but they differ fundamentally from those based directly on data from scientific studies. The physician seeks to ascertain the cause of a patient's symptoms, but within the framework of the physiology of the patient—for example, whether high blood pressure caused the dizzy spells, whether altered electrical activity in the brain caused the seizures, or whether the presence of a tumor caused the pneumonia. Determination of the cause of the high blood pressure, altered electrical activity, or tumor that, in turn, caused the patient's symptoms generally is not within the training or the interest of the physician.[31]

In a medical malpractice case, expert testimony is required to establish both the duty of the defendant physician toward the plaintiff, and the role of the physician's breach of that duty in causing the plaintiff's injury. If the plaintiff offered testimony from a licensed physician having a Board certification in the medical specialty involved in the case, the physician would likely be permitted to opine regarding any medical issue in the case, including the question of causality. In essence, qualification as a medical expert is based on the physician's status, as certified by the relevant state or professional accrediting agency. If accepted, the expert may testify regarding causality on the basis of the expert's experience as a physician and his treatment of many patients with medical problems similar to those of the plaintiff. This form of expert reasoning is based on anecdotal knowledge, which may or may not be based on scientific knowledge. Such testimony, therefore, cannot serve as a substitute for the scientific reasoning the plaintiff must provide to sustain his case in toxic tort.

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30. It does not follow, however, that someone having an M.D. (or lacking a Ph.D.) is unqualified to testify regarding scientific matters because an earned Ph.D. is neither a necessary nor sufficient indicator of expertise.

31. The oncologist, for example, conducts tests and examinations to determine whether an identified mass is malignant or benign, but does not engage in a causal analysis to determine why the tumor mass occurred in the patient. Such an inquiry might be made by a scientist studying a group of similar patients to test a hypothesis about a cause, causal mechanism, or cure, but the clinical oncologist is ordinarily not trained for or concerned with such an inquiry. If the oncologist tested a hypothesis during the course of the patient's treatment, then to the extent the oncologist followed the rules and procedures of scientific methodology, he would be functioning as a scientist rather than as a clinician.

In a medical malpractice case, there are many potential expert witnesses. In toxic tort cases, however, where scientific rather than anecdotal knowledge must form the basis of the expert testimony, there will usually be only a few persons who possess the requisite knowledge.[32] When courts fail to recognize the causal issue in toxic torts is distinct and different from that in medical malpractice, the typical result is acceptance of medical credentials in the context of disputes over scientific issues.[33]

IV. VALIDITY OF SCIENTIFIC KNOWLEDGE

A. Intrinsic Validity

An expert's opinion depends on the supporting data. The validity of the scientific studies and reports used by a qualified expert in toxic tort cases, therefore, should be an important consideration for the expert, the court, counsel, and the trier of fact. Scientists have long recognized the need for a process by which the validity of scientific data can be assessed. The process that developed to meet this need is one of the most important and pervasive features of science—*peer review*.

The peer review process may vary among different scientific specialties, but the process' essential features are universal. After an experiment is conducted and evaluated, the investigator submits a written description of the work to a scientific journal that specializes in reviewing, evaluating, and publishing such research. The editor of the journal sends copies to persons the editor deems to be knowledgeable regarding the subject of the study.[34] The

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32. In a medical malpractice action against an orthopaedic surgeon, 20,000 experts potentially could testify because there are approximately that many practicing orthopaedic surgeons. On the other hand, a claim that a toxic agent caused harm to the plaintiff's bones can be sustained only by the testimony of an expert regarding the scientific knowledge of the effects produced by that agent, specifically regarding the effects on bone.

33. For example, in *Cantrell v. GAF Corp.*, the court allowed a physician to make an inference of a causal relationship between asbestos and cancer partly based on anecdotal data gained through the witness's clinical experience. 999 F.2d 1007, 1013-14 (6th Cir. 1993). Courts have rarely recognized the impropriety of physicians testifying to causal links that are determinable only by the methods of science rather than medicine. *See, e.g.*, Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1535 (D.C. Cir.) (allowing physicians to testify regarding the ability of PCBs to cause pulmonary fibrosis), *cert. denied*, 469 U.S. 1062 (1984); Osburn v. Anchor Lab., Inc., 825 F.2d 908, 915 (5th Cir. 1987) (allowing physicians to testify regarding the ability of chloramphenicol to cause leukemia), *cert. denied*, 485 U.S. 1009 (1988); Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1204 (6th Cir. 1988) (allowing physicians to testify that contaminated water caused the plaintiffs' medical problems); Hines v. Consol. Rail Corp., 926 F.2d 262, 273 (3d Cir. 1991) (permitting physician to testify regarding ability of PCBs to cause cancer). *But see* Mason v. Texaco, Inc., 741 F.Supp. 1472, 1497 (D. Kan. 1990) (noting that scientists are more qualified to testify regarding causation, and that a medical degree or training does not necessarily confer the ability to testify to causation), *aff'd and remanded*, 948 F.2d 1546 (10th Cir. 1991), *cert. denied*, 504 U.S. 910 (1992).

34. If an editor rejects a manuscript, but the author believes it has scientific value, the author remains free to submit it to another journal. Neither the substance nor the fact of previous reviews are disclosed to subsequent editors. When a manuscript involves arcane areas of biology, there may exist only a few journals that would be appropriate for its publication, but in other areas there might be several hundred journals that would consider publishing a manuscript. In neuroscience, for example, a manuscript might undergo

reviewers, whose identities are not disclosed to the authors, comment on the scientific merit of the work described in the manuscript, including the following: the adequacy of experimental design; the appropriateness of statistical analysis; methods, and procedures used for handling animals or other research subjects; and the relationship among the stated aims of the study, the data obtained, the interpretation given, and the conclusions stated.

The reviewers do not consider either the method by which the study was funded or the ultimate reason it was performed when evaluating the merits of a particular report.[35] Since the method of funding a study is not a factor in the review process, authors do not disclose funding to journal editors unless the authors choose to do so, or unless the funding source expects or requires disclosure.[36]

The reviewers provide a written evaluation covering the pertinent points of the manuscript, and the editor either accepts or rejects the manuscript, or accepts it conditionally. The latter decision is a recognition that the work merits publication, but only after comments raised by the reviewers have been adequately addressed. If the revised manuscript is deemed acceptable by the editor, the work appears in the journal in due course and becomes a permanent addition to the corpus of science, since journals are maintained in perpetuity in archival scientific libraries. Such a manuscript is said to have been peer reviewed, meaning the work has met a minimum standard within the particular scientific discipline regarding the quality of the work described therein, as determined by the journal editor.[37]

The peer-review process confers no express or implied warranties regarding the truthfulness, importance, or general acceptance of the methods or data in the report.[38] Nevertheless, the peer-review process serves its

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numerous sequential independent peer reviews before it is finally published.

35. For example, suppose a study concluded that a food additive manufactured by ABC, Inc. produced no harmful effects in the gastrointestinal tract of animals, and consequently the author judged the additive to be safe for human use. Since peer review focuses solely on purely scientific considerations, it would be irrelevant to the reviewers whether the author was an independent scientist with an academic interest in the physiology of the gut, or an employee of ABC, Inc. seeking to allay concerns raised by the FDA.

36. For example, the National Institutes of Health and many private foundations require authors to acknowledge receipt of their grant support. Where the author of a study of food additives is an employee of a food additive company, such an affiliation would likely be disclosed when the report was actually published because it is the custom to publish the professional affiliations of the authors. If, however, the study was performed by a contractor, rather than an employee, the relationship would normally not be disclosed because the authors' affiliations listed in the published report would be their employers, not the party that awarded the research contract. Some journals recently have begun requiring authors to disclose whether they have received, or will receive, personal or professional benefits from a commercial party related directly or indirectly to the subject or conclusions of the report. This practice, however, is not widespread.

37. Nevertheless, the report may be largely ignored for a variety of reasons, including a lack of importance of the results, or a judgment by scientists other than the peer reviewers that the work has no merit. Such is the fate of most published scientific reports.

38. See Symposium, *Editorial Peer Review in Biomedical Publication: The First International Congress*, 263 JAMA 1317, 1317-1444 (1990) for a detailed description of the inherent limitations and practical difficulties associated with peer review.

intended purposes of screening for obvious errors in methodology and reasoning and ensuring the work is not simply a rehash of previously performed work. Peer-reviewed studies are the means by which scientific knowledge is normally disseminated, learned, opposed, improved, corrected, or rejected. Consequently, peer-reviewed studies constitute and embody the knowledge that the expert in toxic torts should ordinarily use to perform analyses and reach conclusions. The peer-reviewed reports could be used, attacked, or reanalyzed to make inferences warranted by the data, but not made by the original authors. In each instance, however, it is the peer-reviewed publication[39] that experts normally look to as the source of scientific knowledge, and therefore as the basis of scientific judgments.[40]

B. Extrinsic Validity

The source of funding of a scientific experiment is not a factor in the peer review of a manuscript because the review process is limited to scientific considerations. Nevertheless, the nature of the privity between the author of a scientific study and a party in a toxic tort case can affect the weight that should be accorded the study.[41] Suppose an employee of a defendant power

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39. Scientific journals are overwhelmingly the most significant repository of the world's scientific knowledge. The number of scientific journals worldwide is uncertain, but the number probably exceeds 100,000. A data base organized by the National Library of Medicine (NLM) subscribes to more than 4,000 biological journals and organizes the information therein to permit searching by topic or by key word, using either text or a computer. Both information-retrieval systems, known respectively as "Index Medicus" and "Medline," are readily available, relatively inexpensive, and permit nearly instant access to knowledge concerning any topic in biology. In addition to the NLM data bases, many private, more specialized data bases permit access to journals not covered by the NLM.

40. Although independent peer review and publication in an archival scientific journal is the most common method of disseminating scientific information, there are other methods. For example, research may be performed, reviewed, and published by corporations, private research organizations, or governmental agencies. In such instances, the researchers, reviewers, editors, and publishers are employees of one organization, as opposed to work performed at academic institutions and published in scientific journals, where the respective parties are independent of each other.

41. The following is an example of how the manner of disclosure of a study can affect its interpretation. Since the mid-1970s, investigators at Battelle Pacific Northwest Laboratories have performed contract research, partly funded by the Electric Power Research Institute (a consortium of U.S. electrical power companies) to show the safety of high voltage powerlines. One experiment involved the effects of long-term exposure to electromagnetic fields on the growth rate of mice. In the experiment, one group of animals was exposed to the field, and the other served as the comparison group to permit assessment of the effects of the field. The result was that the mice in the exposed group were smaller, on average, compared with the controls, and the difference could not be attributed to chance (less than a 5% possibility). The result was unexpected, and the experiment was repeated; this time, however, the exposed mice were found to be larger than their corresponding controls. Again, the results could not be attributed to chance. If the data from each study was evaluated separately, which was the initial plan, and the data properly interpreted according to the established rules of science, it would be concluded that exposure to electromagnetic fields can decrease or increase growth in mice, depending upon the presence or absence of other, unascertained factors. Instead, the investigators averaged the results of the two studies, and thus concluded that electromagnetic fields had no effect on growth in mice and, consequently, that the studies did not suggest a likelihood of harm to similarly exposed human subjects. R.D. PHILLIPS ET AL., U.S. DEPT. ENERGY, BIOLOGICAL EFFECTS OF HIGH STRENGTH ELECTRIC FIELDS ON SMALL LABORATORY ANIMALS, DOE/TIC-10084 (1979) (available from

company published a study that concluded that living near powerlines does not result in increased risk of disease. It would be reasonable for the expert relying on this study, as well as the court and the trier of fact, to be aware that an employee of a party to the dispute performed the study. Even though the employee-employer relationship does not affect the peer evaluation, ordinary human experience suggests that such studies might be biased in some manner, and the relationship may properly serve as a basis for giving less weight to the results of the study. Thus, depending on a study's funding, a question concerning its extrinsic validity may arise.

A *contract* is a method of funding research to provide knowledge desired by the funding party. Data obtained pursuant to a contract is owned by the funder, which therefore has the right to determine the data's disposition and the extent of access that will be permitted.[42] A typical investigator performing contract research is an employee of a private research organization or national laboratory.[43] Investigators working under contract may be permitted to submit some of their work for peer review, depending on the sponsor's needs and desires and the policy of the scientist's organization. The sponsor, however, may have concerns regarding patentability, competitor advantage, or potential liability that may encourage secrecy regarding some or all of the study results. The lack of academic freedom to publish any data one chooses is a well-understood aspect of contract research. In agreeing to perform contract research, an investigator acknowledges that the primary goal is the satisfaction of the contract, not contribution to the corpus of public knowledge in science.

Another way of funding scientific research is the *grant*, a method whereby the goals of the research are chosen by the investigator, and the primary interest of the granting organization is the contribution to public knowledge within the particular branch of science.[44] Under a grant, data

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National Technical Information Service (NTIS), U.S. Dept. of Commerce, 5285 Port Royal Road, Springfield, VA 22161); *see also* ROBERT O. BECKER & ANDREW A. MARINO, ELECTROMAGNETISM & LIFE 150 (1982); ANDREW A. MARINO & JOEL RAY, ELECTRIC WILDERNESS 98 (1986).

42. In 1994, federal spending for research and development in health was about $12 billion. Spending by industry was almost $16 billion. *See* Tim Beardsley, *Big-Time-Biology*, SCI. AM., Nov. 1994, at 90, 92.

43. Such entities include Battelle, Midwest Research Institute in San Antonio, Texas, and the Oak Ridge National Laboratory in Oak Ridge, Tennessee.

44. Grants from the National Institutes of Health (NIH) or the National Science Foundation (NSF) are the backbone of independent science in the United States. These grants are awarded for one to five years. The sole consideration for funding is the scientific merit of the proposed work. Generally, it is irrelevant to the investigator and the funding agencies whether the implications of a particular study might tend to support or refute allegations of causal connections between particular toxins and particular diseases. Such research is performed pursuant to a specific plan, and the plan itself, as well as all data reported to the granting agency, is available under the federal Freedom-of-Information Act. Freedom of Information Reform Act of 1986, 5 U.S.C. § 552 (1994). Moreover, both the NIH and the NSF have promulgated policies directing that raw data and associated materials obtained during the research should be made available to all interested parties. No other federal agencies, state agencies, or private organizations have adopted such a policy.

Under the common law, work performed by an employee in the course of his employment is owned by the employer because it is work-for-hire. Thus, research data produced by a faculty member with institutional support is owned by the academic institution. Institutions also retain legal title to the scientific data produced

produced in the experiment is ordinarily subject to the exclusive control of the investigator. At the investigator's discretion, data is submitted for peer review and published in scientific journals. The typical grantee[45] is an academician who is expected to perform research and publish as a condition of academic employment.

Although the idea of dishonesty in science in any form and to any degree is repugnant, various species of dishonesty do occur. An expert witness who relies on particular scientific reports, therefore, has a responsibility to consider the reports' extrinsic validity, particularly its source of funding.

C. Reliance on the Work Product of Blue-Ribbon Committees[46]

Opinions concerning scientific matters pertinent to toxic tort litigation are sometimes provided by a *blue-ribbon committee*, a group of scientists appointed by a public or private organization with an interest in the analysis of a particular scientific issue that impacts society.[47] Several factors indicate that

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by faculty members who are supported by NIH and NSF funds. *See* Administration of Grants, 45 C.F.R. part 74 (1993); Representation of Limited Rights Data and Restricted Computer Software, 48 C.F.R. § 52.227-15 *et seq.* (1993). Since the institution owns the work, it has the copyright. 17 U.S.C. § 201(b) (1994). Hence the institution is legally entitled to decide issues of publication and access. Although the academic institution is entitled to claim the copyright, it normally *chooses* not to do so. Instead, the academic tradition is that faculty members are permitted to claim the copyright for their research. Since there is no national registry of research pertinent to drugs or toxic torts, it is not possible to establish research that is occurring or has occurred.

45. The actual grantee is the academic institution which employs the scientist. The institution maintains the financial and administrative records, sets and implements purchasing procedures, retains title to equipment purchased with grant funds, and is vicariously liable for any scientific misconduct on the part of the grant's principle investigator. Nevertheless: (1) grant funds are provided for the services of a specific investigator; (2) expenditures of grant funds can be initiated only by the investigator; (3) the investigator has the unilateral and exclusive authority to vary the actual research conducted based on new information obtained subsequent to the award of the grant; (4) normally, the investigator has unilateral and unrestricted authority to determine access to the research data. Because of these factors, it *appears* the investigator is the grantee, and is commonly referred to as the grantee.

46. This subsection deals with whether an expert should rely on the work product of a blue-ribbon committee. See *infra* notes 99-101 and accompanying text for a discussion of the admissibility of the work product of a blue-ribbon committee into evidence.

47. Usually, blue-ribbon committees are established to allay public concerns regarding an issue, according to the collective judgment of the committee's members. For example, the American National Standards Institute (ANSI) formed a committee to choose safe levels of electromagnetic fields. INST. OF ELEC. AND ELEC. ENG'RS, AMERICAN NATIONAL STANDARD SAFETY LEVELS WITH RESPECT TO HUMAN EXPOSURE TO RADIO FREQUENCY ELECTROMAGNETIC FIELDS, 300 KHZ TO 100 GHZ, ANSI C95.1-1982 10 (1982) (available from The Institute of Electrical and Electronics Engineers, Inc., 345 East 47th Street, New York, NY 10017). It is historically true that privately appointed blue-ribbon committees called upon to evaluate chemical or physical agents present in the environment usually conclude that such agents do not pose a health risk. For example, the safe level chosen by ANSI is 200,000 times higher than the median exposure level in urban areas of the United States determined by the Environmental Protection Agency. In other words, according to the ANSI committee, essentially everyone is safe from harm due to electromagnetic fields. *See* U.S. ENVTL. PROTECTION AGENCY, POPULATION EXPOSURE TO VHF AND UHF BROADCAST RADIATION IN THE UNITED STATES, ORP/EAD 78-5 (1978) (available from United States Environmental Protection Agency, Office of Radiation Programs, Las Vegas Facility, P.O. Box 15027, Las Vegas, NV 89114).

the work product of blue-ribbon committees is not a reliable source of knowledge for an expert witness. First, the primary goal of a blue-ribbon committee is to arrive at a consensus, while the primary goal of an expert witness is to convey knowledge to the court in a truthful and accurate manner. Since there is no necessary connection between the consensus of a committee and the accuracy of its work product, an expert generally has no reason to accept a blue-ribbon committee's consensus as accurate.

Second, a blue-ribbon committee's consensus has no practical value unless it is formed by a representative group of individuals. Only then would it be reasonable to regard the committee's opinion as an accurate characterization of the state of the pertinent science. If the forming organization choses committee members *because of* their opinions, an expert witness would have no basis for according the committee's opinion more weight than the members' individual opinions.[48]

Third, the qualifications of the blue-ribbon committee members must be established before an expert may reasonably rely on the committee's opinion. But an expert witness will frequently lack personal knowledge regarding the expertise of at least some committee members, and will therefore lack a basis to assess their qualifications to offer such an opinion. Even if the witness believed that all members were qualified, a question arises concerning the extent of time and effort actually expended by each member during committee deliberations.

Fourth, because blue-ribbon committees are formed by organizations with an interest in the results, blue-ribbon committees often have obvious conflicts of interest, and an expert would be naive to ignore them.[49] Conflicts of interest occur even when a blue-ribbon committee is appointed by a federal[50] or state[51]

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48. For example, since the ANSI committee was not chosen randomly from among all qualified persons, its consensus is not likely to be similar to one that would have been reached by a representative group of qualified experts. The ANSI committee consisted of 53 members. Judging from the professional affiliations and degrees of its members, we estimate that there are more than half a million persons who could have qualified as members. Although the number of possible committees is unimaginably large, the one actually chosen is not representationally valid because at least some members were chosen *because of* their opinion. The theoretical rationale for a blue-ribbon committee is the same as that for a jury. The validity of a jury's verdict is derived from its representative nature. Since the rationale for a blue-ribbon committee is that its conclusion is representative of those that would be reached by a larger group, and such is not the case with ANSI, adoption of the ANSI committee's opinion as an authoritative statement of scientific fact is not justifiable. Instead, it is the opinion of the persons who chose the committee.

49. The ANSI committee, for example, consisted of employees of business organizations that manufactured devices that emit electromagnetic fields, but no representatives of those who are regularly exposed to electromagnetic fields. It is not reasonable to expect employees of companies that derive profit from manufacturing devices that emit electromagnetic fields to adequately represent the interests of those who are exposed to the emissions of these devices.

50. The National Academy of Sciences (NAS), in cooperation with the United States Navy, appointed a blue-ribbon committee to evaluate the safety of a large antenna that would emit electromagnetic fields similar to those emitted by power lines, except that the fields from the antenna would be 100,000 times weaker. Three experts, who previously testified that power line electromagnetic fields create no health risk

agency. Over-arching governmental involvement in blue-ribbon committee selection, therefore, is not a substitute for choosing a balanced committee as a condition precedent to the representational validity of the committee's opinion.[52]

The expert in a toxic tort case must recognize the work product of a blue-ribbon committee is unavoidably shaped by the appointing authority through its choice of committee members. If the expert lacks knowledge of the qualifications and extent of effort of the committee members, he has no rational basis for accepting their opinion. An expert should suspect conflicts of interest whenever the results of a blue-ribbon committee are dispositive of a scientific issue in a toxic tort suit, because such issues are often controversial and incapable of resolution on a purely scientific basis. While an expert witness is necessarily confined to the scientific facts, value and policy considerations are usually incorporated into the opinion of a blue-ribbon committee. For these reasons, the expert should refrain from substituting a blue-ribbon committee's

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were appointed to the NAS committee. Not surprisingly, the NAS committee found that the proposed antenna would be safe. NAT'L ACADEMY OF SCIENCES, BIOLOGIC EFFECTS OF ELECTRIC AND MAGNETIC FIELDS ASSOCIATED WITH PROPOSED PROJECT SEAFARER: REPORT OF THE COMMITTEE ON BIOSPHERIC EFFECTS OF EXTREMELY-LOW-FREQUENCY RADIATION (1977); Philip M. Boffey, *Project Seafarer: Critics Attack National Academy's Review Group*, 192 SCI. 1213 (1976); *see also* ANDREW A. MARINO & JOEL RAY, *supra* note 41, at 98.

NAS committees are the most prestigious blue-ribbon committees in the United States. Although approximately 900 NAS committees are presently evaluating science policy in various areas, only about 100 of the more than 1600 NAS members serve on the committees. Critics of the NAS members' absence argue that the quality of the reports would improve if more NAS members served on blue-ribbon committees. The president of the NAS, however, noting that most NAS members are older white males, suggested that any gain in wisdom might be offset by other factors. The mechanism by which individuals are chosen for the NAS committees has not been publicly disclosed. *See* Robert Langreth, *Members Seek More Active Role*, 263 SCI. 23 (1994).

51. A Florida state agency appointed a scientist who performed contract research on behalf of a national consortium of electric power companies to chair a blue-ribbon committee regarding powerline safety. The committee generally exonerated state regulatory practices, which did not require any special efforts to lessen exposure to electromagnetic fields or to apprise the public of the nature or extent of the exposure. Shortly thereafter, the chairman became the chief of staff for a law firm that represents power companies in legal actions involving allegations of health risks due to electromagnetic fields from powerlines. *See* FLA. ELEC. AND MAGNETIC FIELDS SCIENCE ADVISORY COMM'N, BIOLOGICAL EFFECTS OF 60-HZ POWER TRANSMISSION LINES, FLORIDA ELECTRIC AND MAGNETIC FIELDS SCIENCE ADVISORY COMMISSION REPORT (1985) (H.B. Graves, Chairman); *see generally* 8 MICROWAVE NEWS, Mar.-Apr. 1988.

52. A concept similar to the blue-ribbon committee, called the *Science Court*, was proposed by a Presidential advisory panel as a means of resolving scientific disputes. *See* Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, *The Science Court Experiment: An Interim Report*, 193 SCI. 653, 653-56 (1976). The basic idea of the *Science Court* was that scientists would be appointed as judges to resolve issues such as: Should hydrofluorocarbons be banned because of their impact on the ozone layer? Is red dye #40 safer than red dye #2? Should water supplies be fluoridated? Such questions are value-laden, and consequently can be resolved only if value judgments are incorporated into the decision making process. Since the values that must necessarily be applied are those of society as a whole, not those of science or particular scientists, the *Science Court* concept was fatally flawed. For a description of the failure of attempts to form a *Science Court* to consider whether electromagnetic fields from powerlines are a health hazard, see Allen Mazur et al., *Separating Factual Disputes from Value Disputes in Controversies over Technology*, 1 TECH. IN SOC'Y 229, 229-37 (1979).

judgment for his own. If the witness must rely on the work of a blue-ribbon committee, he is probably not an expert.

V. APPLICATION OF SCIENTIFIC REASONING IN TOXIC TORT CASES

The expert in a toxic tort case must rationalize an assertion that the plaintiff's disease and the dosage of the toxin received were causally related and not merely a chance association. For example, in the case of a traffic-control officer who used a radar gun and developed cancer, the plaintiff's exposure to electromagnetic fields and his disease occurred in the context of many factors, among others: the plaintiff ate peanuts; smoked cigarettes; wore blue socks; drove a motorcycle; lifted weights; collected coins; lived near a superhighway; and had arthritic knees. The question arises, therefore, why the expert singled out electromagnetic fields as the causative agent, as opposed to myriad other co-existing circumstances.[53]

If the expert is to rationalize the causal relationship, the rationalization must be done on the basis of scientific knowledge, namely, an appropriate and reliable corpus of scientific data that permits the expert to infer that the plaintiff's disease was a consequence of exposure to the toxic agent. Scientific studies potentially available regarding the question of causality are test-tube, animal, and epidemiological studies, and each has particular strengths and weaknesses.[54] Moreover, the methodology by which the scientific data is analyzed must itself be appropriate and reliable.

Although the expert must always consider the limitations of scientific studies with regard to inferring causal relationships in human subjects, such data are appropriately used to form causal inferences in proper situations. Animal and human studies are routinely used in science for this purpose. Indeed, most human and animal studies are performed with the intent to make

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53. The expert cannot rely on personal observation as the basis for asserting a causal relationship because the expert made no direct observations pertinent to the plaintiff or the conditions of his exposure. Even if the expert had observed the plaintiff continuously from the inception of exposure to the toxic agent until the plaintiff's disease was diagnosed, the expert still could not testify to the fact of causality based on direct observation because causation of human disease—as distinguished from its existence—is not amenable to direct observation.

54. *See* discussion *infra* Appendix, at 58-62. Test-tube studies are the premier method for studying causal mechanisms, but they constitute such a vast oversimplification of animal physiology, that they are essentially useless in direct assessment of the overall effects of human exposure to a putative toxin. Animal studies are capable of providing relatively clear demonstrations of cause-and-effect relationships and the results can be applicable to human exposure. Animal studies also have the following drawbacks: (1) relatively short exposure durations, often requiring large doses of the toxic agent; (2) biological endpoints that may not be directly relatable to a recognizable disease because they constitute physiological changes that are only precursor stages of disease; and (3) arguable inapplicability to human subjects based on physiological differences between laboratory animals and human beings. Epidemiological studies are directly relevant to toxic tort cases because they involve human beings who were actually exposed to the toxic agent and developed the disease. All epidemiological studies are confounded to some degree by the problem that unknown factors, rather than the toxic agent being studied, may have caused the observed change in the incidence of disease.

such inferences. Causal inferences must be proved or disproved using such data before a drug can legally be advertised, an additive can be incorporated into a food product, a pesticide can be sprayed into the environment, or a powerline, nuclear power plant, microwave tower, or other facility that will emit potentially toxic agents into the environment can lawfully be constructed.[55] It is quite clear, therefore, that the expert's use of scientific studies to rationalize causal links in toxic torts is identical to the use of such data in myriad other areas.

A. Principal Inductive Opinion

The logic of scientific reasoning constrains the order in which the expert must approach a determination of whether the plaintiff's exposure and the subsequent disease were causally related. Since the plaintiff was exposed to the toxic agent and developed a disease, the expert must first determine whether the toxic agent caused the effects in laboratory studies or the diseases in epidemiological studies that it appears to have caused. In other words, the seminal question is whether the toxic agent *can cause* the plaintiff's disease, given the available information characterizing the effects the agent is capable of causing. If the evidence did not support an opinion that the toxic agent *can cause* the plaintiff's type of disease, it would be logically impossible for an expert witness to conclude that it did so in the plaintiff's case. The expert's opinion whether the toxic agent can cause the disease complained of must be based on the strength of existing scientific studies; that is, on the basis of the

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55. Many federal laws and accompanying regulations require the use of animal studies to assess human health risks. *See* Federal Pesticide Act of 1978, 7 U.S.C. § 136 et seq. (1994); Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq. (1994); Consumer Product Safety Act, 15 U.S.C. § 2051 et seq. (1994); Toxic Substance Control Act, 15 U.S.C. § 2601 et seq. (1994); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (1988 & Supp. V 1993); Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq. (1988 & Supp. V 1993); Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq. (1988 & Supp. V 1993); Safe Drinking Water Act, 42 U.S.C. § 300 et seq. (1988 & Supp. V 1993); Resource Conservation and Recovery Act of 1976, 42 U.S.C. § 6901 et seq. (1988 & Supp. V 1993); Clean Air Act, 42 U.S.C. § 7401 et seq. (1988 & Supp. V 1993).

Federal public health authorities invariably consider both animal and epidemiological studies. *See* U.S. Envtl. Protection Agency, *Final Guidelines for Developmental Toxicity Risk Assessment*, 56 Fed. Reg. 63798, 63799 (1991) ("[H]azard identification/dose-response evaluation involves examining all available experimental animal and human data."); U.S. Envtl. Protection Agency, *Proposed Guidelines for Assessing Female Reproductive Risk*, 53 Fed. Reg. 24834, 24836 (1988) (EPA consistently relies on "evaluation of toxicological data from humans and experimental animals" in assessing reproductive and developmental risks.); U.S. Occupational Safety and Health Admin., *Final Standard for Occupational Exposure to Ethylene Oxide*, 49 Fed. Reg. 25734, 25743 (1984) (OSHA ruling rested on a "comprehensive review of the scientific evidence . . . based on information from many investigations in several species of experimental animals . . . as well as positive results from several human studies."); U.S. Occupational Safety and Health Admin., *Final Rule for the Identification, Classification, and Regulation of Potential Occupational Carcinogens*, 45 Fed. Reg. 5002, 5040-59 (1980) (requiring data from other human studies or from experimental studies in test animals).

studies' number, quality, and degree of relevance to the toxic agent involved in the case.[56]

The legally significant question that arises concerning the *can cause* opinion is: Considered as a scientific statement, is it true?[57] No witness can testify with complete freedom from possible error because sensory physiology and rational inference are fallible. These are the only two processes by which a witness can acquire knowledge cognizable at law. Thus, an expert who testifies on the basis of scientific studies cannot do so with absolute certainty.

Although the individual studies considered by the expert usually involve cause-and-effect relationships that are ninety-five percent,[58] the expert necessarily incorporates subjective considerations in forming a *can cause* opinion.[59] Thus, it is not possible for an expert to conclude with a numerical degree of certainty that a toxic agent *can cause* the plaintiff's type of disease. As with all conclusions in science that are not themselves the direct result of scientific studies, the inductive inference must be stated using qualitative terms such as "possible," "likely," or "nearly certain."

There is no explicit scientific convention regarding the exact meaning of the various terms routinely used to qualify the degree of truth of a generalization, but the definition of these terms can be discovered from an analysis of their use patterns. Not surprisingly, truth-qualifying terms are used in science as in other areas of human endeavor. "Possible" means only that the causal relationship is not impossible. In science, "possible" can be applied to *any* asserted causal relation because none are impossible.[60] The term "reasonably possible" refers to causal statements whose probability of truth is greater than the naked minimum (anything greater than zero). "Probable" and "likely" indicate that the statement is more than fifty percent certain. The *can cause* opinion in a toxic tort case necessary to subject the defendant to liability is that,

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56. Banal as it may sound, the proffer of an expert witness' opinion in a toxic tort case neither presupposes nor guarantees actual knowledge. Moreover, status does not imply knowledge as it does, for instance, in a medical malpractice action (a board-certified orthopaedic surgeon is presumed to have knowledge regarding orthopaedic surgery).

57. Truth, with respect to causal statements in science that are derived directly from controlled scientific studies, is a measure of the degree to which an effect measured in the study is attributable to the specific factor that was controlled. The degree of truth, or certainty, can be expressed on a numerical scale between 0 and 100%. By convention, a level of 95% is accepted as practical certainty. The degree of certainty can be specified numerically for individual scientific studies, but not for the causal conclusions directly pertinent to legal questions in toxic torts, because such conclusions are not directly based on scientific studies, but rather on inferences made from such studies.

58. *See supra* note 57.

59. Among the most important subjective considerations are the choice of studies to be considered and the weight to be given to individual studies. Additional considerations may be appropriate (whether the statistical test used in a particular study was conducted incorrectly) or inappropriate (the results of the study are adverse to the client's interests).

60. For example, consider the assertion that "bouncing a basketball can cause it to pass through the floor of the basketball court." While such a result is bizarre, according to the laws of modern physics there is an infinitesimally small but non-zero possibility that such an event could happen.

"it is probably true that X can cause Y," because the burden is on the plaintiff to establish his case by a preponderance of the evidence.

Disease is a complex process involving many biological changes. Any cause-and-effect relationship between a toxic agent and a biological change is probative with regard to the fundamental issue of disease causation in human subjects. For example, if test-tube and animal studies show the toxic agent affected cell division, cell metabolism, the immune system, growth, healing, or reproduction, as reflected in the relevant laboratory variables, it might be reasonable to infer that the toxic agent probably can cause disease in human subjects because changes in one or more such variables invariably manifest when disease occurs. Similarly, if associations appear in epidemiological studies between exposure to the toxic agent and the plaintiff's type of disease, then, depending on the number and quality of such studies, the proposition "it is probably true that X can cause Y" may be justified.

The question often arises as to how many test-tube, animal, and human studies are needed before an expert is justified in asserting that the causal relationship is "probably true." This question can be resolved only by ascertaining how many such studies, and of what type and quality, ordinarily are required when the toxic agent or other similar agents are considered in relation to issues other than those involved in toxic tort lawsuits. Such issues include claims of medical efficacy of a drug, specification of the nature and severity of likely side effects of such drugs, and assertions of the absence of adverse health impacts due to a food additive or air pollutant.[61]

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61. It is worthwhile to consider the process of generalization in greater detail to emphasize its routineness and societal importance. For example, suppose that a drug company believed a particular drug would be an effective antibiotic. In preparing the drug for market, the company would ordinarily perform test-tube studies to establish the drug's effectiveness, and thereafter would test it using an appropriate animal model, such as rats that had purposely been infected. The studies would ascertain whether, to a 95% certainty, animals that were infected and then given the drug faired better than infected animals that did not receive the drug. Several studies would ordinarily be performed to test the drug under different circumstances (for example, three kinds of microbes, each placed into different organs). When the data is presented to the FDA to justify human experiments using the drug, the company experts will opine that the animal studies indicate the likelihood of efficacy of the drug in human subjects. That is, based on a consideration of the experimental design, the animal species used, and the unlikeliness that the observed correlation was due to chance, the company experts will conclude that the drug will likely be effective in human patients. The FDA may accept or reject this generalization. In the latter case, more animal studies may be required to permit rationalization of the drug company's desired inference that the drug is likely to be effective in patients. No amount of animal studies could ever permit a stronger inference, such as "very likely" (merely a semantic, not a measurable scientific difference from the original opinion), or "certain." Additional studies might give particular scientists more confidence in a "likely" conclusion, but this is a judgment upon which individual scientists may differ—in the present example, the FDA's opinion, which would be determinative. Assuming the requisite number of animal studies needed to justify "likely" had been performed, the FDA staff would grant the drug company permission to use the drug in a limited human study (that is, under particular circumstances and in specific types of patients at specific institutions) for the purpose of scientifically testing the drug company's belief that the drug is effective. Following completion of these studies, if the drug company experts observe a statistical association between use of the drug and clinical improvement, the FDA will consider allowing the drug to be marketed, not because it *will* help a particular patient or because it is *likely* to help, but because it *might* help individual patients. In other words, the FDA

The alternative to a *can cause* conclusion is not a *can't cause* conclusion. Rather, the conclusion is that the evidence does not warrant an inference of *can cause* according to the subjective level of certainty used in asserting a causal connection ("possible," "likely," and so forth).[62] In other words, the two possible results of an individual experiment are either that the investigator found or did not find that "x" caused "y". The alternative to "I found that x caused y," therefore, is "I did not find that x caused y," rather than "I found that x did not cause y," because not finding "y" is not a possible observation.

B. Exposure to the Toxic Agent

Normally, the expert in a toxic tort case has no personal knowledge of the amount of the toxic agent received by the plaintiff because the expert neither measured nor observed it. In the radar gun example, the officer was exposed to different strengths of the radar field depending on the angle between the axis of the gun and the officer's body, the reflection characteristics for electromagnetic fields of the patrol car's glass and metal surfaces, the number of hours per day the officer operated the radar gun, and the years of exposure. The expert did not observe any of these factors during the time the plaintiff operated the radar gun. Nevertheless, the expert must demonstrate that he possesses the requisite knowledge regarding the plaintiff's exposure to the toxic agent.

The expert must know the plaintiff's dose of the toxic agent relative to the doses employed in relevant animal studies, and to the doses received by the subjects in relevant epidemiological studies. If, in the previous example, the amount of electromagnetic fields the officer received was similar to the amount received by a person who did not operate a radar gun, there would be no basis to assert that the cancer was caused by the fields produced by the radar gun, as

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staff will permit use of the drug for the treatment of infection if the human studies show that a likelihood that at least some patients who receive the antibiotic will improve, compared with the fate of the same subjects if they either had not been treated, or had been treated with a standard drug (actually, the applicable law provides that the new drug need only be *as effective as* the drug already in use). A parallel set of studies and analyses must be conducted to characterize and delimit the nature of side effects that likely will be associated with the drug.

The process of scientific generalization is routine in areas that directly affect society at large, and generally accepted rules and procedures exist for implementing a generalization. It is unnecessary to specifically discuss the rules here. It is sufficient to recognize that the rules exist. The *purpose* for which the rules are applied to the scientific data (to persuade FDA staff in this example or to persuade a jury in a toxic tort case) is irrelevant to the issue of the validity of the rules and procedures. For example, if four animal studies involving rats performed with a particular standard of care and analyzed with a specific statistical test are sufficient to form the basis for a generalization that the drug under study will likely be effective in patients, then a similar number of comparable studies can also form the basis for a generalization that the test agent will likely cause an *undesirable* effect in patients. The rules for generalization are the same in both cases. The expert witness must use these rules in a toxic tort case in generalizing or refusing to generalize. Application of the norms for scientific generalization cuts both ways in a toxic tort case. If a method of reasoning does not exist, an expert cannot validly create it in a courtroom, and if the process does exist, an expert cannot ignore it merely because its applicability would lead to a result adverse to his client's interest.

62. *See supra* notes 20-21 and accompanying text.

opposed to the levels generally present in the environment. Thus, the expert must show that the plaintiff's level of exposure to the toxic agent was greater than that ordinarily received by persons who do not develop the plaintiff's type of disease.

An expert's knowledge regarding the absolute and relative amount of a plaintiff's exposure to a toxic agent is based on the testimony of other witnesses and the results of tests and measurements made to mirror the plaintiff's exposure to the toxic agent. On the basis of this knowledge, the expert must construct and render plausible a model of the plaintiff's exposure that, to a legally acceptable level of certainty, permits the expert to estimate the dose the plaintiff actually received.[63]

C. Principal Deductive Opinion

If the expert sustains the burden of showing that "it is probably true that X can cause Y," the question then arises whether the amount of toxic agent the plaintiff experienced probably caused his disease. Assume the plaintiff had no exposure to any other agent that also could cause his type of disease, and his exposure to the toxic agent occurred at significantly greater levels than those routinely experienced by persons who do not manifest the plaintiff's type of disease. An expert could justifiably conclude that, although the possible causative role of unknown factors cannot be eliminated, the existence of only one potential cause sufficient under the circumstances makes it likely that it was the actual cause of the plaintiff's disease. On the other hand, if the plaintiff had been exposed to additional agents shown by scientific studies to be sufficient causes of the plaintiff's disease, a more complex factual issue exists. Accordingly, the relative importance of multiple agents in causing the plaintiff's disease must be determined from an analysis of the quality and amount of pertinent scientific evidence.

When reasoning deductively in a toxic tort case, the concept of causality employed by the expert is identical to the *but for* conception employed by the layman in everyday life. The *but for* concept of causality is ordinarily the basis of liability in tort and is the core meaning of *cause* throughout the law.[64] The expert's testimony will be that the plaintiff's disease probably would not have occurred when it occurred "but for" his exposure to the toxic agent. From an operational viewpoint, this testimony is equivalent to an assertion that erasing

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63. For example, based on testimony that a police officer used a particular type of radar gun for a certain number of years, and that the gun was held in certain positions in particular circumstances for varying lengths of time during the typical work day, an expert could conclude the plaintiff was actually exposed to electromagnetic fields emanating from the gun. Additionally, based on measurement data, such as the electrical characteristics of the gun, the angle of the spread of the beam as it exited the barrel of the gun, and the amount of reflection the beam produced when it strikes metal and glass surfaces, the expert could estimate the dosage the plaintiff experienced.

64. HART & HONORÉ, *supra* note 3, at 428-30.

the history of the plaintiff's exposure to the toxic agent, but making no other changes in the circumstances involving the plaintiff's life, probably would have eliminated the occurrence of the plaintiff's disease at the time it actually occurred.

VI. ADMISSIBILITY OF SCIENTIFIC EVIDENCE IN TOXIC TORT CASES

The court must evaluate the admissibility of the expert testimony before it may be considered by the trier of fact.[65] The basic question a court must consider when determining the legal admissibility of scientific testimony is the reliability of the expert's scientific knowledge. Since the court cannot decide the scientific issues,[66] it must focus on the expert's decision-making process, that is, the method by which the expert arrived at the opinion.

The court essentially must answer two questions: (1) Was the expert's conclusion based on controlled observations of nature published in peer-reviewed scientific literature?; and (2) Were the applicable principles of scientific inference properly applied to the scientific data? If the court answers both questions affirmatively, it follows that it is "reasonably possible" the testimony is true, and therefore reliable. The court's gatekeeping function, therefore, has been fulfilled. Any standard of truth greater than "reasonably possible" would usurp the function of the trier of fact.[67] Conversely, a lesser standard would amount to an abrogation of the court's responsibility to assess reliability. The court's function is to determine whether an inference may reasonably be drawn by a jury, or whether it must necessarily be drawn. The jury's role is activated whenever the court finds the degree of certainty of the inference is between the two poles.

A. Modern American Jurisprudence Regarding Reliability of Expert Testimony: Frye *to* Daubert

Modern American jurisprudence regarding reliability of expert testimony began in a 1923 criminal case, *Frye v. United States*.[68] This jurisprudence developed primarily in the criminal law, but ripened for definitive analysis in

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65. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993).

66. Suppose an expert offers to opine "X can cause Y," where "X" is a toxic agent and "Y" is the plaintiff's disease. For example, "asbestos can cause cancer" or "Bendectin can cause birth defects." One possible approach to the issue of reliability would be for the court to evaluate the scientific evidence and decide whether the inductive generalization was probably true according to applicable scientific principles, as the expert purports. An affirmative answer equates to a finding of reliability. But a court is incapable of determining whether cause-and-effect relationships reported in particular studies were validly inferred according to orthodox rules of scientific procedure and analysis because these matters are purely within the scientific domain. Therefore, only scientists can initially resolve such issues.

67. An example of a standard greater than reasonably possible is a determination by the court whether the testimony is likely to be true.

68. 293 F. 1013 (D.C. Cir. 1923).

a toxic tort case, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[69] decided in 1993. In *Daubert*, the Supreme Court parsed the Federal Rules of Evidence and held reliability of scientific testimony must be determined by considering how the expert arrived at his opinion.[70]

Although *Daubert* has been significant in the development of the toxic tort cause of action, the implications of *Daubert* extend far beyond tort law to all cases in which scientific evidence is sought to be introduced. Before *Daubert*, courts had historically treated science as objective and dispassionate—a source of knowledge but not a source of error.[71] Based on this deferential view of science, courts found it unnecessary to ask the scientific expert, "How do you know?" In reality, however, science is no more objective and free of bias than are other areas of human endeavor. The courts' absolute faith in scientists, therefore, was misplaced. Had it not been for the mid-course correction of *Daubert*, the law would have continued to evolve along a path that is hopelessly inconsistent with the nature of modern science.

The initial standard for determining the reliability of expert testimony was laid down in *Frye*, which otherwise was an ordinary murder case. James Frye, the defendant, passed a lie-detector test, and offered the polygrapher's testimony regarding the results as evidence of his innocence.[72] The defendant's expert maintained that lying was always accompanied by a fear of being caught, and that this fear produced a rise in blood pressure that could be detected by a machine.[73] The court held that "the thing from which the deduction is made[74] must be sufficiently established to have gained general acceptance in the particular field to which it belongs."[75] The Court concluded that lie detectors "ha[d] not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting testimony deduced from the discovery, developments and experiments thus far made."[76] Although the "general acceptance" requirement was first applied *against* a criminal defendant in *Frye*, for the next half century, criminal defendants invoked the rule to prevent prosecutors from using new scientific developments to achieve unjust convictions.

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69. 113 S. Ct. 2786 (1993).

70. *Id.* at 2795.

71. United States v. Baller, 519 F.2d 463, 466 (4th Cir. 1975), *cert. denied*, 423 U.S. 1019 (1975) ("[B]ecause of its apparent objectivity, an opinion that claims a scientific basis is apt to carry undue weight with the trier of fact."); United States v. Addison, 498 F.2d 741, 744 (D.C. Cir. 1974) ("[S]cientific evidence may assume a posture of mystic infallibility in the eyes of a jury of laymen."); United States v. Amaral, 488 F.2d 1148, 1152 (9th Cir. 1973) (noting scientific testimony has an "aura of special reliability and trustworthiness."); D'Arc v. D'Arc, 385 A.2d 278 (N.J. Super. Ct. Ch. Div. 1978), *aff'd*, 421 A.2d 602 (N.J. Super. Ct. App. Div. 1980) (stating scientific evidence has an "aura of mystic infallibility."), *cert. denied*, 451 U.S. 971 (1981).

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

73. *Id.* at 1013.

74. That is the inductive generalization.

75. *Frye*, 293 F. at 1014.

76. *Id.*

While *Frye* was adopted in criminal cases in all the federal circuits and most state courts, it had no significant impact in civil cases.[77] The advent of the toxic tort cause of action, however, provided a new area for application of *Frye* because each toxic tort case involved an assertion that an agent previously regarded as safe was not safe under some circumstances.[78] Consequently, defendants found it advantageous to assert the "general acceptance" rule in toxic tort cases and thereby gain the benefit of the pre-existing presumption of safety. The effect of the rule when applied in toxic tort cases was to permit a party to shield its activities from substantive evaluation.[79]

The rule equating reliability with general acceptance was a form of judicial solipsism, because the only practical procedure for meeting the burden of *Frye* was to persuade the court to judicially notice the disputed principle. Consider, for example, a good faith attempt to meet the *Frye* burden. Initially, the identity of the persons whose "general acceptance" opinions the court will consider must be ascertained, but this is a difficult task because there are no credentialling agencies in science that designate such persons.[80] A further difficulty arises concerning the reliability of each opinion in the authoritative group: What standard should the court apply? The standard obviously cannot be "general acceptance." The means by which the group of opinion holders should be sampled to obtain their opinion raises an additional problem, because the conduct of valid surveys is itself a science.[81] Therefore, the survey results would be inadmissible based on the *Frye* rule, unless their proponent first showed the principles followed in conducting the survey had gained "general acceptance."

Another fundamental difficulty with applying *Frye* to toxic tort cases is that the rule tends to prevent establishment of precisely the factual conditions

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77. An article on the *Frye* rule published in 1980 did not mention civil cases. Paul C. Gianelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States a Half Century Later*, 80 COLUM. L. REV. 1197 (1980). *Frye* was not applied by a federal appellate court to exclude testimony until 1984. Barrel of Fun, Inc. v. State Farm Fire & Casualty Co., 739 F.2d 1028, 1031 (5th Cir. 1984).

78. Historically, the absence of *acute* effects nearly always provided the basis for regarding toxic agents as safe. It is frequently impossible, however, to evaluate causes of *chronic* effects based on data related to acute effects. In *Ferebee v. Chevron Chem. Co.*, the court recognized the distinction between acute and chronic effects of toxic chemicals by refusing to exclude the plaintiffs' expert testimony on chronic effects regardless of defendants' ability to prove the plaintiff could not have suffered acute effects. 736 F.2d 1529, 1536 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984).

79. For example, when testimony was first given that electromagnetic fields from powerlines could cause disease it was true that the theory was not "generally accepted." *See* Minutes of Public Hearing from Public Service Commission of New York, Common Record Hearings on the Health and Safety of 765 kV Transmission Lines, Cases 26529 & 26559 (Oct. 1974) (pre-filed testimony of Robert O. Becker, M.D.). Subsequently, in legal actions founded on the theory of harm induced by electromagnetic fields, the adverse party sought to exclude expert testimony under the *Frye* rule.

80. Not surprisingly, no court has provided pertinent guidance, even though particular choices could greatly enhance the chances of finding "general acceptance." For example, radar guns are generally accepted as safe by scientists who are employed by radar-gun manufacturers.

81. *See* ARLENE FINK & JACQUELINE B. KOSECOFF, HOW TO CONDUCT SURVEYS: A STEP BY STEP GUIDE (1985).

required to satisfy it. Testimony by the plaintiff's expert that a toxic agent can cause disease will always be met by contrary testimony from the defendant's expert.[82] The defendant's expert testimony is frequently based on scientific studies designed or controlled by the defendants. Thus, a rule that predicates the absence of reliability solely on the presence of controversy induces a defendant to create controversy, and thereby gain standing to invoke the rule.[83]

The United States Supreme Court, in *Daubert*, considered whether a plaintiff's principal inductive opinion, in a toxic tort case or otherwise, need be generally accepted before it may be presented to the trier of fact.[84] *Daubert* involved the morning-sickness drug Bendectin. The FDA approved Bendectin in 1956, and millions of pregnant women took the drug.[85] Subsequently, concern arose that Bendectin might be capable of causing birth defects in the

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82. Contrary testimony has been presented in cases involving asbestos, Agent Orange, PCBs, cigarettes, drugs, and electromagnetic fields.

83. Generally, the defendant advances the affirmative defense that a controversy over "general acceptance" exists.

84. The issue was argued extensively prior to *Daubert*. In the following cases the expert was allowed to introduce a scientific principle in court. The court assessed reliability by determining how the expert arrived at the opinion. *See* United States v. Jakobetz, 955 F.2d 786 (2d Cir. 1991), *cert. denied*, 121 L. Ed. 2d 63 (1992); United States v. Williams, 583 F.2d 1194 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990), *cert. denied*, 114 S. Ct. 691 (1994); United States v. Ferri, 778 F.2d 985 (3d Cir. 1985), *cert. denied*, 476 U.S. 1172 (1986); United States v. Downing, 753 F.2d 1224 (3d Cir. 1985); Clinchfield R.R. v. Lynch, 784 F.2d 545 (4th Cir. 1986); United States v. Baller, 519 F.2d 463 (4th Cir. 1975), *cert. denied*, 423 U.S. 1019 (1975); Spryncynatyk v. General Motors, 771 F.2d 1112 (8th Cir. 1985), *cert. denied*, 475 U.S. 1046 (1986); United States v. Luschen, 614 F.2d 1164 (8th Cir. 1980), *cert. denied*, 446 U.S. 817 (1980); United States v. Bennett, 539 F.2d 45 (10th Cir. 1976), *cert. denied*, 429 U.S. 925 (1976); Mustafa v. Brown, 22 M.J. 165 (C.M.A.), *cert. denied*, 479 U.S. 953 (1986); Carter v. St. Vincent Infirmary, 690 S.W.2d 741 (Ark. Ct. App. 1985); State v. Hall, 297 N.W.2d 80 (Iowa Ct. 1980), *cert. denied*, 450 U.S. 927 (1981); Andrews v. State, 533 So.2d 841 (Fla. Dist. Ct. App. 1988); State v. Williams, 388 A.2d 500 (Me. 1978); State *ex rel.* Elg v. Erickson, 363 N.W.2d 859 (Minn. Ct. App. 1985); Barmeyer v. Montana Power Co., 657 P.2d 594 (Mont. 1983); State v. Dorsey, 539 P.2d 204 (N.M. 1975); Minot Sand & Gravel Co. v. Hjelle, 231 N.W.2d 716 (N.D. 1975); State v. Johnston, 529 N.E.2d 898 (Ohio 1988); State v. Brown, 687 P.2d 751 (Or. 1984); State v. Walstad, 351 N.W.2d 469 (Wis. 1984).

The following are cases in which the court required prior to trial that the scientific principle be introduced by other scientists and to be generally accepted by scientists. The court deferred to its own perception of what scientists believe or accept. United States v. Shorter, 809 F.2d 54 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987); United States v. McDaniel, 538 F.2d 408 (D.C. Cir. 1976); United States v. McBride, 786 F.2d 45 (2d Cir. 1986); Christophersen v. Allied-Signal Corp., 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 503 U.S. 912 (1992); Barrel of Fun, Inc. v. State Farm Fire & Casualty Co., 739 F.2d 1028 (5th Cir. 1984); United States v. Kozminski, 821 F.2d 1186 (6th Cir. 1987), *aff'd*, 487 U.S. 931 (1988); United States v. Distler, 671 F.2d 954 (6th Cir. 1981), *cert. denied*, 454 U.S. 827 (1981); United States v. Brady, 595 F.2d 359 (6th Cir. 1979), *cert. denied*, 444 U.S. 862 (1979); United States v. Smith, 869 F.2d 348 (7th Cir. 1989); United States v. Carmel, 801 F.2d 997 (7th Cir. 1986); Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991), *vacated and remanded*, 113 S. Ct. 2786 (1993); United States v. Kilgus, 571 F.2d 508 (9th Cir. 1978); Lynn v. Helitec Corp., 698 P.2d 1283 (Ariz. Ct. App. 1984); People v. Wochnick, 219 P.2d 70 (Cal. Ct. App. 1950); KN Energy, Inc. v. Great Western Sugar Co., 698 P.2d 769 (Colo. 1985), *cert. denied*, 472 U.S. 1022 (1985); State v. Atwood, 479 A.2d 258 (Conn. Super. Ct. 1984); State v. Marks, 647 P.2d 1292 (Kan. 1982); Reed v. State, 391 A.2d 364 (Md. 1978); People v. Pullins, 378 N.W.2d 502 (Mich. Ct. App. 1985); State v. Danielski, 350 N.W.2d 895 (Minn. Ct. App. 1984); State v. Maule, 667 P.2d 96 (Wash. Ct. App. 1983); State v. Bohner, 246 N.W. 314 (Wis. 1933).

85. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993).

offspring of women who took it early in their pregnancy.[86] Laboratory, animal, and epidemiological studies were performed to evaluate the issue.[87] The FDA periodically revisited its original decision, but continued to permit the sale of Bendectin.[88] Nevertheless, Merrell Dow, Bendectin's manufacturer, eventually took Bendectin off the market in the face of several thousand lawsuits alleging that use of Bendectin had resulted in harm.[89]

In the trial court, the *Daubert* plaintiffs presented eight experts who concluded, on the basis of laboratory, animal, and epidemiological studies, that Bendectin can cause birth defects.[90] Merrell Dow moved for summary judgment based on the affidavit of one expert who testified that the opinions of the plaintiff's experts were not generally accepted.[91] The court granted summary judgment in favor of Merrell Dow, citing *Frye*,[92] and the Ninth Circuit affirmed on the same basis.[93]

The question presented to the Supreme Court was whether "general acceptance" was the appropriate standard for admitting scientific testimony that was contested for unreliability.[94] The Court specifically rejected the *Frye* rule and held that "scientific ... knowledge" was the applicable standard as provided in Rule 702 of the Federal Rules of Evidence.[95] *Daubert* reaffirmed

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86. *See id.* at 2791.

87. *Id.* at 2791-92.

88. The FDA was required by law to consider all the pertinent research, some of which the pharmaceutical industry produced.

89. Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 310 (5th Cir. 1989).

90. *Daubert*, 113 S. Ct. at 2791-92.

91. *Id.* at 2791.

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

93. Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991).

94. *Daubert*, 113 S. Ct. at 2792.

95. Over the objections of Chief Justice Rehnquist and Justice Stevens, the Court made "general observations" regarding the characteristics of "scientific knowledge," and it listed two factors that were discussed *supra*. *Id.* at 2796. First, the technique or theory being offered by the expert should have been tested. *Id.* at 2796-97. In practical terms, this means the induction itself should have been considered by experts who then prospectively conducted experiments to test the theory. *Id.* Second, the existence of peer review is a factor that should be considered in the preliminary hearing to determine whether an opinion is scientific knowledge. *Id.* at 2797.

The remaining two factors the Court mentioned were unartfully described, and are not scientifically significant in comparison with the other two factors discussed in the opinion and the other factors described supra that were not mentioned by the Court. The Court's third factor was "the known or potential error rate." *Id.* In the context of causal analysis, *error* refers to statistical probabilities. *See* WILLIAM MENDENHALL, INTRODUCTION TO PROBABILITY AND STATISTICS 202-03 (7th ed. 1987). In the context of scientific measurement, error refers to precision and accuracy. *See id.* Since the most common substantive characteristic of the peer-reviewed scientific literature is the use of statistics to analyze data, it is unlikely that proffered testimony satisfying the Court's first two factors would fail to meet its third factor. Finally, although the Court said that "general acceptance" cannot serve as a rule of exclusion, it suggested that it might continue as a rule of inclusion. *Daubert*, 113 S. Ct. at 2799. But it is difficult to visualize a situation in which this suggestion would have any practical meaning. If the theory was disputed by the parties, then the applicable test would be "scientific ... knowledge;" otherwise, the theory could be put into evidence via judicial notice. *See id.* at 2795. Consequently, there seems to remain little room for an independent rule of inclusion.

The intrinsic validity of scientific knowledge derives from the method by which the knowledge was

the proposition that the reliability of an expert opinion is a question of evidentiary law. If the opinion is "scientific ... knowledge," it is sufficiently reliable and can be admitted if it is relevant and not prejudicial.[96] The standard for the degree of certainty that ultimately must be met is defined by the applicable substantive law.

The *Daubert* Court found the authority for a standard based on scientific knowledge in the Federal Rules of Evidence. Regardless of whether Congress or the drafters of the rules actually intended this result, the nature of modern science has rendered such a standard inevitable. Historically, juries regarded scientists with awe,[97] but the judicial tendency toward such reverence has decreased in recent years. Perhaps this change reflects an evolving perception that scientists are not deserving of, and therefore should not be routinely accorded, an exalted status. Historical metaphors of the scientist as devoid of emotions, bias, error, and personal values are now commingled with other metaphors such as that of the partisan and the spin doctor.[98]

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inferred, and is independent of the purpose for which it was inferred (the motivation of the investigators), and for which it may be employed. Compare with "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes," where the Court majority confused *validity* with *relevance*. *Daubert*, 113 S. Ct. at 2796.

96. See *infra* notes 99-102 and accompanying text for a discussion of the admissibility of expert testimony under the hearsay rule.

97. United States v. Baller, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975) ("[B]ecause of its apparent objectivity, an opinion that claims a scientific basis is apt to carry undue weight with the trier of fact."); United States v. Addison, 498 F.2d 741, 744 (D.C. Cir. 1974) ("[S]cientific evidence may assume a posture of mystic infallibility in the eyes of a jury of laymen."); United States v. Amaral, 488 F.2d 1148, 1152 (9th Cir. 1973) (noting scientific testimony has an "aura of special reliability and trustworthiness"); D'Arc v. D'Arc, 385 A.2d 278 (N.J. Super. Ct. Ch. Div. 1978), *aff'd*, 421 A.2d 602 (N.J. Super. Ct. App. Div. 1980) (noting scientific evidence has an "aura of mystic infallibility"), *cert. denied*, 451 U.S. 971 (1981).

The supposed aura of infallibility of scientific evidence and its consequent impact on a lay jury, notwithstanding the fact that the evidence might be specious, is often cited in arguments for a relatively high judicial threshold for admissibility of scientific testimony. The perceived abuse, however, would not be remedied by raising the threshold for admission because a judge is also a layman with respect to science. Hence, a judge is also susceptible to the layman's perception of infallibility. If an expert undeservedly creates an aura of infallibility, the fault resides with the opposing counsel for failing to make effective use of the panoply of powerful tools available to the cross-examiner.

It may be worthwhile to consider the situation from the viewpoint of the expert. An expert witness is a highly, but narrowly, educated specialist called upon to translate knowledge from an arcane scientific specialty to the real world of ordinary people so that its potential importance can be evaluated. Frequently, scientists perceive the legal system as unfamiliar and intimidating, with its complex rules, non-intuitive procedures and central authority figure who exercises a near dictatorial control over events in the courtroom.

98. Essentially every toxic tort case involves two schools of thought regarding the scientific evidence, one of which is generally favorable toward each party. Science on the opposing side of the dispute is called "junk science" to distinguish it from the "good science" advanced by the other side, thereby illustrating the contentious nature of science; "good science" is my science, and "junk science" is the other guy's science. Science probably never deserved a free ride with regard to determining what the law should accept as truth; even if it did, that day has passed.

The writings of Peter W. Huber indirectly promote the idea that scientific issues having economic consequences are inherently controversial. PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991). Huber popularized the term "junk science." *Id.* Huber argued that tort law, particularly toxic torts, had run amok and was becoming a system for arbitrary redistribution of wealth. He opposed the use of science in the courtroom unless the scientific issues had been completely settled by the scientists

B. The Hearsay Rule

With the exception of scientific data actually obtained by the expert, scientific knowledge that forms the basis of an expert's testimony regarding causality is hearsay.[99] Nevertheless, the interests of justice sanction the use of one scientist's *data* by another scientist. There are several cogent reasons, however, that the hearsay exception should prohibit the expert witness from relying on the *opinion* of another scientist or of a blue-ribbon committee,[100] either in support of or in lieu of the expert's own analysis.

First, the court has a nondelegable duty to assess the testimony of each expert whose opinion is offered as evidence in support of the truth of the matters contained therein. If the testifying expert is permitted to rely on the opinions of others, it is the expert, rather than the court, who effectively determines the admissibility of the testimony with regard to the qualifications and competency of the hearsay sources. Second, if experts testify on the basis of opinions held by others, opposing counsel is effectively precluded from cross-examining those who formulated the opinions. Important considerations, such as the potential bias or lack of credibility of the scientists or committee members, therefore, could not be pursued.

Third, with regard to a blue-ribbon committee report, the consensus language contained therein is frequently ambiguous. As a result, it may be merely the witness's spin on the committee's report that is actually placed into evidence. Fourth, blue-ribbon committees often confound the scientific issues regarding causality with policy considerations involving cost, fairness, allocation of the burden of proof, and subjective notions regarding the quantum of proof needed to prove the existence of a causal relation. The role of an expert witness in a toxic tort case involves only factual issues. All questions relating to policy and values should be reserved for the court. It would be an abrogation of the court's role as the sole determiner of legislative intent to permit such decisions to be made by a blue-ribbon committee appointed by an executive authority, or by a private party.

Fifth, the possibility of bias should ordinarily exclude the use of hearsay sources of opinion. Individual scientists and blue-ribbon scientific committees

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themselves (because, otherwise, it was "junk"). *Id.* Huber's thesis was based on his economic and political views, not on legal or scientific analysis or fact. Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637 (1993). Huber's writings emphasized the controversial nature of science, and thus tended to bring about exactly what he opposed, namely recognition of the need for an expanded role for the courts.

99. Rule 810(c) of the Federal Rules of Evidence defines hearsay as " a statement, other than one made by the [person making the statement] while testifying at [a] trial or hearing, offered into evidence to prove the truth of the matter asserted." A statement is defined as an "oral or written assertion or . . . [the] non-verbal conduct of a person, if it is intended by the person as an assertion." FED. R. EVID. 810(a).

100. *See supra* notes 47-52 and accompanying text.

ordinarily do not render spontaneous opinions regarding controversial scientific issues for purely altruistic and scientific purposes.[101] Some bias-free information would be excluded by a rule that excludes reports of blue-ribbon committees, and such a rule would involve the court more deeply in adjudicating scientific matters than would otherwise have been the case. But when a choice must be made between relying on either a technically elite and knowledgeable group that is biased or potentially biased, and a scientifically unsophisticated but unbiased court, society is better served by the latter choice.

For these reasons, courts normally should not accept expert testimony based on the opinions of other experts. The scientific expert addressing causality in a toxic tort case should be restricted to testimony regarding his own opinions. The expert witness' expertise lies in evaluating scientific data and rendering opinions thereon, not in conducting polls to apprise the court of the opinions of others, or in parroting the results of analyses performed by others. The individual reports on which an expert will rely should be established prior to trial, and a court order should be granted to limit or control the use at trial of specific hearsay items, which are frequently well-known among those having an interest in particular toxic agents.[102]

VII. EVALUATION OF SCIENTIFIC REASONING BY THE TRIER OF FACT

A. The Expert's Choices of Method and Data

If the court is satisfied with the expert's qualifications, and with the basis upon which the principal inductive and deductive opinions were formed, the

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101. Blue-ribbon committees are usually created by an agency or organization with a vested interest in a particular solution to a scientific question. This interest may influence the choice of the individual committee members, resulting in a quasi-judicial body that lacks the detachment and independence of a court. It is not surprising that particular organizations will attempt to portray controversial scientific issues in a light most favorable to their interests. It cannot be plausibly maintained that the work product resulting from such efforts is unbiased, and should therefore be accepted by courts. Blue-ribbon committees often represent the opinion of one set of interests. Although those represented may be the most powerful or prominent in the industry, it does not automatically follow that the opinion is the common wisdom within the area, the best grounded in scientific facts and knowledge, or that which best serves the interests of society as a whole.

Furthermore, not all members of blue-ribbon committees are intellectually free to analyze pertinent data and reach an appropriate conclusion based solely on the scientific data. An employee of a particular industry would not normally be expected to enjoy the prerogative of freely commenting on scientific evidence when acting as a member of a blue-ribbon committee. Rather, the employee would be expected to represent the company's interest on the committee, which normally includes non-scientific considerations. Similarly, a government employee lacks academic freedom as a member of a blue-ribbon committee because such an individual is bound by the views of his agency. A blue-ribbon committee member who is an employee of a governmental organization would be expected to advance the agency's view during committee deliberations. These views necessarily incorporate value judgments and political considerations in formulating any position, including positions involving potentially controversial scientific matters.

102. For examples of judicial acceptance of opinions of other experts see Johnston v. United States, 597 F. Supp. 374, 410-11 (D. Kan. 1984) (stating that plaintiff's experts are not credible because they disagree with a blue-ribbon committee that contained "the most eminent scientists in the radiation community"); *In re* Agent Orange Prod. Liab. Litig., 611 F. Supp. 1223, 1240 (E.D.N.Y. 1985) (stating that government studies are reliable and impartial), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

expert will be permitted to opine to the trier of fact that "X can cause Y" and "x caused y."[103] The trier of fact then determines whether the expert's opinions are probably true, after considering the method by which the expert reached his opinions. The proper basis for the expert's opinion normally consists of nonpartisan scientific data published in the peer-reviewed scientific literature. On their face, these studies will purport to have established, or to have failed to establish, various cause-and-effect relationships involving the toxic agent under the particular circumstances of the studies. The plaintiff's expert must rely on a group of such studies which he finds were performed at an acceptable level of competence. With respect to each study the plaintiff's expert finds trustworthy and pertinent, he must make the basis for his view clear to the trier of fact. The plaintiff's expert must explain why the studies are pertinent and trustworthy using layman's terms.[104] If the expert is unable to do so, the plaintiff cannot sustain his evidentiary burden.

The defendant's expert, if attempting to persuade the trier of fact that a study contains errors which make it unreliable, is subject to the same rules that apply to the plaintiff's expert.[105] In particular, the defendant's expert must produce the objective factors that guided his judgment, and it must appear that his judgment was a consequence of these objective factors. The questions regarding whether the expert has chosen, analyzed, and relied upon particular scientific studies on the basis of a scholarly and dispassionate analysis of all the pertinent literature, and whether the opinions based thereon are probably true, are fundamentally important in every toxic tort case. Determination of these issues is a difficult challenge to judges, lawyers, and the trier of fact because they often involve arcane scientific terms and concepts.

Many factors may affect the trier of fact's determination of the credibility of a particular expert's testimony. The trier of fact could decide that an expert's opinion was improper if the expert accepted or rejected studies based on his *a priori* opinions rather than on the scientific merits. For example, in a

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103. Where "X" is the toxic agent in the case, "x" is the dose received by the plaintiff, "Y" is the type of disease manifested by the plaintiff, and "y" is the plaintiff's disease.

104. Acceptability of scientific data by scientists is determined by standards involving compliance with various methodological and statistical rules. *See supra* notes 34-45 and accompanying text. In contrast, acceptability of scientific data by laymen is determined by an examination of the circumstances attendant its production, distribution, and general use within the scientific community. If a study were of a type routinely performed by the investigator irrespective of considerations involving toxic tort cases, the study methods and statistical procedures were both routine and common within the specialty, and the results of the experiment were published in the open peer-reviewed scientific literature, the trier of fact would be justified in accepting an expert's confidence in the published data. The plaintiff must provide such evidence in order to carry his burden of proof with respect to the assertion "X can cause Y."

105. An expert may opine that many, or all, of the scientific studies relied upon by another expert were inferior, defective, or otherwise not suitable as a basis for generalization. Such conflicting opinions raise questions of fact and credibility. Suppose, for example, the defendant's expert uncovered a fatal defect in the statistical analysis of a study relied upon by the plaintiff's expert. In such a case, one element of the plaintiff's expert's opinion is refuted because he relied on faulty data. Additionally, the credibility of the plaintiff's expert concerning his opinions of other studies might be diminished because the trier of fact could reasonably conclude that if the expert relied on one study that was seriously flawed, he could have done so in other instances.

hearing involving the safety of powerlines, an issue developed concerning whether electromagnetic fields produced by powerlines could cause biological effects in exposed animals.[106] The opposing counsel challenged an expert for the power company on cross-examination with studies that reported biological effects in animals due to electromagnetic fields, and asked whether the expert had considered them in reaching his conclusion that no effects existed.[107] The expert elaborated criteria for accepting scientific data, applied them to the positive studies, and concluded that those studies had no scientific value. The cross-examiner then asked whether the expert had similarly applied the criteria for acceptable scientific data to the negative studies.[108] The expert stated he had not done so, and that he simply accepted the results of such studies because the results were as he believed they should be.[109]

The generation of expertise in contemplation of litigation may also signal to the trier of fact that a witness has failed to adhere to proper norms of scientific analysis. A witness who acquires his expertise regarding the causal potential, or lack thereof, of a particular toxin solely to take part in a specific legal dispute may have done so without thoroughly considering the pertinent scientific data. Examples include a physician who is not knowledgeable regarding the pharmacology of Bendectin or other similar drugs, or an electrical engineer with no knowledge of biology. If these experts are hired to give testimony and subsequently opine that Bendectin can cause birth defects or that electromagnetic fields can cause cancer, their testimony would be of dubious validity because their principal inductive opinions were based on knowledge acquired in contemplation of litigation. It is not reasonable to expect that such an instant expert would have developed the experienced judgment necessary to testify on such matters. The expert should possess knowledge that is pertinent to the case and acquired pursuant to a course of study and experimental inquiry, rather than for the purpose of litigation.

A related kind of dubious expertise consists in the proffering of testimony not actually authored by the testifying witness. This occurs when opinions for or against the view that "X can cause Y" reside in the word processor of a consulting company, which then hires scientists with an appropriate educational background and teaches them the canned analysis.[110] The integrity of the

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106. Minutes of Public Hearing from Public Service Commission of New York, Common Record Hearing on the Health and Safety of 765 kV Transmission Lines, Cases 26529 & 26559 (1976) (testimony of Hermann Schwan at 6731).

107. *Id.*

108. *Id.*

109. The expert further testified that when the experiment concluded that there was no effect, "I was not further interested in digging into the material." *Id.*

110. For example, in a proceeding involving the health hazards of high-voltage powerlines, an epidemiologist working for a consulting company hired by the defendant power company filed a detailed report that analyzed studies of the health hazards of powerlines, and exonerated them as a possible cause of disease. *See* Andrew A. Marino, Editorial, *Trust Me, I'm a Doctor*, 8 J. BIOELECTRICITY v-vi (1989). The expert's knowledge regarding the subject of her testimony, however, was acquired within the six-week period between the time she began working for the company and the day she testified, and her report was similar

law's reliance on an expert requires that the witness actually possess substantive knowledge in the subject of the testimony and not merely be an actor playing a dramatic role in the courtroom. It is the responsibility of counsel to demonstrate such shortcomings on the part of opposing witnesses.

B. Principal Inductive Opinion

In a toxic tort case, the plaintiff's experts, relying on a number of scientific studies in which the toxic agent was observed to produce various biological changes under different circumstances, will opine that it is probably true that the toxic agent *can cause* the particular disease involved in the case.[111] The ethically preferable method of evaluating the likely effects of putative toxic agents on human beings is to observe the effects on animals and extrapolate the results to human beings.[112] Indeed, an intention to reason in such a fashion is usually the justification for performing animal studies.

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to that provided in other forums by other company experts. *Id.*

111. Some courts have held that only epidemiological studies may be used to assess the causal role of toxic agents in human disease. *See, e.g.*, Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1161-62 (D.C. Cir.), *cert. denied*, 498 U.S. 950 (1990); Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 313 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); Richardson v. Richardson-Merrel, Inc., 857 F.2d 823, 830-31 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); *In re* Agent Orange Prod. Liab. Litig., 611 F. Supp. 1223, 1240-41 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988). In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the respondent urged this serious error on the Supreme Court (see Respondent's Brief at 41-44) but the Court rejected the concept in favor of the "scientific . . . knowledge" standard, which includes but is not limited to epidemiological knowledge. 113 S. Ct. 2786 (1993).

112. Why are animal studies ethically preferable? The possible types of relevant studies are animal studies, human experiments (studies employing experimental designs normally used with laboratory animals), and epidemiological studies (human studies in which statistical associations are sought in the absence of investigator *control* over the behavior of the study subjects). A human experiment could test a hypothesis that a toxic agent causes disease. In such a study, healthy subjects would be randomly assigned to either the exposed or control groups, and the percentage of subjects in each group that developed disease would be compared. Obvious ethical and practical factors prevent such a study: (1) no authority exists which is capable of assigning subjects to particular groups; (2) the putative study is inherently costly because great numbers of subjects must be followed to ascertain the existence of a relatively small number of subjects that develop the disease; (3) it is impossible to maintain the comparability of the two groups because the daily activities of the subjects cannot be controlled for the time needed to perform the study.

Because of these difficulties, the less logically powerful but more practical designs for epidemiological studies were developed. *See* discussion *infra* Appendix, at 58-62. It is reasonable to perform epidemiological studies to gain insight into whether human beings have suffered disease as a result of an agent whose danger was, in good faith, not initially appreciated by the party responsible for its dissemination. It would be quite a different matter, however, to simply presume that an agent has no long-term side effects, with that presumption tested only retrospectively, if at all, in naive and nonconsenting subjects. Such premeditated reliance on epidemiological studies to assess toxic effects is unethical because it amounts to using human beings as subjects in scientific experimentation without their informed consent. The applicable ethical principle is that of personal autonomy: each person possesses a set of individual rights, and among them is the right to determine how and in what manner one's own body will be used or employed. This principle should ordinarily exclude a purposeful reliance on epidemiological studies as the primary means for evaluating the risks due to toxic agents. Additionally, it is obviously better to ascertain whether agents are harmful *before* human beings suffer and die as a result of exposure to the agents. Thus, (1) use of animals is the ethically preferable method for generating scientific knowledge pertinent to toxic tort cases, and (2) the animal studies ought to be performed *prior* to use of the toxic agent.

If animal studies showed that a disease similar to the plaintiff's disease occurred in the test animals, the data would obviously be directly probative of the principal inductive opinion "X can cause Y." Unfortunately, the animal version of a corresponding human disease is rarely a suitable observational endpoint because of time and cost considerations associated with animal studies.[113] Consequently, although animal studies constitute the bulk of scientific research performed for the purpose of evaluating health risks, only a tiny portion of animal research is directly aimed at producing disease states in animals. Thus, scientific knowledge from animal studies is normally used *indirectly* to evaluate the correctness of the inductive inference.[114]

Frequently, the role of environmental factors in causing human disease is first discovered through epidemiological studies. The links between cigarette smoking and cancer, asbestos and cancer, and Agent Orange and certain skin diseases were all inferred from an analysis of disease patterns in exposed subjects. If an expert's principal inductive opinion cannot be sustained on the basis of animal studies, it should be based on epidemiological studies. Further, if the peer-reviewed scientific literature contains both animal and human studies, the expert must demonstrate that both kinds of studies have been considered and that the inferences independently derived from each type of study are consistent. Any apparent conflict must be resolved before the expert's overall conclusion can be accepted by the trier of fact.

The defendant's expert carries a similar burden in situations in which there exist relevant data from both animal and epidemiological studies. In other words, if the defendant's expert is to sustain an opinion that "X can cause Y" is untrue or unproven, he must do so based on all, not part, of the evidence. For example, in a trial involving the issue of whether electromagnetic fields from powerlines can cause cancer, the power company presented an expert who testified that the principal inductive opinion was untrue based on animal studies.[115] A second expert reached a similar conclusion, based solely on an analysis of the epidemiological studies.[116] In closing arguments, counsel for

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113. For the same reasons, animal studies often employ high doses, as compared with human exposure to determine whether the agent could have *any* effect on human beings.

114. Biological effects in test animals are probative with regard to the principal inductive opinion because all disease-causing agents cause biological changes that do not themselves indicate the presence of cancer. It could be reasoned that, because the putative toxic agent was capable of causing various immunological, hematological, endocrine, and other types of changes in test animals, and since such changes are the prius of the cancerous state, the animal studies are probative with regard to the expert's principal inductive opinion. If the law is to permit the use of animal research in toxic tort cases, it must sanction scientific reasoning from biological effects produced in animals that are something other than the type of disease manifested by the plaintiff.

115. Zappavigna v. New York, Claim No. 74085, at 80 (N.Y. Ct. Cl. 1988) (testimony of Richard Bockman, Oct. 11, 1988) (stating that powerlines are safe based on animal studies) (unreported).

116. *Id.* at 5 (testimony of Margaret Tucker, Oct. 13, 1988) (powerlines are safe based on epidemiological studies).

the power company asserted that since neither the animal nor the epidemiological studies supported the plaintiff's principal inductive opinion, it was untrue or at least not proven to be true to an acceptable degree of certainty.[117] It is improper, however, for an expert to opine regarding the truth of a proposition without considering all of the available relevant data. Even if the defendant's first expert could explain away the animal studies, his conclusion would be improper in the absence of a simultaneous consideration of the human studies because that data could cure or overcome the perceived shortcomings in the animal data. A similar point can be made regarding the testimony of the defendant's second expert. The conjunction of the experts' testimony does not cure the defect inherent in each expert's reasoning.

The expert's reasoning regarding the truth or falsity of "X can cause Y" can be further assessed from the perspective of its implications. For example, consider a claim that Bendectin can cause birth defects. Animal studies have shown that Bendectin can cause various physiological changes. Based partially upon evidence of these changes, the drug was claimed to be beneficial for treatment of morning sickness and approved for sale by the FDA.[118] The drug company's experts applied scientific principles of reasoning to extrapolate animal data to human subjects and motivated the FDA to infer a benefit to humans.[119] Thus, an expert may undercut his credibility if he argues that some animal studies cannot be interpreted or extrapolated to human subjects so as to indicate human *risk*, when he or his client have extrapolated animal studies to human subjects to rationalize a conclusion of human *benefit*. There is only one set of scientific rules governing the application of animal data to humans, and it is not dependent upon the result of the inference—whether it portends good or harm for human beings.

The trier of fact, particularly when properly assisted by counsel, can also evaluate the trustworthiness of an expert's reasoning process by considering the expert's nature and degree of advocacy. It is natural for an expert to display conviction, interest, and even passion regarding the various scientific studies he discusses, because the proper expert will be a person who has devoted a significant portion of professional time and effort to the subject of the testimony. In the process, the expert may, understandably, have developed subjective feelings regarding his testimony's importance, but an expert who functions as an advocate, by emphasizing the evidence that supports his opinion and de-emphasizing data that suggests a contrary inference, fails in his basic responsibility—to teach the trier of fact the meaning of the applicable corpus of scientific knowledge.

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117. *Id.*

118. See *supra* note 61 and accompanying text for a description of the approval process.

119. The same scientific rules of interpretation and extrapolation apply to other animal studies to determine whether an inference of *harm*, under other circumstances, is warranted.

For example, in a hearing regarding the safety of high-voltage powerlines, a power company expert testified regarding the implications of a scientific study, authored by Dr. Good, with regard to the possibility that electromagnetic fields can be hazardous. Dr. Good's report described an effect on cells caused by electromagnetic fields, thereby suggesting that similarly exposed human subjects might also be affected. Initially, the expert believed the fields Dr. Good used were different from those produced by powerlines, and consequently concluded the study results had no implications regarding possible risks from powerline fields. The expert also testified that Dr. Good's study was excellent. Following extensive cross-examination, however, the expert was forced to agree with the cross-examiner that the two fields were essentially comparable. This being the case, the cross-examiner suggested that Dr. Good's study indicated that powerline fields were a human health risk. The expert then changed his previous testimony and said that Dr. Good's study was inferior and of no scientific use.[120]

Unfortunately for the trier of fact, there are many shades and styles of scientific advocacy, and they are usually less obvious than that of the witness in the previous example. Furthermore, scientific advocacy may involve concepts that are pertinent to only one form of toxic agent and not to another.[121] Consequently, a high degree of vigilance on the part of the opposing counsel is required with regard to each step in the expert's chain of reasoning.

Attention to the structure of the expert's chain of reasoning may reveal the tacit incorporation of assumptions that could sustain the expert's opinion if true, but that are in fact false or unproven. One example is the implicit assumption that "X can cause Y" is true only if all or a majority of the pertinent animal and human studies were positive. For example, in a case in which the plaintiffs sought an injunction to overturn a school board requirement that their children must attend a neighborhood school that had been constructed next to a high-voltage powerline, the expert for the power company testified that some studies of the association between electromagnetic fields and cancer were positive and others negative. According to the expert, in the face of this conflicting evidence, it would be untrue to say that powerlines can cause

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120. Minutes of Public Hearing from Public Service Comm'n of New York, Common Record Hearing on the Health and Safety of 765 kV Transmission Lines, Cases 26529 & 26559, at 5921 (Apr. 28, 1976) (testimony of Morton Miller); *see also* MARINO & RAY, *supra* note 41, at 41.

121. The epidemiological studies linking cigarettes and cancer do not list the actual cigarette brands. The epidemiological studies linking electromagnetic fields and cancer do not (for the most part) identify the frequency of the field as being that of powerlines, broadcast towers, cellular telephones, or radar. It would be result-oriented advocacy to argue that only evidence that a specific brand, for instance Camels, or that a specific frequency, for instance radar, can cause cancer should be considered with regard to the link with cancer because there is no proper scientific basis for the distinction. Hutchison v. Kustom Signals, Inc., Civ. No. C91 1174 BAC (N.D. Cal. May 29, 1992) (deposition of Linda Erdreich, at 12) (arguing that only data from epidemiological studies of police radar guns (of which none exist) are relevant to the question whether they can cause cancer) (unreported).

cancer.[122] The fallacy of such an argument lies in the assumption that all or most of the pertinent studies must be positive to warrant acceptance of a causal relationship. As discussed above, a negative study does not mean "X can't cause Y," but rather that the investigator found insufficient evidence to support the truth of the proposition that "X can cause Y." If there is 1 positive study and 100 negative studies, and it is assumed that all 101 studies were done properly, the only correct inference would be that "X *can* cause Y." An expert who evaluates scientific studies on the basis of relative numbers signals to the trier of fact either a result-oriented or policy-driven analysis.[123]

Another style of faulty reasoning is the invocation of the necessity to know the mechanistic causes of disease. The expert who can delineate the specific causal chain by which a particular toxic agent produces disease would be a powerful witness, and the testimony would undoubtedly merit acceptance by the trier of fact. But no such witness exists with regard to any toxic agent. No witness, for example, can authoritatively opine as to which of the several thousand agents present in cigarette smoke causes cancer, how such agents enter a cell, are transported or cause other substances to be transported into the cell nucleus, or how any such nuclear substances interact with the cell's genetic material thereby resulting in genetic aberrations that manifest as cancer. Absence of knowledge regarding cellular or molecular mechanisms that give rise to carcinogenesis is irrelevant to the consideration whether a cause-and-effect relationship between a toxic agent and a disease actually exists. Consequently, it is specious scientific reasoning to urge that mechanistic understanding is a condition precedent to acceptance of the principal inductive opinion.[124]

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122. Rausch v. School Board of Palm Beach County, Civ. No. CL 8810772 AD (D. Fla. 1989) (testimony of Phillip Cole), *aff'd*, 582 So. 2d 631 (1991). For further details see Andrew A. Marino, *Negative Studies and Common Sense*, 8 J. BIOELECTRICITY v (1989). Courts have frequently relied on the volume of negative data to reject the existence of an asserted causal link. *See, e.g.*, Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 831 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1162 (D.C. Cir. 1990). *But see* Ongmore v. Merrell Dow Pharmaceuticals, Inc., 717 F. Supp. 1117, 1120 (D. Idaho 1990) (holding that the court's focus should not be on the number of negative studies but on the soundness of the methodology employed by plaintiff's expert).

123. *See* Kenneth R. Foster et al., *Science and the Toxic Tort*, 261 SCI. 1509 (1993). The authors argued that it would be unreasonable to conclude that video display terminals or Bendectin could cause disease because "the epidemiologic evidence regarding miscarriage and the use of video display terminals or birth defects and the morning sickness drug Bendectin includes a sprinkling of positive results in a body of overwhelmingly negative findings." *Id.* But overall conclusions cannot be reached simply by counting and classifying studies—the studies themselves must be considered. If there were only one positive study involving video display terminals, it would then be correct to conclude that they can cause disease. Suppose, further, the negative studies were performed by scientists working for the manufacturers of video display terminals. It would be a question of fact whether the studies could reasonably be relied upon. This example illustrates both the futility of an argument based on counting studies, and the excessive naivete inherent in the failure to consider the origins of the studies relied upon.

124. *See, e.g.*, Alabama Power Co. v. Western Pocahontas Props., No. CU88-676 (Ala. Cir. Ct. Apr. 17, 1992) (deposition of Mary Ellen O'Connor, at 213) (stating that knowledge of underlying mechanisms is required to show a causal relation between electromagnetic fields and health risks) (unreported).

C. Principal Deductive Opinion

In a toxic tort case, the plaintiff must prove by a preponderance of the evidence that he was actually exposed at a particular level or range of the toxic agent. This may necessitate a witness with technical expertise in the method of measurement or characterization of the toxic agent. For example, if the plaintiff alleged that his disease was caused by an electromagnetic field produced by a high-voltage powerline located near his home, it would be necessary to show the existence and amount of the electromagnetic field created by the powerline at the plaintiff's home, either by measurements or calculations. On the basis of lay testimony regarding the conditions of exposure to the toxic agent and expert testimony regarding pertinent characteristics and properties of the toxic agent, the expert must present a plausible model of the plaintiff's activities from which the actual amount and duration of the plaintiff's exposure to the toxic agent can be determined.

The expert must consider two distinct relationships involving the dose of the toxic agent the plaintiff received. The first involves the nexus between the levels of the toxic agent used in the pertinent scientific experiments and the dose the plaintiff actually received. Consider the case in which the scientific data linking the toxic agent and human disease were obtained using amounts of the agent that far exceeded the doses the plaintiff actually received. In such a case, the plaintiff's expert faces a heavy burden in rationalizing the application of the scientific data to the plaintiff's exposure because an agent that is harmful at high doses may not be harmful at low doses. Conversely, the defendant's expert's worst-case situation occurs when the dose of a toxic agent received by the plaintiff far exceeds the dose associated with adverse effects, as determined by the applicable human and animal studies.[125]

The second pertinent relationship the expert must consider is between the plaintiff's dose of the toxic agent and the dose routinely received by members of the public from sources for which the defendant has no responsibility. Irrespective of whether the toxic agent can cause the plaintiff's disease, it

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125. For some toxic agents, such as pesticides, human risks must be estimated from animal studies employing dosages that far exceed those ordinarily encountered in the environment because low-dose animal studies are incapable of yielding biological effects sufficient to be observable over a reasonable period of time. But other toxic agents produce biological effects at doses far less than those routinely present in the environment. For example, electromagnetic fields far weaker than those produced by ordinary powerlines altered calcium levels in animal brains, affected human body rhythms, human brain electrical activity, and increased the risk of childhood leukemia. *See* S.M. Bawin & W.R. Adey, *Sensitivity of Calcium Binding in Cerebral Tissue to Weak Environmental Electric Fields Oscillating at Low Frequency*, 73 PROC. NAT. ACAD. SCI. 1999 (1976); R. Wever, *The Effects of Electric Fields on Circadian Rhythms in Man*, 8 LIFE SCI. SPACE RES. 177 (1970); Glen Bell et al., *Human Sensitivity to Weak Magnetic Fields*, 338 LANCET 1521 (1991); Nancy Wertheimer & Ed Leeper, *Electrical Wiring Configurations and Childhood Cancer*, 109 AM. J. EPIDEMIOL. 273 (1979).

would be improper to hold the defendant liable for the plaintiff's disease if the public, including the plaintiff, experiences comparable exposure to the same agent from sources not controlled by the defendant.[126]

In a toxic tort case, the plaintiff ultimately must establish that exposure to the toxic agent was sufficient in the circumstances to bring about the plaintiff's disease. In other words, the plaintiff must establish that his disease would not have occurred when it did but for the dose of the agent he received. In this regard, the expert's *caused* opinion is similar to his *can cause* opinion, and it is similarly subject to inquiry regarding the matters that affected its formation.

If the expert demonstrates from an analysis of the scientific literature and the evidence presented in the case that: (1) the plaintiff's disease can be caused by the toxin; (2) the doses of the toxic agent used in scientific studies involving the agent were comparable to the dose the plaintiff actually received; and (3) the plaintiff was exposed at levels substantially in excess of those experienced by ordinary members of the public, then the necessary conditions for scientific deductive reasoning have been met. In the simplest case, the plaintiff would have been exposed to only one risk factor, namely the toxic agent for which the defendant was responsible, and the plaintiff would have had no exposure to other known or suspected risk factors. In that situation, the expert's principal deductive opinion—that the plaintiff's exposure caused his disease—could be based squarely on the presence of one, and only one, known risk factor for the disease. The logically compelling force of the deduction would be derived from the elimination of all other known causes. Conversely, if multiple risk factors were present, serious questions of fact regarding the apportionment of cause might be raised.[127]

The expert's reasoning that forms the principal deductive opinion is essentially identical to the reasoning process performed by experts more familiar at law, such as the expert who testifies in a medical malpractice case.

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126. For example, all members of the public are exposed to electromagnetic fields. Thus, the relationship between the level to which the plaintiff was exposed and the average exposure level experienced by the public is a consideration in a suit alleging injury due to field exposure. When the difference between the two is large, the possible causal role of background exposure can be rejected. *See, e.g.*, DONALD L. LAMBDIN, U.S. ENVTL. PROTECTION AGENCY, AN INVESTIGATION OF ENERGY DENSITIES IN THE VICINITY OF VEHICLES WITH MOBILE COMMUNICATIONS EQUIPMENT AND NEAR A HAND-HELD WALKIE TALKIE, ORP/EAD-79-2 (1979) (available from U.S. Environmental Protection Agency, Office of Radiation Programs, Electromagnetic Radiation Analysis Branch, P.O. Box 15027, Las Vegas, NV 89114); RICHARD A. TELL & EDWIN D. MANTIPLY, U.S. ENVTL. PROTECTION AGENCY, POPULATION EXPOSURE TO VHF AND UHF BROADCAST RADIATION IN THE UNITED STATES, ORP/EAD-78-5 (1978) (showing that a typical walkie-talkie or cellular telephone user is exposed to a dosage 100,000 times greater than background) (available from U.S. Environmental Protection Agency, Office of Radiation Programs, Electromagnetic Radiation Analysis Branch, P.O. Box 15027, Las Vegas, NV 89114).

127. For example, if the plaintiff lived beside a high-voltage powerline, operated a radar gun, smoked, had extensive exposure to diagnostic x-rays, and worked in the petrochemical industry, the resulting Gordian knot of toxic exposures might obscure the extent of legal liability of particular parties.

A medical expert testifies that the plaintiff's injury normally does not occur in the absence of a breach of due care. It is true, of course, that the plaintiff's injury could, in principle, result from many different causes, and it is theoretically possible that one or more of the other possible causes could have been operative in a given malpractice case, despite the absence of affirmative evidence thereof. The medical expert can only indicate that a cause sufficient in the circumstances to result in the plaintiff's injury was present, and that no other cause known to be sufficient in the circumstances was shown to be present. This fact pattern does not, of course, establish the truth of the medical expert's opinion beyond a reasonable doubt. It does, however, establish the truth of the opinion to the degree of certainty deemed by the law to be sufficient for the imposition of civil liability. In the proper toxic tort case involving an expert's testimony, both the procedure of the plaintiff's expert in forming his principal deductive opinion, and the law's rationale for accepting the form of the expert's analysis used by the plaintiff's expert, are essentially identical to the corresponding elements in the medical malpractice cause of action.

VIII. *DOE V. BLUE:* A HYPOTHETICAL TOXIC TORT CASE

John Doe wore blue socks daily for more than ten years, and then developed a melanoma skin cancer. He sued Blue Company, the manufacturer of blue dye #2, the dye used in the socks, claiming the dye caused his cancer. Doe obtained affidavits from two experts in support of his case, Bill Breakground and Donna Dyer.

Bill Breakground earned a Ph.D. in biochemistry and became an Assistant Professor in the Department of Toxicology at State University, where he taught biochemistry and toxicology, and conducted biological research on the effects of a class of organic chemicals, including blue dye #2. Breakground published prolifically, and consequently moved rapidly through the academic ranks to became a full professor at State University.

Animal research in the 1950s had shown that large quantities of chemicals similar to blue dye #2 produced convulsions, internal bleeding, and death from renal or cardiac failure within one to ten hours of administration. Breakground's research interest involved the effect of low doses of blue dye #2 over long time periods. His research goal was to determine the nature of the effeets produced, and the specific cellular and molecular mechanisms by which they occurred. Breakground received funding from two sources: a grant from the National Institute of Health to study basic mechanisms, and a contract with the Good Drug Company (GDC) to evaluate possible side effects.

GDC had been conducting in-house research to obtain data in support of an application to the FDA for permission to sell blue dye #2 as a food additive under the trade name Blutiful® for use in canned fruits and vegetables. The FDA had requested animal data to establish the safety of Blutiful's® proposed

use. State University and GDC entered into a contract providing for Breakground to be the principal investigator in animal studies of the effects of Blutiful®. The contract provided that Breakground would administer Blutiful® to rats throughout their two year lifetime, and conduct various tests to determine whether any side effects had developed. The dose level was chosen so that, on an equivalent weight basis, a human being could not acquire a comparable dose unless he ate 1,000 times more canned fruits and vegetables than the average consumer. GDC believed the data would show that the rats were unaffected by Blutiful®. The FDA had previously agreed that such a result would justify an inference of human safety for the company's contemplated use. Breakground's contract allowed him to freely publish study results thirty days after they were presented to GDC.

Ultimately Breakground found that chronic administration of Blutiful® to the animals resulted in kidney enlargement, decreased fertility, and an increased incidence of skin rashes. Breakground duly communicated the results to GDC, and subsequently submitted them for publication in a peer-reviewed journal. Breakground's results ultimately were published. In other publications, Breakground presented evidence suggesting the particular cellular pathways that mediated the observed effects. Other scientists, however, have published data implicating entirely different processes. Consequently, the issue remains unsettled.

Doe's other expert, Donna Dyer, was the acknowledged world expert on the structure and chemical properties of blue dye #2. During a field trip to the Brazilian rain forests, Dyer found plants that had blue flowers. She took specimens back to her laboratory, extracted the coloring agent, and in a painstaking series of studies, determined its exact chemical composition and atomic structure. Thereafter, Blue Company, the defendant, used genetic engineering to create a strain of bacteria capable of producing unlimited quantities of the agent, which became known as blue dye #2, for sale to the textile industry.

Blue Company obtained affidavits in support of its position from two medical doctors, Gene Causitall and Harriet Healer, and from an epidemiologist, Frank Findit. Causitall did an internship and residency in internal medicine at a prestigious eastern university, took a fellowship training in medical oncology,[128] and ultimately became Board certified in both internal medicine and medical oncology. Causitall joined the University Medical School as a faculty member in the Department of Medicine, Section of Oncology, where he became professor and head of the Section of Medical Oncology. Causitall routinely treats patients with a variety of different kinds of cancer, including melanoma. Causitall also heads an extensive research effort aimed at understanding the molecular basis of cancer. His hypothesis is

128. Oncology is the treatment of various forms of cancer using drugs.

that cancer is caused by a particular gene carried by viruses. Causitall's research has led to many peer-reviewed publications involving cellular and animal studies of the putative oncogene.

Harriet Healer operates a private clinic specializing in the diagnosis and treatment of melanoma. Patients are referred to her for treatment from all over the United States and abroad. Healer uses a variety of combinations of accepted treatments for melanoma, in an attempt to improve the five-year survival rate which, unfortunately, is still quite low.

Frank Findit is chairman of the Department of Epidemiology at State University. Findit wrote a textbook on epidemiology and has published more than 100 epidemiological studies, including studies of the relationship between cigarette smoking and heart disease, asbestos and lung disease, and agricultural pesticides and cancer in farm workers.

After submitting the experts' affidavits, Blue Company moved to strike the testimony of Breakground and Dyer because they were unqualified to offer medical testimony. Blue Company also moved to dismiss the suit because the theory that blue dye #2 can cause cancer is not generally accepted. Doe opposed the motions. In addition, Doe moved to limit Healer's testimony to the diagnosis and treatment of melanoma and to medical matters involving Doe's medical condition, and to exclude her testimony dealing with causation of cancer. Doe also moved to limit Findit's testimony to epidemiological studies and the inferences reasonably based thereon, and to exclude any testimony from Findit involving animal studies. In his deposition, Findit cited reports of various blue-ribbon committees to support his conclusions. Doe moved to exclude the use of these reports except for purposes of impeachment.

Judge Learned was called on to resolve the issues, and he ruled as follows:

> The disputes regarding the experts' qualifications will be considered first. The issue presented by a motion to exclude an expert witness for lack of qualifications is not whether the proffered witness is the best imaginable, the best available, or one of the most knowledgeable. Rather, it is whether the witness is minimally qualified to offer the testimony. Dr. Breakground was formally trained in the scientific methods and procedures for inferring causal relationships, and the many scientific studies he has published in peer-reviewed literature provide evidence of a proficiency regarding that process. Further, Breakground has many years' experience studying the biological effects of blue dye #2 and related chemical compounds and has, himself, contributed to that area of science. Since he has measured, administered, and controlled the application of blue dye #2 in scientific studies, there exists a reasonable indication that he can evaluate the dose aspects of the application and administration of the dye by others. Dr. Breakground is therefore qualified to offer testimony regarding the implications of the scientific literature with regard to the biological effects of blue dye #2, including its alleged causal role in the development of plaintiff's cancer.
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> Dr. Dyer is not qualified to offer opinion testimony regarding the biological effects of blue dye #2 because her expertise is limited to measuring, characterizing, and elaborating the structure and nature of blue dye #2 in relationship to other chemical compounds. She has not conducted studies to ascertain what

effects might reasonably be expected from the dye when it is introduced into the body of animal or human subjects. As an expert on the chemical properties of blue dye #2, however, the court will permit testimony from Dr. Dyer regarding non-causal issues that may be relevant, such as the solubility of blue dye #2 in weak salt solutions which, the plaintiff alleges is important to an understanding of how the dye in plaintiff's socks actually entered plaintiff's body through his sweat. Thus, the court will accept Dyer as an expert on the chemical properties of blue dye #2 and her testimony will be limited to that topic.

Dr. Causitall was trained as a physician, but thereafter acquired the skills and abilities of a scientist as demonstrated by his many contributions to the scientific literature dealing with the role of genes in causing cancer. It is not possible to determine, prior to trial, the extent of Dr. Causitall's experience with regard to chemical cancer-causing agents in general, or blue dye #2 in particular, but those matters will be resolved during the trial and will bear directly on the weight to be afforded his testimony. As a practicing scientist with a demonstrated history of knowledge of factors that can cause cancer, Dr. Causitall has at least the minimal qualifications required of a causal expert in this case.

Dr. Healer's background gives no indication of training or experience in scientific principles and practices. While the court recognizes her superior clinical skills in the diagnosis and treatment of melanoma, the existence of those skills does not imply knowledge regarding the proper manner for inferring the cancer-causing potential of a putative carcinogen from the pertinent scientific studies. It is common knowledge among oncologists that certain agents are carcinogenic. If this case involved such an agent, the court might indeed find Healer's opinions helpful. The knowledge with respect to cancer causation that is required in this case, however, is not commonly known among oncologists. This knowledge must be inferred from the scientific data, and Dr. Healer has not shown that she possesses the requisite skill to do so. Consequently, Dr. Healer's testimony shall be limited to issues that may arise involving the diagnosis and treatment of melanoma, and to medical opinions regarding plaintiff's diagnosis or prognosis.

Dr. Findit is a trained and experienced expert in performing and evaluating human studies involving the possible association of various environmental factors and diseases. He is, consequently, qualified to offer opinions concerning the implications of the human studies involving blue dye #2 with respect to its association with cancer. While the record does not reveal the extent of Dr. Findit's knowledge concerning dosimetry of chemicals in general, or blue dye #2 in particular, it will be the responsibility of the trier of fact to determine whether his knowledge in this area is sufficient to form a reasonable basis for evaluating the various studies. Dr. Findit, however, has had no experience performing laboratory studies involving animals, and thus there is no basis for the court to accept him as an expert in evaluating animal studies with regard to cause-and-effect relationships, or with regard to the implications they may have for the cancer-causing capability of blue dye #2.. Consequently, Dr. Findit's testimony will be restricted to an evaluation of the human studies, and the jury will determine whether it is reasonable to base conclusions solely on such studies.

The Court will now consider the reliability of the proffered testimony. Before doing so, however, the court will directly address the defendant's argument that the appropriate place to decide scientific issues is in the laboratory, not the courtroom. This court agrees with this view, provided the issues are such that it is appropriate that they be decided in the laboratory. The issues in this case, especially the question whether blue dye #2 can cause cancer, will be resolved according to the standards of certainty and concepts of causality that are routinely followed in the law. The law does not require near certainty, or clear and compelling evidence, prior to assessing liability or reaching other final determinations that affect the rights and relationships between individuals.

It is true the scientific community may find little value in this court's decision regarding the role of blue dye #2 in causing cancer because of the court's failure to apply what science might consider to be the applicable standard for a scientific decision. Nevertheless, it is similarly true that this court would not be bound or guided by any purely scientific decision against the possible causal role of blue dye #2 because the scientific standard for certitude far exceeds that of the law in civil cases. The court concludes, therefore, that its consideration regarding whether blue dye #2 can cause cancer as determined by a preponderance of the evidence is not a purely scientific issue that must be decided in the laboratory. Rather, it is a legal question and therefore appropriate for consideration in the courtroom.

Dr. Breakground's affidavit described ten animal studies published in the peer-reviewed scientific literature, including two studies that he performed, which showed a variety of biological effects in animals that had been exposed to blue dye #2. In the studies, which were performed on rats, mice, and rabbits, weak solutions of the dye were applied daily to the skin on the leg or the back of the animals. The animals were then killed at various intervals to obtain tissue specimens to evaluate the effect of chronic administration of the dye; the experiments lasted one year in the rats and mice, and two years in the rabbits.[129] None of the animal studies actually showed that blue dye #2 increased the rate of cancer in the exposed animals, but the studies did reveal a variety of adverse effects[130] in the animals, thereby providing a reasonable basis to conclude that the dye was potentially hazardous. Since such studies are frequently performed to establish the safety of an agent by the process of inference from negative study results, it must also be valid to make a contrary inference when positive results of a certain type are found—otherwise, there would be no reason to perform the studies in the first instance.

Dr. Breakground also cited ten epidemiological studies, including two that he co-authored, involving the occurrence of cancer among workers in the chemical dye industry, and among residents who lived in neighborhoods near factories that manufacture chemical dyes. Two of the studies reported a statistical association between workers who manufactured blue dye #1 and leukemia, and another study found an association between red dye #1 and brain cancer; both dyes were similar in chemical composition, though not identical, to blue dye #2. In addition, three studies Dr. Breakground cited showed an association between cancer, regardless of type, and living near chemical dye factories. Four studies were performed on workers in the textile industry who routinely handled cloth that was colored with blue dye #2. In three of these studies, significantly increased rates of cancer of the eye, brain, breast, and colon were observed, however, a consistent elevation in each type of cancer, considered alone, was not observed. None of the ten studies specifically involved the relationship between blue dye #2 and melanoma. Dr. Break-

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129. Although the studies' durations were short compared with typical human lifetimes, the affiant states that since they represent typical lifetimes for the respective species, they are comparable to human lifetimes. In other words, exposure for one year in rodents or two years in rabbits is equivalent to lifetime exposure in human beings.

130. The studies performed on the tissues of the exposed animals were highly technical in nature. For example, they included measurement of the amount of acetylcholine released at the neuromuscular junction, and the blood and tissue levels of various substances termed "cytokines." Apparently, normal levels for the different parameters have been established, and although it is possible to assess whether deviations from normal have occurred, frequently it is not possible to objectively characterize the change as good or bad—only that it differs from the norm. Since blue dye #2 is not supposed to produce any biological changes in the person wearing socks that were colored with the dye, any change that it does produce must be presumed to be adverse. Therefore any predicate changes in the animals must also be viewed as being adverse.

ground concluded the animal and human studies, taken together, showed that blue dye #2 could cause cancer in human beings.

Dr. Dyer performed calculations based on the established chemical properties of blue dye #2, the average number of hours per day plaintiff's feet were in contact with the blue socks, the number of years he wore blue socks, the change in concentration of the blue dye in the socks depending on the number of times they were washed, the salt content of human sweat, and other pertinent factors. Dr. Dyer concluded that the dose of blue dye #2 plaintiff experienced was one microgram per day throughout the ten year period between the time he started wearing blue socks and the diagnosis of his melanoma. Dr. Breakground compared this value with the dose of blue dye #2 employed in the animal studies and the estimated amount of chemical dye inhaled by residents near the dye factories in the epidemiological studies in forming his opinion that blue dye #2 caused plaintiff's cancer.

Dr. Causitall was unimpressed with the published studies involving the biological effects of blue dye #2. He said that several of the animal studies were seriously flawed in the way they were conducted, and in other cases the changes produced were small, and could therefore easily be handled by the body with no adverse effects. Consequently, Dr. Causitall did not believe these studies warranted an inference that similarly exposed humans would be at any kind of a risk. Dr. Causitall deferred to Dr. Findit's evaluation of the epidemiological studies, but agreed with him regarding the overall inconclusiveness of the human studies. Dr. Causitall also listed seven animal studies funded by Blue Company that failed to find any effects of blue dye #2. Dr. Causitall concluded that since there were almost as many negative studies as positive studies, it would be unreasonable to conclude that the evidence showed the dye could be a health risk.

Dr. Causitall pointed approvingly to a report by the state health department which concluded that health risks due to dye that escaped from dye factories had not been conclusively proven. Dr. Causitall also cited to the results of an analysis by a panel of the American Association of Specialists in Toxicology that studied the health-risk issue associated with chemical dyes and concluded that there was no convincing evidence that dyes constituted a human health risk. Dr. Causitall concluded that, despite the concerted effort made to uncover any health hazards from blue dye #2, no clear evidence that such hazards actually exist had been discovered. Thus, Dr. Causitall inferred that there are no health risks and that blue dye #2 is safe, as was concluded by the various authoritative groups that considered the issue.

The defendant's motion to dismiss, if granted, would be a substantive determination of plaintiff's rights because if it were true that the scientific evidence were unreliable when offered by Dr. Breakground, a qualified expert, it would be unreliable when offered by any other expert. Since evidence concerning scientific causality can only be presented by an expert, plaintiff would effectively be precluded from obtaining his day in court. Consequently, the motion to dismiss will be treated as a motion for summary judgment, and the disputed items of fact will be viewed in favor of plaintiff.

The seminal issue is whether the proposition that blue dye #2 can cause cancer is true, or can reasonably be said to be true, based on the available scientific evidence. By "cause," the court means that a population exposed to blue dye #2 will show a greater incidence of cancer than the same population would have shown in the absence of the added dye.[131] Regardless of education or respect in one's field, persons may not offer expert testimony in the courts of

131. *See* Ayers v. Township of Jackson, 525 A.2d 287, 301-02 (N.J. 1987) (defining "cause" in relation to cancer).

this state unless they possess knowledge of the type needed in the case. Scientific experts must possess scientific knowledge, which is that material and information contained in the scientific journals and publications that are traditionally used to disseminate and memorialize such information. Breakground cited ten animal studies and ten human studies upon which he based his opinion that the dye can be carcinogenic in human beings. Dr. Causitall appears to conclude that blue dye #2 does not cause cancer in human beings, whereas Dr. Findit says that there is not enough evidence to support Dr. Breakground's position, and thus does not agree that blue dye #2 can cause cancer. The methods and procedure followed by Dr. Breakground in reaching his conclusion were in accordance with those normally followed in determining whether any particular factor can be responsible for producing biological changes. Dr. Breakground relied on animal and human studies that were published in the peer-reviewed literature and which, therefore, can properly be viewed by the expert and this court as evidence of the truth of what they purport to show. Thus, Dr. Breakground can properly employ these studies to form inductive inferences. Drs. Causitall and Findit disagree with Dr. Breakground regarding the scientific integrity of some of the studies, but until these witnesses are subjected to cross-examination, it will not be possible to determine which view of the studies is correct.

Drs. Causitall and Findit cited many negative studies in support of their position. Since negative studies can be probative, depending on other studies that may also exist, some concern is raised by Dr. Breakground's failure to discuss the negative studies. On the other hand, neither of the defendant's experts raised a negative study in the context of directly opposing or invalidating an inference that could otherwise be drawn from any particular positive study. Thus, it appears the negative studies cited by the defendant's experts were performed under conditions and circumstances that differed materially from those attendant the positive scientific studies. Consequently, it is possible that all the positive studies cited by plaintiff and all of the negative studies cited by the defendant are scientifically valid. If so, it would follow that the negative studies were simply not probative with regard to plaintiff's inductive inference that blue dye #2 can cause cancer. Again, these are factual matters that can be resolved only upon trial.

The court has carefully considered the report by the state health department upon which Dr. Findit relies. The court is sensitive to defense counsel's argument that the state health department contains experts in the fields of epidemiology and public health, among other scientific disciplines. The health department is therefore in a position superior to that of the court with respect to determining whether blue dye #2 can cause cancer. The argument of counsel is, however, not persuasive because both the goal and the methods of the health department are far different than those of this court. The health department must consider both the scientific evidence regarding risk and the financial burdens that might result from any decision before it makes a finding that might involve remedial action resulting in great costs, or that could lead to apprehension and concern by the public of possible health hazards. Such a risk-benefit analysis is a fundamental part of the evaluation of the health hazards of a toxic agent by a state agency. But it is not pertinent to the issue in this case whether blue dye #2 can cause cancer. That issue must be decided solely on the basis of scientific knowledge.

The health department report is also inadmissible as evidence of the truth of what it says because its authors cannot be cross-examined. Although the report was jointly written by five staff scientists, it was adopted and issued by the health department, and is therefore an official report of the health department. The officials who speak for the department are appointed by the governor, and they cannot be required to explain and defend their discretionary acts. The department staff persons who drafted the report cannot speak for the depart-

ment. Therefore, whatever value the health department report might have in other forums, it is not admissible in court as evidence of the truth of the facts it recites. It should be noted that the defendant is free to present one or more of the authors of the report in their private capacity, and through them place into evidence the scientific knowledge upon which the conclusions of the report are based.

Dr. Findit also relied on a report by a blue-ribbon panel of professional toxicologists. The court has no way of evaluating the basis upon which the experts reached their opinion, the fidelity of Dr. Findit's description and characterization of the panel's report, or the extent to which the panel members may have been affected by bias arising from consulting and other financial relationships between one or more of the panel experts and the defendant in this case. If the defendant believes the committee's report contains information relevant to this case, the proper way to introduce it would be for the defendant to call one or more of the experts from the committee and elicit the requisite testimony. It is not the committee report that is relevant to this case, but rather the scientific knowledge that was relied upon in forming the conclusions reached in the report, and the methods by which the conclusions were reached.

The issue of potential bias among scientists is important, and must be specifically addressed during trial. If, as plaintiff alleges, several of the studies upon which the defendant relies were designed and controlled by the defendant, the jury would be justified in discounting the data obtained from them. For each study that forms an important part of the basis of any expert's conclusion, an inquiry regarding how that data was obtained must be made, and a determination reached regarding whether the data was produced by one of the parties in contemplation of litigation.

Many factual issues remain to be resolved, and plaintiff is entitled to a favorable view of the disputed facts under a motion for summary judgment. Since numerous supportive scientific studies have been cited by plaintiff, the court concludes that it is reasonably possible that blue dye #2 can cause cancer.

Plaintiff's witness, Dr. Dyer, concluded that plaintiff received a specific amount of blue dye #2 into his body as a consequence of the prolonged direct contact between the dyed material and his skin. Dr. Breakground testified that the dose level calculated by Dr. Dyer was equal to or greater than the dose levels employed in most of the scientific studies upon which he relied, and that members of the public ordinarily do not receive doses of blue dye #2 as great as that said to have been received by plaintiff. Dr. Findit disputes both the dose level received by plaintiff and the doses received by ordinary persons who do not develop cancer, and these issues must be resolved at trial, where the assertions of various experts can be tested upon cross-examination. Also to be considered at the trial is the issue of the presence of any confounding factors with regard to the cause of plaintiff's cancer. For plaintiff to validly conclude that his cancer was caused by blue dye #2, the possible role of other known cancer-causing factors must be eliminated because plaintiff's rationale is based on a process of elimination of other possible causes. The proper forum for evaluation of these matters, however, is at trial, and not on a motion for summary judgment. The defendant's motion, therefore, is overruled.

Based on these various considerations, Judge Learned denied the motion for summary judgment and issued an order limiting the testimony of the witnesses and the use of various reports in accordance with the findings recited in his opinion.

IX. CONCLUSION

The requisite evidence in a toxic tort case regarding causation consists of scientific knowledge, which is the collective result of individual scientific experiments as memorialized in peer-reviewed scientific journals and other appropriate written repositories, and appropriate inductive generalizations and deductive inferences. In contrast to what is true of individual scientific studies, the degree of certainty of an inductive inference based on the studies cannot be stated in mathematical terms because it is a judgment. Thus, the inference that "cigarette smoking causes cancer" cannot be stated with numerical precision, although the results of particular experiments involving animals or human subjects exposed to cigarette smoke under particular conditions can and must be quantified to constitute part of the corpus of scientific knowledge.

The expert must possess training and experience sufficient to enable him to analyze and explain the laboratory and epidemiological studies pertinent to the effects of the toxic agent on cells, animals, and human beings. The training ordinarily expected of such an expert includes a Doctor of Philosophy degree in science, because it is evidence that the witness received the highest level of formal training in scientific methodology and reasoning. Scientific expertise is best evidenced by performance of experiments involving the toxic agent and subsequent publication of the results in the scientific literature. If the witness earned a Ph.D. in science and performed many experiments and published many scientific articles involving the biological effects of the toxic agent involved in the case, the court would have a firm basis to regard the witness as qualified to offer opinions in the case.

The amount of the toxic agent present in particular scientific studies in relation to the amount actually received by plaintiff is always a fundamental issue regarding whether the toxic agent caused plaintiff's disease. Thus, the expert's training and experience must also include knowledge of the laws or principles that govern the dosimetry of the toxic agent.

Unlike the physician or the technical expert, who is permitted to testify on the basis of professional status and anecdotal evidence, the toxic tort expert must testify on the basis of scientific knowledge. Consequently, there cannot be a scientific expert in the absence of scientific knowledge. The customary process for evaluating the validity of scientific knowledge is peer review, whereby anonymous peers judge the merits of scientific experiments or studies and the results are offered for publication. The peer-review process does not attempt to establish whether the results are the product of good science or bad science. Peer review is not a litmus test for truth, validity, or general acceptance. Rather, it is the standard assessment procedure that precedes the addition of a particular study to the corpus of scientific knowledge. The expert in a toxic tort case should ordinarily rely on peer-reviewed reports to perform analyses and reach conclusions.

Peer review is an indication of the acceptability of a scientific report with regard to its *intrinsic* validity. A further question extends to the *extrinsic* validity of a scientific study designed, conducted, or otherwise influenced by one of the parties in the litigation, or by someone in privity with these parties. An expert witness who chooses to rely upon particular scientific reports, therefore, has a responsibility to make a reasonable effort to establish their extrinsic validity. The court, opposing counsel, and the jury should also consider the extrinsic validity of the reports relied upon by the expert when determining whether the expert's testimony is admissible, or how it should be weighed.

Blue-ribbon committees should enjoy no presumption regarding the qualifications or validity of their work product because both the membership and work product of such committees are invariably shaped by the appointing authority. The committee's decisions represent a consensus of the persons recognized as experts by the appointing authority, but those decisions bear no necessary relation to a consensus of all qualified experts. Consequently, the reports of blue-ribbon committees should not be admissible as evidence of the truth of the propositions they recite.

Scientific studies potentially available for consideration by the toxic tort expert are test-tube, animal, and epidemiological studies, and each has particular strengths and weaknesses. The scientifically and ethically preferable data is that obtained from animal studies. Although the expert must always consider the limitations of animal or test-tube studies with regard to inferring causal relationships in human subjects, it is unquestionably correct, under the proper circumstances, to use such data to form causal inferences.

The expert in a toxic tort case must rationalize an assertion that the plaintiff's dosage of the toxin and the plaintiff's disease were causally related, and not merely associated with each other. The expert cannot rely on personal observation as the basis of a cause-and-effect relationship because the onset of human disease in a particular person is simply not amenable to direct observation. Since an expert cannot rationalize a cause-and-effect relationship based on direct observation, the causal conclusion must be derived from scientific evidence, namely, an appropriate and reliable corpus of scientific data that permits the expert to infer what happened within the plaintiff's body as a consequence of exposure to the toxic agent.

The logic of scientific reasoning constrains the order in which the expert must approach a decision whether the plaintiff's exposure to the toxic agent and his subsequent disease were causally related or merely associated. The expert must first consider the pertinent laboratory and epidemiological studies, and determine whether the toxic agent caused the effects reported in the studies. Thus, the seminal question is whether the toxic agent *can cause* the plaintiff's disease, given the available information that characterizes the effects the agent is capable of causing. The expert's opinion must be based on the strength of the scientific studies. No causal assertion in science is certain, and

only some causal assertions can be expressed to a numerical degree of certainty with numerical precision. The *can cause* conclusion of the expert is not the result of a particular experiment, and therefore must be stated using qualitative terms such as "possible," "likely," or "nearly certain."

If the expert sustains the burden of showing that "X can cause Y," the question then arises whether the amount of toxic agent the plaintiff experienced probably caused his disease. The expert must show that the plaintiff's exposure to the toxic agent was greater than that ordinarily received by persons who do not develop the plaintiff's disease. Assuming the plaintiff was not exposed to any other agent that can also cause the plaintiff's disease, and that the plaintiff's exposure to the toxic agent occurred at high levels of the toxic agent, an expert could justifiably conclude that, although the possible causative role of unknown factors cannot be eliminated, the existence of only one known sufficient cause makes it likely that the single known risk factor present was the actual cause of the plaintiff's disease.

The court has a gatekeeping role regarding the admission of scientific evidence. Before the expert's conclusions may be presented to the trier of fact, the court must be satisfied that it is reasonably possible that the conclusions are true. In making its determination, the court's focus must be on the expert's decision making process. Was the conclusion based on controlled observations of nature published in the peer-reviewed scientific literature? Were the applicable principles of scientific inference properly applied to the scientific data? If the court answers both questions affirmatively, it is reasonably possible that the testimony is true, and therefore is reliable.

The scientific studies and reports that form the basis of the expert's opinion are exceptions to the hearsay rule as they relate to scientific data, but not as they relate to opinion. The scientific expert may not invoke the opinion of another scientist or a blue-ribbon committee, either in support of or in lieu of the expert's own analysis. The representations of opinions are not acceptable as a substantial part of the basis for an expert to testify for or against the truth of the proposition that "X can cause Y."

An expert in toxic tort cases carries a heavy burden. In the face of cross-examination and direct testimony by opposing witnesses, the expert must choose valid scientific data on which to rely, and form his principal inductive and deductive opinions thereon in a lucid and credible manner so as to be understood and believed by the lay trier of fact. It is unlikely that the trier of fact will be swayed by an expert who testifies in a manner that is inconsistent with the scientific facts when the adverse party is represented by able counsel.

X. GLOSSARY[132]

BELIEF: A psychological state regarding the truth or falsity of a proposition.

BIAS: In science, an undisclosed or unappreciated factor that was, in fact, partly or wholly responsible for a particular observation.

BIOLOGICAL EVENT: An event, motion, or other property uniquely associated with living organisms. Self-initiated motion, wound repair, and food consumption are biological events. The motion of the moon around the earth, a chemical reaction, and the propagation of light are non-biological events.

BIOLOGICAL SCIENCES: The sciences that deal with living objects.

BLUE-RIBBON COMMITTEE: A group of scientists appointed by a public or private organization for the purpose of making scientific and value judgments regarding a matter of interest to the organization.

CAUSE: Generally, a relationship between a factor and an observation such that the observation would not have occurred when and how it did, but for the factor; a factor that influenced an event. In science: With respect to non-living objects, a necessary and sufficient condition for an observation. With respect to living objects, a sufficient but not necessary condition to modify an observation.

CONTRACT: A method for funding scientific research desired by the contracting party providing the funds, intended principally to provide knowledge pertinent to the aims of the funding party.

CONTROLLED OBSERVATION: Method applied to the study of living objects for the purpose of determining causal relations.

DEPENDENT VARIABLE: In a scientific study, the response parameter chosen for measurement. For example, in a study of the ability of asbestos particles to penetrate cell membranes, the amount of asbestos inside the cells is the dependent variable.

DISEASE: A pathological physiological state not attributable to trauma.

DOSIMETRY: The study of the amount (dose) of a toxic agent actually received by a subject under a specified set of conditions.

EFFECT: Correlative of *cause*; also called motion, event or observation. *Biological* effect, an effect manifested only by a living organism (e.g., disease); distinguished from *physical* effect, which can be manifested by any object (e.g., heat). *Acute* effect, an effect that occurs immediately after its cause (e.g.,

132. The definitions are not meant to be exhaustive, but rather to convey the essential notion that is denoted when the words are used in the text (unless the context obviously requires a different meaning).

death from a fatal gunshot); distinguished from *chronic* effect in which the cause, effect, or both are manifested over time (lung cancer from cigarettes).

EPIDEMIOLOGICAL STUDY: A scientific study usually involving human beings in which the investigator does not exert control over the application of the toxic agent to the study subjects. The three major types are case-control study, proportional mortality (or morbidity) study, and the standardized mortality (or morbidity) study.

EXPERT: A person having knowledge not ordinarily possessed by the layman.

EXPERT WITNESS: An expert in an area of interest to the court who is thereby permitted to offer opinions and make causal inferences to the trier of fact.

FACT WITNESS: One who testifies on the basis of sensory-derived knowledge pertinent to case-specific issues.

FORCE: A necessary and sufficient condition for motion. An entity postulated to exist for the purpose of rationalizing causal relationships. The four kinds recognized are the strong, weak, gravitational, and electromagnetic forces.

GRANT: A method for funding scientific research in which the aims and goals of the research are chosen by the scientist, and in which the granting organization's chief interest is in contributing to knowledge within the particular branch of science.

KNOWLEDGE: Justified belief in the truth of a statement. The three sources of knowledge are the senses, the intellect, and authority. *Sensory knowledge*: knowledge obtained directly and immediately through the senses. *Intellectual knowledge*, knowledge derived from the application of experience and understanding to sensory knowledge. *Authoritative knowledge*: a statement whose justification is provided by the source of the statement. *Scientific knowledge*: knowledge obtained from the application of the methods of science. *Anecdotal knowledge*: knowledge other than scientific, that is, knowledge based on observations, judgment, or authority, but not on a specific and reproducible set of experiences or observations.

NEGATIVE STUDY: A study in which the agent studied and the effect searched for could not be related to a statistical degree of certainty greater than ninety-five percent.

OPINION: A statement colorably sounding as intellectual knowledge which the speaker accepts as true (that is, sufficiently justified) but for which the speaker's rationale for truth is either not accepted or has not yet been accepted by the listener.

PARTISAN RESEARCH: A scientific study designed or controlled by a party having a proprietary interest in the outcome of the study.

PEER REVIEW: A procedure involving an editor of a scientific journal, an author of a scientific article, and a reviewer of the article chosen in secret by the editor, performed for the purpose of controlling the quality of specific additions to the corpus of scientific knowledge.

POSITIVE STUDY: A study in which the agent studied and the effect searched for were found to be associated to a statistical degree of certainty greater than ninety-five percent.

PRINCIPAL DEDUCTIVE OPINION: An assertion by an expert that plaintiff's disease was caused by exposure to the toxic agent (*"x caused y"*).

PRINCIPAL INDUCTIVE OPINION: An assertion by an expert that the toxic agent to which plaintiff was exposed can cause the type of disease manifested by plaintiff (*"X can cause Y"*).

REASON: A factor accepted as a justification for a subsequent observation.

RELIABILITY (of expert testimony): The minimal extent to which proffered testimony must be true as a matter of law before it can be evaluated by the trier of fact.

RISK FACTOR: A factor which, if present, renders a particular outcome more likely than would otherwise have been the case.

SCIENCE: A human activity that consists of making valid observations, inferring reasons for the observations, and offering mechanistic answers.

SYSTEMATIC VARIATION: The scientific method used to study nonliving objects for the purpose of inferring causal relationships.

TOXIC TORT: A cause of action that arises when the mechanism of the harm suffered by plaintiff is alleged to involve a long-term interaction between plaintiff's body and a physical or chemical agent produced by the defendant.

TRUTH (of a statement): Corresponding to, representing, or characterizing reality.

TRUSTWORTHINESS (of a statement): Meriting acceptance as likely being truthful.

VALIDITY (of expert testimony): Testimony made pursuant to the applicable scientific and legal principles.

VALIDITY (of a scientific study): A scientific study in which the inference of a cause-and-effect relationship was made pursuant to the applicable scientific and statistical principles normally applicable to scientific studies.

"x": A designation for a specific cause. One of the specific circumstances associated with an effect that is regarded as the cause of the effect in the totality of the circumstances. In a scientific study, "x" is the independent variable. In a toxic tort, "x" is the toxic exposure experienced by plaintiff.

"X": A designation for a general cause. For example, in "X can cause Y," "X" can be asbestos, chemical dyes, or electromagnetic fields.

"y": A designation for a specific effect. In a scientific study, "y" is the dependent variable. In a toxic tort, "y" is plaintiff's disease.

"Y": A designation for a general effect. For example, in "X can cause Y," "Y" can be pain, death, or cancer.

XI. APPENDIX

The Logical Structure of Scientific Studies Relevant to Toxic Tort Cases

Consider an analysis of the effect of breathing asbestos on the development of cancer in rats. A population of identical rats is randomly divided into two groups which are housed and fed in exactly the same manner, except one of the groups receives a predetermined amount of asbestos. The dose of asbestos constitutes the "x" in the putative causal statement "x caused y," and the percentage of animals that develop cancer is the "y." Since asbestos is not necessary for cancer to occur, some members of both groups are expected to develop the disease. The point of the experiment is to determine whether the cancer rate in the exposed group is higher than in the control group.

Suppose that after an observation period of two years, twenty percent of the asbestos-breathing animals and ten percent of the control rats developed cancer. It might seem proper to conclude that asbestos caused an increase in the incidence of cancer, but such a conclusion could not be justified (based on the hypothetical facts thus far given) over the conclusion that, despite the difference in percentages, reliable evidence of a causal relationship was not adduced. Why? Because it is possible that the dose of asbestos and the increased cancer rate were simultaneous but wholly independent events—like the relation between the length of women's skirts and the stock-market average. If the study were repeated, it is unlikely that the precise percentages observed in the first study would be found in the second study because it is a biological fact that groups of animals are inherently different despite all efforts to make them identical. Consequently, successive studies using different but nominally identical groups of animals are expected to yield a range of values. It is possible the group of rats used to form the control group naturally fell in the low part of the range, whereas the animals assigned to the asbestos group fell at the high end of the range. If so, natural biological variation accounted for the observed differences in percentages.

Statistical methods have been developed that permit an objective answer to the question whether the asbestos caused the difference in cancer rates. Some methods are preferable to others, depending on considerations such as

what was measured, how it was measured, and how much the data varied from animal to animal. The feature common to all the statistical methods is that they permit an objective answer to the question whether the apparent difference between an experimental and control group is real, and that answer can be expressed mathematically in the form of a probability.

An impossible event has a probability of zero, whereas an event that is certain is assigned a probability of one; all other possible outcomes have probabilities between these two extremes. The general convention in science (the standard used by most practicing experimental scientists and broadly enforced by journal editors and peer review panels of public and private granting and contracting agencies) is that if the calculated probability that the results are different is greater than .95, or ninety-five percent, they are then accepted as actually being different, absent a supervening consideration. Thus, if the calculated likelihood that the observed cancer rates in the asbestos study were different was greater than ninety-five percent, it would follow that asbestos *caused* the cancer as that concept is used in *science*. As a scientific statement, the phrase *caused the cancer* means that, to a certainty of greater than ninety-five, the observed difference in cancer rates would not have occurred but for the presence of the asbestos.[133]

The possibility of supervening factors in a biological experiment is termed *bias*, and may manifest itself as follows. Assume that the results of the statistical analysis of the asbestos study justified a statement of the form "x caused y," where "x" is the concentration of asbestos and "y" is the observed difference in cancer rates. The experimental and control groups were formed at the beginning of the experiment by randomly assigning animals to the respective groups. The purpose of the randomization was to insure that all factors actually or potentially pertinent to the development of cancer would be, on average, identical between the two groups and hence not a possible explanation for a subsequently observed intergroup difference. If this assumption is violated, the logical structure of the experiment is complicated because the investigator must now justify "x caused y" when "z caused y" (where "z" is the biasing factor) may be true, based on the experimental procedures followed. In general, if the groups differed with regard to any

133. This method of scientific decision-making is known as significance testing at the 95% level. Less frequently employed methods include the use of confidence intervals, meta-analysis, Bayesian analysis, and significance testing using levels less than 95%. Significance testing at the 95% level is the established and generally applicable norm for scientific reasoning in present-day science, but one or more of the various alternatives may be appropriate in particular cases. Courts have sometimes accepted alternatives to standard significance testing. *See* In re Paoli R Yard PCB Litig., 916 F.2d 829, 857 (3d Cir. 1990) (accepting testimony based on meta-analysis), *cert. denied*, 494 U.S. 1046 (1990); Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 311-12 (5th Cir. 1989) (accepting confidence-interval testing), *cert. denied*, 499 U.S. 961 (1991).

factor whatsoever, that difference could, in principle, serve as a supervening factor that destroys the logical structure of the inference "x caused y."[134]

In performing scientific studies, care is taken to avoid bias and thereby foster the situation drawing the inference of causation, the possible existence of which is actually the point of the study. But some bias exists in every experiment, and consequently it is always a matter of judgment whether that bias was causally related to the result observed. The biasing factors may be regarded as minor; for example, the asbestos rats were located on a different shelf than the control rats, and exposed to slightly different light levels. Alternatively, potential bias may be of greater concern; if, the asbestos rats were located closer to the door of the animal care facility where the average temperature was lower than the location of the control rats. If a strong biasing factor were present—for example, eighty percent of the asbestos rats but only ten percent of the control rats were males—the groups would be essentially non-comparable and the results of statistical testing would therefore be useless.

A criticism based on bias can be asserted against any controlled observation,[135] and evaluation of the potential role of the bias involves the exercise of judgment within the orthodox framework of the particular branch of science. The judgment regarding possible supervening bias is made first by the investigator conducting the study; thereafter, the question is further evaluated by other scientists, journal editors, peer review panels at government granting agencies such as the National Institutes of Health, and by other mechanisms that may be created by governmental or industrial entities that paid for the research.

Successful scientists develop powers of judgment regarding whether the costs involved in controlling specific factors are warranted in view of the aims of the particular study. For this reason, and because an investigator can exert great control over both environmental factors and experimental subjects, the question of bias in a laboratory study involving animals or human subjects is relatively rare. However, there are biological studies, called *epidemiological studies*, in which bias is common because the experimental and control groups

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134. There are many possibilities in a scientific study for bias to occur, even when it would not be reasonable to expect that a prudent scientist would have recognized the problem initially and changed the procedure to eliminate it. Thus, scientific bias may involve a kind of negligence, but it does not involve intent. Intentional bias, in contrast, is a species of fraud; it is an attempt to shape the inference of a study so that some desired conclusion is reached, irrespective of that which naturally flows from the data. Suppose, for example, an investigator conducted two experiments, one of which supported a particular hypothesis and one of which did not. If the results of only the first were disseminated, the inference drawn within the scientific community would be quite different than if both studies were published. This discussion focuses solely on scientific bias.

135. This is similar to the process of distinguishing prior cases in law that are apparently similar to the case at bar. There are nearly always differences that may arguably justify or require a contrary view.

almost certainly differ with regard to characteristics other than those chosen for study.

In an epidemiological study,[136] the investigator does not exert control over the experimental subjects. Instead, the subjects either intentionally or inadvertently apply the potentially toxic agent to themselves. The amount of exposure the subjects receive is usually assessed indirectly based on job categories or place of residence because it is impractical or impossible to actually measure exposure levels for each subject.

Epidemiological studies have the advantage of providing scientific data about the effects of toxic agents on human beings, as opposed to laboratory animals. Consequently, the information obtained from epidemiological studies is directly relevant to toxic tort cases because there is no need for extrapolation. On the other hand, the omnipresence of bias in epidemiological studies complicates the interpretation of epidemiological studies, and renders it improper to use data from a single study to justify a causal assertion.[137] For these reasons, the statistical link between "x" and "y" in an epidemiological

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136. Three types of epidemiological studies are important for toxic tort cases. In a *case-control* study, subjects having the disease chosen for study are identified, and the proportion of the diseased subjects that were exposed to the toxic agent is determined. A control group is chosen (some of whom, unknown to the investigator, may also have been exposed to the toxic agent), and the proportions of exposed subjects in the two groups are compared to determine whether those who had the disease were more likely to have had exposure to the toxic agent. If the control subjects were disease-free, then the hypothesis tested when the data was subjected to the appropriate statistical test would be whether exposure was more likely among diseased subjects compared with healthy subjects; thus, the tendency of the toxic agent to cause disease in healthy subjects — which is the basic issue of concern — would be assessable. If the study subjects had a particular disease, such as leukemia, and the control subjects had non-leukemia cancer, then the hypothesis actually tested would be whether exposure was more likely among leukemia subjects compared with subjects having other forms of cancer.

A *proportional mortality* (or *morbidity*) study (PMR) permits a determination of whether a particular disease was more likely among dead exposed subjects, than among dead subjects generally. Since a PMR study includes only dead subjects, and not subjects who were at risk of dying, no direct inferences are possible regarding similarly exposed but healthy subjects. A single PMR study is therefore capable of justifying only the conclusion that an association between a toxic agent and a disease was stronger than the association between the agent and other diseases. The *standardized mortality* (or *morbidity*) study (SMR) is a third practical design. Subjects exposed to a toxic agent are identified and the proportion that developed a particular disease is determined. Comparison with the corresponding proportion in the control group permits assessment of whether the disease was more likely among the exposed subjects. Unfortunately, an unascertained number of subjects in the control group usually will also have been exposed to the toxic agent, and those subjects might contribute disproportionately to the fraction of the control group that develop disease, thereby complicating interpretation of the results. The inherent limitations of PMR and SMR studies render them less useful than case-control studies for evaluating risks of toxic agents; their major advantage is that they are usually much cheaper and easier to perform.

137. Suppose the control group was disease free and it is found that those who had the disease were more likely to have had exposure to the toxic agent: What conclusions follow? The authors will argue that since the agent and the disease were associated, the result suggests the possibility of a causal link, and therefore that more studies are warranted. Those opposed to the authors will identify a possible bias and argue that the two groups were not properly comparable as a result of the presence of the bias, and therefore that there is no evidence of an association, and consequently no suggestion of a causal link. Thus, they will argue, there is no evidence rendering it proper or beneficial to inquire further into the existence of such a link.

study is described in terms of the euphemism "associated," as in "x is associated with y." Only if there exist multiple independent epidemiological studies involving the same or similar "x's" in which similar or consistent "y's" were observed would it be reasonable to infer the existence of a causal relation.[138]

138. In contrast, one laboratory study would be sufficient to support such an inference, although more than one would be needed before the result could be generalized and used to support a medical, business, or regulatory action.